I am the author of the thesis entitled

Folate Fortification: A Case Study of Public Health Policy-Making

submitted for the degree of Doctor of Philosophy

This thesis is not to be made available for consultation, loan or copying for two years following the date this statement was signed. Following that time the thesis may be made available for loan and limited copying in accordance with the Copyright Act 1968.

Full Name...........MARK ANDREW LAWRENCE........................................
(Please Print)

Signed ............. Signature Redacted by Library ............

Date.................28 November 2002/........................................................................
**Consultation of Thesis**

Please sign this form to indicate that you have used this thesis in accordance with the *Access to Thesis* form signed by the author of this thesis.

<table>
<thead>
<tr>
<th>NAME (please print)</th>
<th>SIGNATURE</th>
<th>DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

DEAKIN UNIVERSITY
Library
Folate Fortification:
A case study of public health policy-making

Mark Andrew Lawrence
(BSc (Hons), Grad Dip Nut & Diet,
Grad Dip Epidemiology and Biostats, MSc)

Thesis submitted in fulfilment of the requirements for the degree of Doctor of Philosophy

Deakin University
June 2002
I certify that the thesis entitled

**Folate Fortification: A Case Study of Public Health Policy-Making**

submitted for the degree of **Doctor of Philosophy**

is the result of my own research, except where otherwise acknowledged, and that this thesis in whole or in part has not been accepted for an award, including a higher degree, to any other university or institution.

Full Name .... **MARK ANDREW LAWRENCE** ........................
(Please Print)

Signed ..... Signature Redacted by Library

Date ........28 November 2002.............
Abstract

This thesis investigates the use of scientific evidence in the process of making public health policy. A case study located within a food regulation setting is used. The aim is to test theory against this case study. The outcome is a theoretical understanding of the use of scientific evidence in the policy-making process in a food regulation setting.

Food regulation can influence food composition and food labelling and thereby affect the population’s dietary intake. Frequently there are contested values, beliefs, ideologies and interests among stakeholders regarding the use of food regulation as a policy instrument to effect public health outcomes. The protection of public health and safety, taking into account evidence based practice, is generally employed by food regulators as the priority objective during the policy-making process to adjudicate among the competing expectations of stakeholders. However, this policy objective has not been clearly defined and is vulnerable to interpretation and application.

The process by which folate fortification policy was made in Australia, in response to epidemiological evidence of a relationship between folate intake during the periconceptional period and reduced risk of neural tube defects, was analysed as a case study of the policy-making process. The folate fortification policy created a precedent for both food fortification and subsequently health claims policy in Australia. A social constructivist method was used to analyse the case study. The method involved deconstructing the food regulatory system into three levels: decision-making process; procedural; and political environment. Data aligned with each level of analysis was collected from 22 key informant interviews, documentary sources, field notes and surveys of both a random sample of the Australian population’s knowledge of folate and use of folic acid-containing supplements (n = 5422), and the implementation of folate fortified food products into stores (n = 60).
The insights that emerged from each of the three levels of analysis were assessed iteratively to identify a pattern of interrelationships associated with the policy-making process within the food regulatory system. The identified pattern was interpreted against existing theory to gain a theoretical understanding of the public health policy-making process in this political setting. The central argument of this thesis extends Sabatier and Jenkins-Smith’s Advocacy Coalition Framework theory to a food regulation setting. The argument is that within the contemporary political climates of neoliberalism and globalisation, a coalition between corporate interests and the values of scientists with a positivist-reductionist approach to public health research is privileged so as to invoke certain scientific evidence to, in turn, legitimise food regulation policy decisions. The theory will help to inform policy-makers about how and why the public health policy objective in a food regulation setting is interpreted and applied. This will contribute to improving policy practice intended to effect public health outcomes.

It is concluded that irrespective of the quantity and quality of the scientific evidence that is being made available, scientific evidence cannot be assumed to speak for itself. Policy-making is an inherently political and value-laden process and the potential for politically motivated interpretation and application of otherwise value-neutral scientific evidence can undermine the investment in its generation. From this perspective, evidence based practice, far from liberating policy-making from political influence, can itself become part of the problem rather than the solution. Nevertheless, rational evidence based practice is an ideal to strive for and a series of recommendations is proposed to help make the use of evidence in current food regulation policy processes more transparent and democratic.
Acknowledgements

I would like to acknowledge and thank my Principal Supervisor Professor Sandy Gifford and Associate Supervisors Professor John Catford, Ms Ingrid Coles-Rutishauser and Dr David Crawford for their supervision and reassurance throughout different stages of this study. Their public health expertise and ongoing encouragement was a constant source of assistance during the period taken to complete this thesis.

To my colleagues, both staff members and fellow post graduate students, in the School of Health Sciences, thank you for the opportunity to discuss problems, listen to ideas and make the study experience more enjoyable.

Acknowledgement as well to the many people who assisted with the conduct of the study, including the: key informants who generously made themselves available to be interviewed; staff at the Australia New Zealand Food Authority; and staff at the Commonwealth Department of Health and Ageing.

A special thank you to Ms Barbara Smith for introducing me to a broader and deeper appreciation of the social, political and environmental world, challenging me to think more critically and analytically and being a generous, funny and wonderful mentor.

Most importantly, thank you to my ever-supportive family. To my mother and father, June and Keith Lawrence, and my sister, Andrea, and her family, Warren, Rachel and Kyle, I really appreciate your love and encouragement.

This study was supported with a Public Health and Research Development Committee Scholarship from the National Health and Medical Research Council.
Table of Contents

ABSTRACT .................................................................................................................. III
ACKNOWLEDGEMENTS ............................................................................................. V
TABLE OF CONTENTS ............................................................................................ VI
LIST OF FIGURES .................................................................................................... IX
LIST OF TABLES ....................................................................................................... X
ABBREVIATIONS AND ACRONYMS ................................................................... XI
LIST OF APPENDICES ........................................................................................... XIII
PREFACE .................................................................................................................. XIV

CHAPTER 1 INTRODUCTION ................................................................................. 1
  1.1 Introduction ....................................................................................................... 1
  1.2 Public health policy ......................................................................................... 2
  1.3 Evidence based policy-making ....................................................................... 3
  1.4 The research aim and value ........................................................................... 7
  1.5 The case study method .................................................................................. 7
  1.6 The policy analysis orientation ..................................................................... 9
  1.7 The thesis argument .................................................................................... 11
  1.8 The investigator’s involvement in the case study ....................................... 12
  1.9 Outline of the thesis structure .................................................................... 13

CHAPTER 2 THE FOOD REGULATORY SYSTEM AS A POLITICAL SETTING FOR
ANALYSING THE MAKING OF PUBLIC HEALTH POLICY ................................... 17
  2.1 Introduction ..................................................................................................... 17
  2.2 The rationale for food regulation .................................................................. 18
  2.3 Food regulation as a public health policy instrument .................................. 20
  2.4 The structural and procedural arrangements for setting and enforcing food regulation in Australia ................................................................. 26
  2.5 The politics of food regulation .................................................................... 29
  2.6 A model for analysing the political processes associated with using food regulation as a public health policy instrument ........................................... 30
  2.7 The analytical levels of the food regulatory system ..................................... 33
  2.8 Challenges in using food regulation as a policy instrument to achieve public health outcomes ................................................................. 40
  2.9 Conclusion .................................................................................................... 45
# List of Figures

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>Conceptual model of the relationships among food, nutrition and public health</td>
<td>22</td>
</tr>
<tr>
<td>2.2</td>
<td>A model of the food regulatory system (Adapted from Easton 1965: 110)</td>
<td>32</td>
</tr>
<tr>
<td>3.1</td>
<td>Key stages in the health-policy-making process (Adapted from Anderson 1975: 26)</td>
<td>49</td>
</tr>
<tr>
<td>3.2</td>
<td>The rational-linear approach to the use of evidence in policy-making</td>
<td>50</td>
</tr>
<tr>
<td>3.3</td>
<td>The interrelationship between nutrition policy-making, research and monitoring (Source: US Department of Health and Human Services and US Department of Agriculture 1991: 55716)</td>
<td>51</td>
</tr>
<tr>
<td>3.4</td>
<td>Health policy model (Source: Richmond and Kotelchuck 1991: 450)</td>
<td>56</td>
</tr>
<tr>
<td>3.5</td>
<td>The Advocacy Coalition Framework (Source: Sabatier and Jenkins-Smith 1993: 229)</td>
<td>66</td>
</tr>
<tr>
<td>3.6</td>
<td>A schematic of the contextual influences on the decision-making process (Source: Lomas 1997: 13)</td>
<td>73</td>
</tr>
<tr>
<td>5.1</td>
<td>The research design for the study</td>
<td>111</td>
</tr>
</tbody>
</table>
List of Tables

Table 4.1  An overview of selected characteristics of the public health models 99

Table 6.1  Comparison of the pros and cons of the different policy options available at the time of the policy-making process 161

Table 7.1  Knowledge about folate and use of folic acid supplements in Australian adults by age, sex and State of residence 179

Table 7.2  Median intake and [range] of folic acid and vitamin B\textsubscript{12} from supplements for individuals who had taken a supplement containing folic acid and/or vitamin B\textsubscript{12} on the day before the survey 181

Table 7.3  Percent prevalence and [95% confidence interval] for a nutrient supplement intake by sex and age 182

Table 8.1  The evolution of Standard A9 and the policy response to the folate-NTD evidence 215

Table 8.2  Stakeholders who made comment on folate fortification 220
### Abbreviations and Acronyms

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABCIA</td>
<td>Australian Breakfast Cereal Industry Association</td>
</tr>
<tr>
<td>ACF</td>
<td>Advocacy Coalition Framework</td>
</tr>
<tr>
<td>ACT</td>
<td>Australian Capital Territory</td>
</tr>
<tr>
<td>ANZFA</td>
<td>Australia New Zealand Food Authority</td>
</tr>
<tr>
<td><strong>ANZFA Act 1991</strong></td>
<td><em>Australia New Zealand Food Authority Act 1991</em></td>
</tr>
<tr>
<td>ANZFRMC</td>
<td>Australia New Zealand Food Regulation Ministerial Council</td>
</tr>
<tr>
<td>ANZFRSC</td>
<td>Australia New Zealand Food Regulation Standing Committee</td>
</tr>
<tr>
<td>ANZFSC</td>
<td>Australia New Zealand Food Standards Council</td>
</tr>
<tr>
<td>ARTG</td>
<td>Australian Register of therapeutic Goods</td>
</tr>
<tr>
<td>Codex</td>
<td>Codex Alimentarius Commission</td>
</tr>
<tr>
<td>COAG</td>
<td>Council of Australian Governments</td>
</tr>
<tr>
<td>CSIRO</td>
<td>Commonwealth Scientific and Industrial Research Organisation</td>
</tr>
<tr>
<td>CVD</td>
<td>Cardiovascular disease</td>
</tr>
<tr>
<td>DSHS</td>
<td>Commonwealth Department of Human Services and Health</td>
</tr>
<tr>
<td>Expert Panel</td>
<td>National Health and Medical Research Council’s Expert Panel on Folate Fortification</td>
</tr>
<tr>
<td>FAO</td>
<td>Food and Agriculture Organization</td>
</tr>
<tr>
<td>FDA</td>
<td>United States Food and Drug Administration</td>
</tr>
<tr>
<td>FHC</td>
<td>National Health and Medical Research Council’s Food and Health Committee</td>
</tr>
<tr>
<td>FSANZ</td>
<td>Food Standards Australia New Zealand</td>
</tr>
<tr>
<td>HCC</td>
<td>National Health and Medical Research Council’s Health Care Committee</td>
</tr>
<tr>
<td>MBCM</td>
<td>Multinational Breakfast Cereal Manufacturer</td>
</tr>
<tr>
<td>MRC</td>
<td>United Kingdom Medical Research Centre</td>
</tr>
<tr>
<td>NFA</td>
<td>National Food Authority</td>
</tr>
<tr>
<td><strong>NFA Act 1991</strong></td>
<td><em>National Food Authority Act 1991</em></td>
</tr>
<tr>
<td>NFNMU</td>
<td>National Food and Nutrition Monitoring Unit</td>
</tr>
<tr>
<td>NFSC</td>
<td>National Food Standards Council</td>
</tr>
<tr>
<td>NHMRC</td>
<td>National Health and Medical Research Council</td>
</tr>
<tr>
<td>NNS</td>
<td>1995-96 National Nutrition Survey</td>
</tr>
<tr>
<td>NTD</td>
<td>Neural Tube Defect</td>
</tr>
</tbody>
</table>
Abbreviations and Acronyms (Cont’d)

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>PHC</td>
<td>National Health and Medical Research Council’s Public Health Committee</td>
</tr>
<tr>
<td>PR</td>
<td>Public relations</td>
</tr>
<tr>
<td>Proposal 24</td>
<td>Proposal 24 – Vitamins and Minerals</td>
</tr>
<tr>
<td>RCT</td>
<td>Randomised Controlled Trial</td>
</tr>
<tr>
<td>RDI</td>
<td>Recommended Dietary Intake</td>
</tr>
<tr>
<td>SPS</td>
<td>The Agreement on Sanitary and Phytosanitary Measures</td>
</tr>
<tr>
<td>Standard A9</td>
<td>Food Standard A9 of the Australian Food Standards Code</td>
</tr>
<tr>
<td>TBT</td>
<td>The Agreement on Technical Barriers to Trade</td>
</tr>
<tr>
<td>UK</td>
<td>United Kingdom</td>
</tr>
<tr>
<td>US</td>
<td>United States</td>
</tr>
<tr>
<td>WA</td>
<td>Western Australia</td>
</tr>
<tr>
<td>WARICH</td>
<td>Western Australian Research Institute on Child Health Ltd</td>
</tr>
<tr>
<td>WHO</td>
<td>World Health Organization</td>
</tr>
<tr>
<td>WTO</td>
<td>World Trade Organization</td>
</tr>
</tbody>
</table>
List of Appendices

1. Codex Alimentarius Commission 'General Principles for the Addition of Essential Nutrients to Foods'

2. List of field note sources

3. List of document sources

4. List of key informants

5. Theme list for key informant interviews

6. Deakin University Ethics Approval and Plain language statement

7. Summary of the types of studies and trials conducted on folate and neural tube defects and the relative risks associated with supplementary and dietary folate (Excerpt from the report of the NHMRC Expert Panel on Folate Fortification)

8. Executive summary, Recommendations and Background to the establishment, of the NHMRC Expert Panel on Folate Fortification

9. Revised food Standard A9


Preface

In the mid-1990s I worked for four years as a public health nutritionist at Australia’s national food regulator. It was the most fascinating experience of my professional career. The food regulatory system was, and remains, a political ‘battleground’ for stakeholders with different values, ideologies, beliefs and interests regarding policy matters related to food and health. The addition to food of vitamins and minerals in general, and folate in particular, were defining policy issues for the food regulator. They engaged political debates that ranged from the emotion associated with birth defects through to fundamental issues about the locus of control between the State and food manufacturers for determining the future development of the food supply.

This thesis was not planned during the policy-making process that resulted in the policy of folate fortification of staple foods in Australia. Indeed, when I first presented a proposal for a PhD study related to the folate fortification policy to the National Health and Medical Research Council it was as a conventional epidemiological evaluation of the policy’s implementation and impact. Yet, as I reflected on the policy-making experience and witnessed similar political debates being repeated for other public health policy issues, I reviewed the orientation of the proposal. The study became an analysis of the making of the policy, rather than its impact, in order to gain an explanation that could be generalised to understandings of public health policy-making more broadly.

My intention in undertaking this thesis was to step back from the cut and thrust of the battleground and analyse the making of the folate fortification policy in Australia to make some sense of the bigger picture. The existence of this peculiar case study provided an opportunity to gain theoretical understandings that could shed light on using food regulation as a public health policy instrument. I saw the thesis’ contribution to theoretical understandings as important to provide an informed basis from which to challenge policy practice, to place the value-laden assumptions of many stakeholders associated with the process into perspective and to help improve public health policy-making in a food regulation setting.
CHAPTER 1

Introduction

"In legislation, as in other things, gross ignorance sees no difficulties, imperfect knowledge describes them, perfect knowledge overcomes them."

1.1 Introduction

On 8 June 1995, the Parliamentary Secretary to the Australian Minister for Human Services and Health, Dr Andrew Theophanus, launched revised food Standard A9 to an invited audience and media at Parliament House in Canberra. Revised food Standard A9 regulates the addition of vitamins and minerals to foods in Australia and as such is an important public health policy. When launching the revised food Standard Dr Theophanus said, “This Standard balances consumer choice and market demand with solid scientific evidence underpinning public health and safety” (Theophanus 1995). Of particular importance were the provisions within the revised Standard that for the first time permitted folic acid to be added to staple food products. These provisions had been included in response to epidemiological evidence that folic acid consumed during the periconceptional period helps to reduce the risk of neural tube defects (NTDs).

In spite of the reference to the integral role of scientific evidence in the decision-making process that was presented at the launch of the revised food Standard, the policy outcome and the policy-making process with which it was associated were controversial. The launch did not reveal that various stakeholders had been engaged in a truncated and adversarial process during the four-year period involved in making the policy. Indeed, to coincide with the launch, the Australian Consumers’ Association (ACA) issued a media release entitled ‘Health Ministers sell out Consumers’, attacking the policy decision (Australian Consumers’ Association 1995). Curiously, the then National Food Authority (NFA), now the Australia New Zealand Food Authority (ANZFA), that had been established by the Commonwealth government as the independent, scientific and statutory agency to advise on food regulation matters, had not originally recommended folate

---

fortification of food products as a policy response to the epidemiological evidence of the relationship between folate and NTDs. Nor had the NFA recommended the broader revised food Standard A9 in the form that was launched by the Parliamentary Secretary. By the end of the year in which the launch was conducted, the Managing Director and Chairperson of the NFA, the Consumer representative on the Authority’s Board and myself, the Authority’s Acting Principal Nutritionist at the time, had all resigned at least in part because of the policy-making process and ultimate policy outcome.

The purpose of this thesis is to test theory of how and why scientific evidence is used in making public health policy in a food regulation setting. The policy-making process that led to the folate fortification policy in Australia is analysed as a case study to gain insights into the use of evidence in policy-making. In this chapter I introduce the terms public health policy and evidence based policy-making, explain the rationale to and value of the research and state the study’s aim. The case study research method and the policy analysis orientation employed are also described. The thesis argument and my involvement in the case study are presented. The chapter concludes with an outline of the thesis structure.

1.2 Public health policy

Public health policy is a nebulous term that comprises two distinct concepts in their own right, public health and public policy. How public health policy is defined depends to a large extent on how public health and policy are each defined. The World Health Organization (WHO) has defined public health as “…a social and political concept aimed at improving health, prolonging life and improving the quality of life among whole populations through health promotion, disease prevention and other forms of health intervention.” (Nutbeam 1998: 352). The critical feature of this definition is its emphasis on populations as the unit of analysis as distinct from individuals or physiological and biochemical processes.

The policy science literature provides a diversity of definitions for the term ‘policy’. For example, the leading policy analysts, Hogwood and Gunn, specify ten different uses of the term policy ranging from it being a label for a field of activity to a process to an
outcome (Hogwood and Gunn 1984). According to Short, "... policy refers either to a set of actions and decisions, or to a statement of intention." (Short 1998: 66). Palmer and Short comment that the term ‘public policy’ deals with those policies for which governments are primarily responsible, "... they are carried out in the name of the people as a whole, and they affect the public interest" (Palmer and Short 1994: 23). For the purposes of this thesis, I define public health policy as a position statement that has been made by governments comprising values and a strategic plan of action intended to affect the health of populations.

1.3 Evidence based policy-making

The conventional orthodoxy for making public health policy is that the process should be informed by scientific evidence (Dever 1997; National Health and Medical Research Council 1998; Wooldridge 1998). The appeal of evidence based practice is that it promises rationality and an ideology-free policy-making process (Niessen et al. 2000). Evidence has been described as comprising "... the interpretation of empirical data derived from formal research or systematic investigations which use any of a wide range of different types of scientific methods." (Rychetnik and Frommer 2000: 9). Epidemiology is regarded by many practitioners as the scientific discipline that provides the evidence that forms the backbone of public health policy (Lilienfield and Lilienfield 1980; Paige and Davis 1987; Muir Gray 1997). Epidemiology has been defined as the study of "... the patterns of disease occurrence in human populations and of the factors that influence these patterns" (Lilienfield and Lilienfield 1980: 3).

The acceptance of evidence based practice for public health policy resides within the fundamental epistemologic notion about the role of knowledge as a guide for human action. Moreover, when dispute arises in selecting alternative policy options, scientific evidence is positioned as the arbiter for the policy-making process. The corollary of the concept is that policy decisions made in the absence of evidence are regarded pejoratively as being potentially confused by opinion, anecdote or speculation.

The concept of evidence based policy-making draws on the rationalist assumption that data are systematically collected and then appraised against criteria to generate the most
comprehensive and rigorous evidence foundation to then inform the policy-making process. In this regard, the assessment of aetiological evidence of a potential relationship between a variable and a public health outcome has been supported by the development of causal criteria for the critical appraisal of individual scientific studies (Hill 1965; MacMahon and Pugh 1970; Susser 1977). Also, rules and methods have been developed for evaluating evidence of the effectiveness of health interventions. For example, the development of guidelines for the systematic review of the collective studies for a topic and the use of concepts such as the ‘levels of evidence’ to reflect the degree to which bias has been eliminated by the study design assessing the effectiveness of an intervention (Bandolier; National Health Service Centre for Reviews and Dissemination 1996; Muir Gray 1997; Clark and Oxman 2000; National Health and Medical Research Council 2000).

The modern notion of using scientific evidence from the evaluation of the effectiveness of health interventions to inform public health policy emerged from the concept of evidence based medicine (Dever 1997; National Health and Medical Research Council 1998; Wooldridge 1998). Evidence based medicine has been defined as “… the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” (Sackett et al. 1996: 71). It was the work of Cochrane in the early 1970s that provided the impetus for the contemporary movement for evidence based medicine (Cochrane 1972). Cochrane had bemoaned the lack of critical analysis and perceived haphazard application of the growing amount of scientific data being made available from randomised controlled trials (RCT). The principles and procedures of evidence based medicine are now being adapted for application to a public health context (Rychetnik and Frommer 2000), to the concept of ‘evidence-based nutrition’ (Margetts et al. 2001; Truswell 2002) and to a food regulation policy deliberation related to the scientific substantiation of health claims (Australia New Zealand Food Authority 2000).

There is a fundamental paradox confronting evidence based practice for public health policy. On the one hand, there is a substantial investment both in conducting research to obtain data and in developing criteria for its appraisal so as to assemble a historically unprecedented body of scientific evidence. On the other hand, there is a lack of understanding among practitioners of how and why this scientific evidence is being, or can be, applied to public health policy (Ham et al. 1995; Davis and Howden-Chapman
1996; Atwood et al. 1997; Lomas 1997; Editor 2001; Matanoski 2001; Samet and Lee 2001). Prominent epidemiologists have noted that epidemiology has increasingly focused on technical and methodological sophistication to the possible neglect of its more practical application to public health (Krieger 1994; Pearce 1996; Susser and Susser 1996). Other practitioners have argued that researchers have a ‘moral responsibility’ to turn data into information and also learn to be more strategic and convert this information into policy, otherwise research will be conducted simply for research sake (de Lecuw 1993). As Black comments, “Discussion of the theory underlying evidence based policy might safely be consigned to an intellectual dustbin if it were not for the practical consequences.” (Black 2001: 275).

The challenges associated with assembling scientific evidence and then interpreting and applying the scientific evidence illustrates that public health policy-making, as with all policy-making, is both an art and a science (Milio 1988). Notwithstanding the importance of conducting research to increase the quantity and quality of scientific evidence (the science of policy-making), also there is a need to conduct research to increase understanding of how and why scientific evidence is used in the policy-making process (the art of policy-making).

The premise to this thesis is that the lack of a theoretical understanding of how and why scientific evidence is used in public health policy-making is inexorably linked with the hidden and inherently political nature of policy-making. The experience observed at the launch of revised food Standard A9 demonstrated that different stakeholders can have different values about the preferred policy response to address a given public health issue in a food regulation setting. As Baum argues, “... the tensions within public health policy and practice ... require more analysis to understand and lay bare. They are hidden and invisible, yet operate to influence public health policy and practice as surely as many more evident factors.” (Baum 1998: 64). Others concur with Baum in stressing the need to acknowledge the values that inform the policy-making process rather than hide behind the rhetoric of evidence based practice (Kreiger and Zicler 1996). Values can have a defining influence on policy-makers’ often implicit notions of public health policy and it has been argued that this influence is exerted through ‘hidden arguments’ (Tesh 1988). According to Tesh,
"The point is not that values contaminate policy, not even that values contaminate science. Instead there is an inextricable interrelationship between facts and values, both in the search for causes of disease and in the process of developing the best preventive policy. I argue not that values be excised from science and from policy but that their inevitable presence be revealed and their worth be publicly discussed." (Tesh 1988: 3).

In this study I set out to analyse the so-called hidden processes that are exercised under the guise of evidence based practice and that serve to privilege certain arguments, while obscuring others, so that one set of values prevail in public health policy-making in a food regulation setting.

As I have argued previously, in order to increase its utility for public health policy, evidence based practice needs to be integrated with a theoretical understanding of the policy-making process (Lawrence 1998). From a policy-making perspective, theory can explain how a political system is ‘wired’ in order to know which lever to pull (Goodin 1982). Also, theory assists the policy-maker to anticipate the implications of a public health policy and to predict how the system will respond under altered conditions or in the long term, of which there may be no experience. According to Hempel,

"Theories are the key to the scientific understanding of empirical phenomena, and they are normally developed only when previous research yielded a body of information, including empirical generalizations about the phenomenon in question. A theory is then intended to provide deeper understanding by presenting those phenomena as manifestations of certain underlying processes, governed by characteristic laws which account for, and usually correct and refine, the previously established generalizations." (Hempel 1977: 244).

A policy theory is a strategic device, or tool, which attempts to conceive of what actually exists and to predict what will happen (McCool 1995).
1.4 The research aim and value

The aim of the thesis is to test theory to gain a theoretical understanding of the use of scientific evidence in the making of public health policy in a food regulation setting.

The research is valuable because often the political nature of the policy-making process is hidden, the existence of competing values among stakeholders is not acknowledged and the policy outcomes are presented as non-controversial. The theoretical understanding will contribute to explaining the use of scientific evidence in the making of public health policy in a food regulation setting by elucidating the mechanism that shapes the policy-making process. This theoretical understanding will, in turn, provide an informed basis to challenge the inherently political nature of policy-making and to expose the value-laden assumptions in evidence based practice.

1.5 The case study method

According to a leading food and nutrition policy analyst, Nancy Milio, to understand and improve the practice of public health policy-making,

"... an important priority is development of new types of information – policy-relevant information (as opposed to data on the lifestyles of individuals) - for politically important audiences such as policy-makers, interested groups, and the media. Such information would help advocates of healthy public policy to identify within their own situations points of entry into policy-making processes, sources of support, and strategies to enhance the feasibility of specific health promotion policy options in any given policy sector. ... The best way to find such policy-relevant information is by observing and analysing the real-world experience of public policy-making.” (Milio 1988: 265).

Given the complex pattern of relationships among contexts, actors and processes within which public health policy is embedded, policy outcomes need to be approached with caution, examining them as a web where the linkages between decisions and actions are not always clear. As Gardner and Barraclough comment, “The student of policy should never accept any document as the ‘last word’ but should examine the document in its
wider context, ...[the observer]... must seek to discern policy out of a web of decisions and actions which are often confusing and whose linkages are not always immediately apparent.” (Gardner and Baraclough 1992: 5). From this perspective, policy analysis is about disentangling the values, interests and resource issues involved in policy-making, to identify organisational arrangements and to analyse the way the political process affects policy outcomes (Davis et al. 1993). Because of the current rudimentary state of the art of policy studies, the present thesis proposes to ‘unravel the web’ of policy-making by analysing the making of a specific public health policy.

An adaptation of the case study method was used as the research method for this thesis as it offered features that were especially suitable. A particular strength of the case study method is its ability to accommodate contextual circumstances as important factors in explaining the public health policy-making process. Because public health policy is made within a particular social setting at a particular point in time, the political, economic and social contexts influencing the policy-making process must be understood (Lasswell 1970). As Davis comments, “The major virtue of the case study is that it retains a high degree of faithfulness to real-life processes through its collection of extensive, rich data.” (Davis 1998: 497). In general, the case study method is the preferred strategy when (Yin 1994):

i) Asking ‘how’ and ‘why’ questions that need to explain operational links in a causal chain in real life interventions that need to be traced over time.

ii) The investigator has little or no control over events (the number of variables is too great to be adequately controlled and experimental approaches are not appropriate).

iii) Addressing contemporary, rather than historical events (as this provides two extra sources of evidence – observation and interview).

The research method employed in this thesis was based on an inductive research process, whereby inductive inference is,

"... the inference from particular cases to a general law, or to other unobserved cases of a similar nature. ... Induction has been regarded as a basic method of acquiring general knowledge in the empirical domain; knowledge which, in principle, does not attain full certainty but which can be reconfirmed by repeated
The conclusions from the case study are generalisable only to theoretical propositions, that is, analytical generalisations, and not to statistical generalisations (Yin 1994). The case study method is regarded as having a particular legitimacy as an inductive approach to help understand the influences upon the policy-making process of public health policy (Yin 1994; Stake 1995; Davis 1998). Consequently, the case study method increasingly is used to study processes of policy-making (Yin 1992; Mays and Pope 1995; Stake 1995; Baum 1998).

The case study chosen for the present thesis was the policy-making process that led to the policy of folate fortification of staple food products in Australia in response to epidemiological evidence that folic acid consumed during the periconceptional period helps to reduce the risk of NTDs. The case was defined temporally from the establishment of the NFA (19 August 1991) through to the gazettal of revised Standard A9 on 14 June 1995. The unit of analysis for the thesis was the policy-making process in the food regulatory system (this is the level to which the study findings are generalised).

1.6 The policy analysis orientation

Policy analysis is a component of the broad alliance of disciplines generically referred to as the policy sciences. Harold Lasswell is generally regarded as pioneering the modern concept of the policy sciences, describing them as “... the disciplines concerned with explaining the policy-making and policy-executing process, and with locating data and providing interpretations which are relevant to the policy problems of a given period.” (Lasswell 1951: 14). Policy science is multi-method, multidisciplinary and problem-focused. Its goal is to integrate knowledge into an overarching discipline to analyse public choices and decision-making and thereby contribute to the democratization of society (Lasswell 1971).

Dror describes the purpose of policy science as being “... the contribution of systematic knowledge, structured rationality and organised creativity to better policy making” (Dror
1971: ix). To this end, Dean concludes that "... theory is the most fundamental prerequisite of a policy science, and that the absence of theory and effective theory building are serious weaknesses of much of the existing research available for the policy making process for improving the health of populations" (Dean 1996: 20).

Policy analysts such as Lasswell (Lasswell 1970), Gordon et al. (Gordon et al. 1977) and Hogwood and Gunn (Hogwood and Gunn 1984) conceptualise two main approaches to the policy sciences:

i) Analysis of policy – an academic activity concerned primarily with advancing knowledge of policy processes, to provide information for policy-making.

ii) Analysis for policy – an applied activity concerned primarily with generating knowledge to make policies more effective in solving particular problems and to help policy-makers make better decisions. At the outset of policy-making it is not possible to have access to the impact of that policy or information that becomes available later. Analysis for policy in the form of an evaluation of the policy impact can provide information to then use for feeding back to improve policy design and option choices.

Evaluation studies of the folate fortification policy have been undertaken at the state and national level in Australia as well as in other countries where food products are being fortified with folic acid. These ‘conventional’ evaluation studies are consistent with the policy analysis for policy approach. They have provided valuable information regarding the implementation, impact and outcome of the policy and often have included recommendations for future amendments to the policy. As discussed later in this thesis, these evaluation studies have been unable to provide conclusive evidence of whether the folate fortification policy has succeeded or failed.

Irrespective of whether conventional evaluation studies can establish the success or failure of a policy against its objectives, there is a need for evaluation studies that illuminate the hidden aspects of policy-making to explain how and why a policy might have succeeded or failed. Illuminative evaluation is necessary in order to understand what has happened in policy-making from the perspective of different stakeholders and contexts and to provide sufficient information to improve the process generally (Tones 1997). If we are to learn more about public policy theory in general rather than merely the
outcomes from specific cases we need to undertake evaluations that enable us to
generalise to theories of the policy-making process.

The folate fortification policy has become a popular case study discussed at conferences,
in training courses and recently has been the subject of descriptive reviews (Webb 1998;
Feinleib et al. 2001). However, these reviews have been undertaken from the perspective
of describing the technical aspects involved in translating the epidemiological evidence
into the policy. There has been no in-depth analysis to explain how and why the scientific
evidence was used in the making of the folate fortification policy either in Australia or in
other countries where this policy was made. The purpose of the policy analysis
undertaken in this thesis was to extend beyond description and to evaluate the folate
fortification policy from the analytical orientation of the policy-making process to provide
a holistic understanding to inform public health policy and practice in a food regulation
setting. The policy analysis orientation was chosen so as to have application to the
practice of public health policy-making. The methods used for collecting, analysing and
interpreting the various data are described in the methods chapter of this thesis.

1.7 The thesis argument

This thesis will argue that the making of public health policy in a food regulation setting
is an inherently political process that involves resolving the contested values, ideologies,
beliefs and interests\(^2\) of various stakeholders seeking to secure a specific policy outcome.
I support the concept of evidence based practice to inform the complementary food
regulation objectives of effecting a public health outcome while also protecting public
health and safety. Nevertheless, I demonstrate that evidence does not speak for itself.
Evidence based practice is mediated by the meaning acquired by the public health policy
objectives. These policy objectives are socially constructed and take on meaning in the
context of the prevailing arguments of interested stakeholders. Sabatier and Jenkins-
Smith’s Advocacy Coalition Framework (ACF) (Sabatier and Jenkins-Smith 1993)
provides a relevant theoretical model to explain this phenomenon. The ACF explains that
certain stakeholders share core values towards the relationship between food and health

\(^2\) Throughout the remainder of the thesis ‘core values’ will be used to describe ‘values, ideologies, beliefs
and interests’.
and subsequently they form coalitions. It then conceptualises the processes and circumstances whereby the dominant coalitions' arguments regarding the interpretation and application of the public health policy objectives are privileged while the arguments of other stakeholders and coalitions are obscured. The case study illustrates that the governance and procedures of the Australian food regulatory system operating within a political environment of neoliberalism and globalisation are legitimising the core values of a dominant coalition comprising corporate stakeholders and scientists with a positivist-reductionist approach to public health research in the making of public health policy.

1.8 The Investigator's involvement in the case study

Policy analysis cannot be dispassionate and value-neutral because research is inevitably influenced by the beliefs and assumptions of the researcher (Rein 1976). For example, the analytical framework developed by the analyst and within which a policy is evaluated can influence the nature and scope of the issues that are investigated and what research questions are raised (Ham and Hill 1993). As Allison noted in his classic study of a policy-making process, in which the case study was the Cuban missile crisis, when seeking to explain policy decisions, what we see and judge to be important depends not only on the evidence but also on the 'conceptual lenses' through which we look at the evidence (Allison 1971). What really happened with the case study can never be known, except as constructions viewed through different lenses. As a public health nutritionist I bring to this study my personal experiences and aspirations for public health policy-making in a food regulation setting. My understandings and values serve as 'the standard' against which I analysed the case study argument and politics. Consequently, the thesis is reflexive as I am irrevocably present in the data and I have needed to reflect continually on my own presence in the field of analysis.

Reflecting on the presence of my personal judgements in the study was especially relevant because I was intimately involved with the policy-making process associated with the folate fortification policy in Australia during the period 1992-1996. My original involvement with the case study was as the Consumer representative on the NHMRC's Food and Health Committee (FHC) in 1992-93 when the committee was preparing its policy position on food fortification more generally. Then as the Acting Principal
Nutritionist at the NFA I was responsible for the preparation of the NFA's policy response to the scientific evidence of the folate-NTD relationship during the period 1993-96. My role in being immersed in the phenomena being investigated approximates the role defined by Bernard as that of an 'observing participant' (Bernard 1994)3.

The experience of having been immersed in the case study as it unfolded afforded me a unique opportunity to gain insights into many events, documents, processes and the motivations of stakeholders that otherwise likely would have been inaccessible or hidden from scientific investigation undertaken from an external perspective. Conversely, being an observing participant presents challenges in relation to the potential for manipulating events or the event proceeding differently because it was being observed4 and the potential to produce bias in data collection, analysis and interpretation. Throughout this thesis I attempt to address my personal involvement and judgements with the actual case study and the subsequent data collection, analysis and interpretation to ensure that any influence is transparent.

1.9 Outline of the thesis structure

Section 1: Setting the scene for the study

Section 1 provides the scene setting and theoretical foundation of the thesis. Chapter 2 presents a description of the food regulatory system in Australia as the political setting for analysing the use of scientific evidence in the making of public health policy. The description outlines the rationale for food regulation, the nature and scope of the relationship between food regulation and public health, the structural and procedural arrangements for developing food regulation and the politics of food regulation. A system's approach is used to conceptualise the food regulatory system and to provide a framework for analysing the political processes associated with its operation. The food regulatory system is the unit of analysis for this thesis. The challenges for public health

---

3 My role only approximated that of an observing participant because the PhD study began in 1997, after the folate fortification policy had been launched and as such I had not contrived a research method during the actual case study.

4 As explained in footnote 3, above and in the methods chapter to this thesis, I had not initiated the investigation at the time of the case study and the data collection was predominantly retrospective although peculiar circumstances during the case study meant that many field notes were collected, albeit for other purposes.
policy-making identified in this chapter guide the study and it is to these issues that the findings from the policy analysis will be generalised.

A review of the policy and social science literature is presented in Chapter 3. The purpose of the literature review is to obtain insights into current knowledge to guide the policy analysis and to synthesise a theoretical framework against which the findings from the analysis can be interpreted. The first step towards interpreting empirical data from policy analysis for theory testing is classification. In Chapter 4 a typology of the different socially constructed meanings of public health in a food regulation setting is presented. The typology orders core values that characterise the different meanings of public health into public health model constructs. Principles are proposed for applying the models to the development, implementation and evaluation of public health policy. The typology assists with the testing of theory by providing a classification framework against which the practice of interpreting and applying the policy objectives in the case study can be assessed.

Section 2: The method, the case study and the results from the policy analyses

In Section 2 the method, the case study and the results from the three policy analyses are presented. The research method for the thesis is described in Chapter 5. The method is a social constructivist approach in which the case study is deconstructed from three perspectives in accordance with different analytical levels of the food regulatory system described in Chapter 2. The results that emerge from each of these analyses are assessed iteratively to reconstruct the policy-making process as a coherent story. The assessment is interpreted against policy-making theory to determine the most plausible theoretical explanation of how and why scientific evidence was used in the policy-making process that resulted in the folate fortification policy. The quantitative and qualitative methods for the collection, analysis and interpretation of the data sources, including the semi-structured interviews, field notes, documents and surveys, are described.

Chapter 6 provides a description of the case study. This description is structured around a review of NTDs, the epidemiological evidence for the relationship between folate and NTDs, the uncertainties and dilemmas confronting policy-makers in responding to the available evidence, the detail of the policy that was recommended, and the policy issues that the case study captures. It is because of the unique and revelatory nature of the policy
issues captured by the case study that an opportunity is provided for the policy analysis to reveal otherwise hidden aspects of the policy-making process.

Chapters 7 - 9 present the findings of the analyses of the case study from the decision-making process level, procedural level and political environment level of the food regulatory system respectively. The analysis of the decision-making process level reveals that there were significant oversights, errors and assumptions in reviewing and translating the epidemiological evidence into policy recommendations. The insights provided from this 'first level' analysis raised several questions about the political nature of the policy-making process. The findings of the analysis of the case study from the perspective of the procedural level of the food regulatory system revealed that the policy-making process coincided with the review of Standard A9 and broader public health policy principles associated with food composition and food labelling. The procedural arrangements answer many of the questions raised at the decision-making process level. Nevertheless, further questions were raised regarding how and why these procedural arrangements arose. In Chapter 9 the policy-making process associated with the folate fortification policy is analysed as an event within the political environment within which the food regulatory system operates. The data obtained from this level of analysis provide insights into the influence of the contemporary contexts of neoliberalism and globalisation upon the food regulatory system and assist in answering questions raised from the analysis of the case study at the procedural level of the system.

Section 3: Discussion, conclusion and recommendations

Section 3 presents the discussion of the research findings and the thesis conclusion and recommendations. In Chapter 10 the findings from each of the analyses are synthesised into one coherent assessment of what happened in the policy-making process that resulted in the folate fortification policy. The assessment is then interpreted against the theoretical framework constructed in Chapter 3 to determine the most plausible theoretical explanation of how and why scientific evidence was used in the case study. A program logic strategy is employed as a further test of the rigour of the theory's explanation of the case study. Observed policy outcomes are compared with those predicted from the theory in terms of the policy's implementation and impact, its role in contributing to the review of health claims policy in Australia and New Zealand and the relationship between the food Authority and coalition members. The chapter presents a discussion of the relevance
of the theory in terms of its generalisability to the food regulation setting more broadly. The strengths and limitations of the research are then discussed.

The thesis conclusion and recommendations are discussed in Chapter 11. The conclusion explains how the study’s research aim is fulfilled and what the research contributes to public health policy-making practice in a food regulation setting and why this is important. Finally, a series of recommendations to help improve the public health policy-making process in a food regulation setting is presented.
CHAPTER 2

The food regulatory system as a political setting for analysing the making of public health policy

2.1 Introduction

The State has available a diversity of instruments to achieve public health nutrition policy objectives (Lawrence 1987). Regulation is regarded as a politically and economically strong policy instrument for structuring the environment within which the ‘development’ of the food supply is legally permitted (Milio 1990). Regulation can be used to help effect public health outcomes by intervening at various stages in the food chain ranging from pricing subsidies to promote the production and purchase of low-fat foods (Willumsen 1983) and dietary standards for school lunch programs (United States Department of Agriculture 1994) to controls on advertising directed at children (National Food Authority 1993). For the purposes of this thesis, the analysis of the scope of the relationship between food regulation and public health will be confined to those regulations that affect the nutrition-related composition and labelling of food products. Such regulations are generally either food standards or codes of practice and have a direct influence on the nutrient profile of food products and the information environment within which food is selected. These regulations, in turn, affect the dietary intake and nutritional status of the population and ultimately public health.

The history of public health practice from the first eminent public health practitioner, the barrister Edwin Chadwick, whose work on sanitary reform led to the commencement of public health legislation in England, to contemporary times has been described as a ‘legislative’ history (Reynolds 1997). Food regulation is one of two components of food legislation. In Australia, Commonwealth or Territory or State parliaments make food

5 This chapter is based on a presentation entitled ‘Balancing the necessary with the necessity: Food regulation as a policy tool for public health’ presented at ‘Eating into the Future’ The first Australian conference on food, health and the environment, 11-13 April, 1999, Adelaide, South Australia [http://www.chdf.org.au/catwell_sa].
legislation. The legislation comprises the Act, and the regulations established by authority of the Act. Whereas an Act sets out a Parliament’s intentions in the form of principles and procedures in a given area, the regulations spell out the practical requirements of legislation and the operative details of the Act (Morris et al. 1996).

This chapter presents a description of the Australian food regulatory system as the political setting for analysing the use of scientific evidence in the making of public health policy. The chapter outlines the rationale for food regulation, the nature and scope of the relationship between food regulation and public health, the structural and procedural arrangements for developing food regulation and the politics of food regulation. A system’s approach is then used to conceptualise the political setting within which food regulation is developed and to provide a framework for analysing the political processes associated with its operation. Finally, the chapter discusses the challenges in using food regulation as a policy instrument for achieving public health outcomes. As the political setting for this investigation, the food regulatory system is the unit of analysis for this thesis. The challenges for policy-making identified in this chapter guide the study and it is to these issues that the findings from the case study analysis will be generalised.

2.2 The rationale for food regulation

Human survival depends on the availability of a safe and nutritionally adequate food supply and the knowledge and skills to access this food. Historically, food composition, safety and availability were determined by ecologically mediated parameters. For the vast majority of human existence people have been intimately involved with this ecological ‘food system’. In this context the term food system is a concept that describes the complex links between food production, processing, distribution and consumption (Sobal et al. 1998). Humans learned food hunting, gathering and preparation behaviour through personal experience, cultural transmission and inter-generational teaching.

Given the integral association of food with social, cultural, economic and technological circumstances, change and development of the food system have been interwoven with change in these circumstances. The need for food regulation first emerged as a necessary response in those societies that experienced a change in the structure of the ecological
food system. For example, when hunting and gathering societies shifted to agricultural settlements approximately 10,000 years ago wild grains began to be cultivated and certain animals were domesticated. These developments were both a consequence of a less nomadic lifestyle and a basis for the success of the agricultural revolution. This shift in human society presented the first opportunity for food to be traded as a commodity. Food law has been traced back to biblical times (Hutt and Hutt II 1984).

The social and technological changes associated with the industrial revolution towards the end of the 19th century transformed the food system from a subsistence economy serving local needs to an integral component of an industrial economy. A reciprocal relationship developed between the structure of the food system and the social and technological changes ushered in by the industrial revolution. The mass migration of people from rural areas to cities during this time placed demands on the production, processing and distribution of food to service this social change and the technological change enabled the food system to develop to meet this demand. As the scale of trade in food increased, concerns arose in relation to fraudulent behaviour and food adulteration. The development of public health legislation commenced with the English Public Health Act 1848 (Reynolds 1997). This legislation was tied to the sanitary reform movement and sought to protect the health of the populations of British cities by tackling the poor environmental conditions resulting from the effects of the industrial revolution. The early public health laws did not explicitly address food matters beyond referring to the conditions, such as cleanliness, under which food was prepared and sold. The landmark development in modern food regulation was the release of the British Food Act 1860 as it prohibited the sale of adulterated or unwholesome food (Stanhope 1987).

In contemporary society a combination of social, economic, technological and political factors are creating a historically unprecedented transformation in the profile of the food supply. It has been estimated that during the second half of the 20th century the number of food items available in a typical United States (US) supermarket increased 20-fold from 1,500 to 30,000 items (Kessler 1994). The pace and scale of social and technological change have combined to make people less familiar with the food supply and less able to access traditional means of gaining the knowledge and skills necessary for assessing nutrition and safety aspects of food and their diet (Lawrence and Cumming 1997). Nevertheless, access to a safe and nutritious food supply for individuals and the
population remains as relevant today as it has been throughout history. The majority of the population now is dependent upon others to make available a food supply that is safe and nutritious and also for information about the relationship between food and health. Thus, the environment within which food composition is determined and health and nutrition information is promulgated is assuming increasing importance. Public policy has largely taken the place of ecological parameters, the inter-generational transfer of knowledge and various cultural rules and rituals in protecting public health and safety in relation to food. It is in this context that the need for food regulation is particularly obvious.

2.3 Food regulation as a public health policy instrument

The previous section explained that historically a primary rationale for food regulation was to protect public health and safety in response to fraudulent behaviour and food adulteration associated with the development of the food supply. Yet, regulation can be used by governments not only to safeguard, but also to advance, the interests of individuals and the community. A former director of the US Food and Drug Administration (FDA) commented, “As the FDA continues to meet traditional statutory mandates to preserve the integrity of the food supply, it is broadening its involvement in scientific and policymaking activities designed to promote nutrition as a tool of good health.” (Kessler 1994: xx). Although the iodisation of table salt to prevent goitre began in Switzerland in 1922 (Richardson 1997), it was the discovery of the vitamins and their role in preventing diseases such as pellagra and scurvy that provided the impetus for setting food standards to address food composition and labelling as public health interventions (Council on foods 1939). The 1992 World Declaration and Plan of Action for Nutrition recommended that food standards might be used to improve the nutritional quality of the food supply as one strategy to improve the nutritional status of all people on a global, national and local level (Food and Agriculture Organization & World Health Organization 1992). The Australian national food and nutrition policy refers to food regulation as one strategy to achieve its policy objectives (Commonwealth Department of Health 1992). In this section the nature and scope of food regulation as a policy instrument to effect public health outcomes is described.
The WHO Constitution identifies food as a fundamental prerequisite for health (World Health Organization 1946). Food is the source of energy and nutrients essential to nurture the human body and enable its genetic potential to be expressed. Conversely, inappropriate food consumption patterns influence the aetiology of diseases arising from dietary imbalances (World Health Organization 1990). Food can also be a vehicle for contaminants and microbiological organisms that cause ill health. This present analysis confines its assessment of the relationship between food and health to those processes mediated by nutrition science, i.e. the biological process by which food is metabolised and assimilated into the body. The relationship between food and health is complex. The effect of food intake behaviour on nutritional status and health cannot generally be attributed to direct cause and effect relationships, i.e. ‘exposure’ to single foods. Rather it is the amount and variety of food consumed that is critical and responses to this food intake ‘pattern’ are cumulative over extended time periods.

Public health nutrition has been defined as “... a population approach to the prevention of illness and the promotion of health through nutrition. This approach ... recognizes the wider social and ecological context in which nutrition related health problems arise.” (Margetts et al. 1998: 1). The contribution of food to public health is indicated by the population’s nutritional status, which is influenced, inter alia, by the population’s food intake pattern, that is itself influenced by the interaction between the supply of food and the demand for food. Other behaviour and physiological factors also affect nutritional and public health status either directly or indirectly, e.g. the profile of physical activity across the population. The production, processing, service and retailing components of the food system determine the profile of the food supply. Social, economic, cultural and political factors determine food demand as well as a variety of other factors across the population that influence public health. A conceptual model of the relationships among food, nutrition and public health is proposed in Figure 2.1.
Figure 2.1 Conceptual model of the relationships among food, nutrition and public health

The model outlined in Figure 2.1 provides a structure within which to conceptualise the relationship between food regulation and public health and thereby to analyse the development, implementation and evaluation of public health policy in a food regulation setting. Although there are many assumptions and expectations regarding what can and cannot be achieved by food regulation in general and food standards in particular, food regulations are not a panacea for achieving public health outcomes. They are one of several policy instruments available to the State. According to a policy report of the NFA,

"While a varied diet which contributes to good nutrition is necessary for good health, food standards cannot determine an individual's diet. They may however
create the food environment where a safe and healthy diet is accessible to all consumers. It is not possible for food standards to address the social, cultural and economic determinants of health, although the food regulatory system is an important part of a wider public health system." (National Food Authority 1993: 10).

Food regulation can contribute to the wider public health system by setting food standards to affect the composition and labelling of individual foods and groups of foods. The policy principles that are used to guide the setting of food standards addressing food composition and labelling vary among countries and over time within the one country. The policy principles and criteria for these food standards recommended by the Codex Alimentarius Commission (Codex), which is the principal organ of the joint Food and Agriculture Organization (FAO)/WHO Food Standards Program, are described to reflect the international benchmark.

2.3.1 Standards related to food composition

Food composition standards specify the amount of a nutrient, novel ingredient or substance such as the various additives, organic and inorganic residues in food products in general or in specific food commodities in particular. The present analysis is focussed on those standards that specify the nutrient composition criteria of food products.

Internationally, the policy rationale for the addition of nutrients to food products is articulated by Codex’s ‘General Principles for the Addition of Essential Nutrients to Foods’ (Codex principles) (Codex Alimentarius Commission 1987). The Codex principles are attached at Appendix 1. These principles specify the following conditions for the addition of nutrients to foods:

i) For the purpose of ‘restoration’, which means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures. The levels of the nutrient(s) are restored to those which were present in the edible portion of the food before processing, storage or handling.
ii) For the purpose of restoration whereby the addition to a food of essential nutrient(s) to allow for nutritional equivalence of substitute foods.

iii) For the purpose of 'fortification', which means the addition to a food of one or more essential nutrients over and above the levels normally contained in the food, whether or not it is normally contained in the food, and where there is proven public health and nutrition need.

The Codex principles also state (Codex Alimentarius Commission 1994):

i) Fortification should be the responsibility of national authorities.

ii) The need for fortification should be demonstrated by:
   - Actual clinical or sub-clinical evidence of deficiency.
   - Low levels of intake of nutrients.
   - Possible deficiencies from changes in food habits.
   - Foods so fortified should be consumed by the population at risk.

2.3.2 Standards related to food labelling

Food labelling standards can complement food composition standards to inform the consumer about the levels of nutrients in a food product and relevant health-related information and be an integral component of nutrition education programs to support national nutrition policy (Caswell 1992). The types of nutrition and health-related information, on food labels and in advertising, as defined by Codex are:

i) Nutrient content claim.
   A nutrition claim that describes the level of a nutrient contained in a food, for example, 'source of folic acid' (Codex Alimentarius Commission 1997).

ii) Nutrient function claim.
   A claim that describes the physiological role of the nutrient in growth, development and normal functions of the body (Codex Alimentarius Commission 1997). An

---

6 A substitute food is a food that resembles a common food in appearance, texture, flavour and odour, and is intended to be used as a complete or partial replacement for the food it resembles, e.g. vitamin A and D addition to margarine as a substitute food for butter (Richardson 1997).

7 The Codex standard specifies that a food product must contain at least 10 per cent of the RDI of a particular nutrient in a reference quantity to trigger a 'source' claim.
example of a nutrient function claim is ‘Contains folic acid: folic acid contributes to the normal growth of the fetus’.8

iii) Health claim.

The draft definitions at stage 3 of the Codex procedure are ‘... means any claim establishing a relation between a food or a constituent of that food and health, [whether it is good health or a condition related to health [or disease]],’ or ‘... means any claim which suggests that a food or a constituent of that food has an impact on health.’ (Codex Alimentarius Commission 2000). Although Codex and most countries, including Australia, have a general prohibition on the use of health claims, during the 1990s several countries including the USA, South Africa and Japan developed regulatory frameworks permitting certain health claims to be made, albeit within strict guidelines. It has been suggested that health claims be considered in two distinct contexts in accordance with the health outcome that they purport to describe (Lawrence and Rayner 1998):

- ‘Dietary guideline’ health claim.

These health claims are intended to reinforce dietary guideline messages. They relate a food, or nutrient in a food, to a dietary guideline recommendation. These claims are targeted at the general population. For example, ‘Diets low in saturated fat and cholesterol and rich in fruits, vegetables, and grain products that contain some types of dietary fiber, particularly soluble fiber, may reduce the risk of heart disease, a disease associated with many factors.’ (Department of Health and Human Services 1993).

- ‘Functional’ health claim.

Health claims are interwoven with the concept of ‘functional foods’. According to one definition, functional foods are “… food products modified through the application of advanced technologies with the intention to subserve physiological roles beyond the provision of simple nutrient requirements” (National Food Authority 1994: 3). Currently, the term functional food is not recognised by food regulators in Australia, or internationally. Functional foods essentially are a concept

---

8 This example, suggested by the researcher in his role as a member of the Australian delegation, was adopted to clarify the definition of a nutrient function claim at the 24th session of the Codex Committee on Food Labelling, Ottawa, Canada, 14-17 May 1996.
that will take on meaning in terms of the use of health claims that food regulators may permit certain foods to use on their labels and in advertising. A functional health claim would describe the influence of a food, or biologically active substance in a food, on reducing the risk of a disease or enhancing a physiological function such as immune capacity. These claims are targeted at population sub-groups or individuals. In August 1998 an exemption to the general prohibition on health claims in Australia was made to permit the trialling of a health claim that described the relationship between folate and the reduction in risk of NTDs\(^9\). The health claim was consistent with the functional health claim category. An example of an approved claim was, ‘A woman’s diet rich in folate before and in early pregnancy may help to prevent birth defects like spina bifida in her baby. One serving of this food contains x\% of the 400 micrograms per day intake of folate recommended for women of child-bearing age.’ (Australia New Zealand Food Authority 1998).

### 2.4 The structural and procedural arrangements for setting and enforcing food regulation in Australia

All food sold in Australia must comply with Australian food law and regulations. It is a criminal offence in Australia to supply food that does not comply with relevant food standards. Individual food standards are collated in the Food Standards Code. The legislative and administrative framework for the setting and enforcement of food standards and codes of practice has been established by the State and comprises a large number of agencies and legislation spread across national, state and local levels of government. The structural and procedural arrangements for developing food regulation in Australia have evolved in a series of stages.

Prior to federation, Australia existed as individual colonies with five of the six colonies being self-governed (Sharman 1990). Legislation related to food was determined by each colony’s government through acts of parliament and was mainly developed in response to food safety and fraud concerns. With federation on 1 January 1901, the colonies united as a nation, yet when preparing the Constitution the colonies were cautious about handing over all powers to the Commonwealth. Food regulation was one of several responsibilities

---

\(^9\) The relationship between folate and NTDs is described in detail in Chapter 6.
over which the colonies were not prepared to cede control to the Commonwealth. This division of powers was written into the Constitution and has had a significant bearing on food regulation policy development and implementation capabilities in Australia. Notably, with six different codes of regulations difficulties at the national level were inevitable.

In 1937 the NHMRC was established with one of its objectives being the promotion of closer cooperation between commonwealth and state health authorities (Stanhope 1987). In 1955, following its establishment by the NHMRC, the first meeting of the Commonwealth Food Standards Committee was held. The development of uniform food legislation across Australia continued to be elusive as each of Australia’s States and Territories retained sovereignty over food regulation and were not obliged to adopt the Committee’s advice, or were able to amend the standards to local conditions (National Food Authority 1993).

The premiers of the Australian States and Territories entered into a cooperative arrangement for establishing national food regulation with the signing of the National Food Authority Act 1991 (the NFA Act 1991) (Parliament of Australia 1991). The NFA Act 1991 established the mechanisms for the development of food regulatory measures and created the NFA on 19 August 1991 as the agency responsible for setting draft standards for all food on the Australian domestic market. The NFA was established as an independent, scientific and statutory authority under the jurisdiction of the Commonwealth Human Services and Health portfolio. The NFA replaced the previous multi-committee structure for managing food regulation within the NHMRC and ensured for the first time in Australia’s history uniform application of food standards throughout the country. The NFA Act 1991 also established the National Food Standards Council (NFSC), as a Ministerial Council, to whom recommendations from the NFA were sent before being proclaimed into food law. The NFSC comprised the Health Ministers from the 8 Australian government jurisdictions. Each of the jurisdictions had an equal voting right and decisions required a majority vote. The Chair of the NFSC was the Commonwealth Minister for Human Services and Health. The Parliamentary Secretary to the Health Minister had executive responsibility for NFA in terms of overseeing its day-to-day management.
Because food standards are given legal effect by State, and Territory food Acts, the Food Standards Code needs to be read in conjunction with the relevant food legislation. A ‘Model Food Act’ was developed as a blueprint for other food laws, although it is not legislation in its own right. The States and Territories adopted, without variation, food Standards recommended by the NFA and which the majority of the members of the NFSC had approved. Therefore, if the NFSC adopted an amendment put forward by the NFA, it automatically became law in Australian States and Territories. Even though the NFA and the NFSC were set up under Commonwealth Acts, it is the function of the State health departments to administer and enforce the provisions of their own food Acts. Each State has its own regulatory system for enforcing laws, codes, regulations, by-laws and ordinances. The Commonwealth retains direct enforcement powers in such cases as import and export laws, quarantine and customs.

On 5 December 1995 Australia and New Zealand signed a Treaty establishing joint structural and procedural arrangements for developing food standards in both countries. For the first time two sovereign nations joined forces to create a common set of food standards, as elaborated in the Australia New Zealand Food Standards Code, in order to reduce barriers to trade. The arrangements were based on the NFA Act 1991 that was amended to become the Australia New Zealand Food Authority Act 1991 (the ANZFA Act 1991) which renamed and reconstituted the NFA and its committees so that the NFA became the ANZFA. Also, the NFSC became the Australia New Zealand Food Standards Council (ANZFSC). Under the Australia New Zealand food standards system New Zealand entered formally into an Australian policy making and legislative process and adopted standards developed by the Authority by reference and without amendment (with a few exceptions that fall outside the Treaty arrangements).

Further reforms were agreed with the signing of the Inter-Governmental Food Regulation Agreement 2000. The Agreement has amended both the ANZFA Act 1991 and the Treaty with New Zealand and thereby establishes new structural and procedural arrangements for developing food regulation in Australia and New Zealand. The Agreement amends a number of provisions of the current ANZFA Act 1991, including renaming that Act as the
Food Standards Australia New Zealand Act 1991. It came into force in mid-2002.\footnote{The key structural components of the new regulatory arrangements are:}

For the purposes of this thesis it is the structure and procedures of the NFA for setting food standards, coinciding with the period of the case study, that is, 19 August 1991 to 14 June 1995, which is relevant to the policy analysis.

2.5 The politics of food regulation

Although food is a prerequisite for health, it is also a significant cultural, religious, social and commercial commodity. It is estimated that food contributes over $60 billion per year to the Australian economy and accounts for 12 per cent of gross domestic product and seven per cent of employment (Trade Policy Coordination Section 1999). The different roles for food mean that there are many stakeholders with competing interests regarding how and why the food supply should be developed and the nature and scope of food regulation in managing this development. According to Tansey,

\textit{"... ensuring a well-nourished world is primarily a political and economic problem concerning power and control over a range of resources and the distribution of benefits arising from their use ... The food system, in reality, is not driven by nutritional but market and competitive needs." (Tansey 1994: 45).}

It is the development of food products claiming to promote health that has become a significant battleground for competing interests related to food regulation policy. For example, ever since the discovery of the vitamins, certain food manufacturers have been seeking to add these nutrients to their food products and to make health claims about

\footnote{The key structural components of the new regulatory arrangements are:}
- The ANZFSC to be reconstituted as the Australia New Zealand Food Regulation Ministerial Council (ANZFRMC) with a modified role and composition.
- The Australia New Zealand Food Regulation Standing Committee (ANZFRSC) whose functions include co-ordinating policy advice to the ANZFRMC.
- The ANZFA to be reconstituted as Food Standards Australia and New Zealand (FSANZ), which will be established as a statutory authority under the jurisdiction of the Commonwealth Health portfolio.\footnote{The key structural components of the new regulatory arrangements are:}
these products. Conversely, public health practitioners have raised concerns about the safety implications of such practices and believe that, substantiation notwithstanding, such products should be regulated as drugs, not foods. Following abuses by certain food manufacturers in the early 20th century, food regulations were developed generally prohibiting the use of health claims on food products and restricting the indiscriminate addition of nutrients to food. The ‘relaxation’ of these regulations has been the subject of ongoing advocacy from food manufacturers and certain scientists.

Many commentators believe it is inevitable that public health and commercial interests are in conflict (Burris 1997; Reynolds 1997) and the food industry is regarded as playing politics as well as or better than other industries (Nestle 2002). Stakeholders attempt to influence the definition of problems, the interpretation of policy objectives and the setting of policy agendas in accordance with their interests. It is the existence of competing interests among stakeholders that captures the political nature of using food regulation as a public health policy instrument.

2.6 A model for analysing the political processes associated with using food regulation as a public health policy instrument

Government regulatory processes essentially are adversarial in character (Breyer 1982). Food regulators are positioned as the ‘policy brokers’ for resolving stakeholders’ competing policy interests associated with the development of food. To understand how and why food regulation is used as a public health policy instrument investigators need to extend their analysis beyond the structural and procedural features associated with the development of food regulation to the policy processes involved in managing the competing interests of different stakeholders. As Walt comments,

"... health policy is best understood by looking at both processes and power, which means exploring the role of the state, nationally and internationally, the actors within it, the external forces influencing it, and the mechanisms within the political system for participation in policy making." (Walt 1994: 5).
For the purposes of this thesis a systems approach is used to provide a model from which to analyse the processes of the political setting within which food regulation is developed. The idea of a systems approach is that the various activities, stakeholders and procedures associated with food regulation can be viewed as a system, namely the food regulatory system. A system is an organised or complex whole that has greater explanatory properties for social and political phenomena than the sum of its individual parts (Kast and Rosenzweig 1972). Each part of the system is related either directly or indirectly to the other parts. It is the links among the parts that explain the overall operation of the system.

Easton’s systems model of a political setting is one of the most commonly cited policy models for making sense of the dynamics of the policy processes in institutions (Easton 1965). Easton’s model emphasises processes rather than the formal structures of institutions to conceptualise complex political phenomena. The model represents the policy process as a dynamic system of inputs, processes and outputs embedded within a wider political environment. At the centre of the model is the decision-making process of the political system. The system is subject to the demands of interest groups who seek to shape the policy outcome. The participation of those placing these demands into the political system serves to support the political system, and thereby stabilise the system, by acknowledging its authority to adjudicate between competing demands and to make binding decisions (Gardner and Barraclough 1992). The system can itself be a source of supports and influence the inputs. For example, supports may arise in the form of responses to calls for submissions into the process. Collectively, these demands and supports constitute inputs into the system. The policies that are made constitute the outputs of the political system. Outputs can, in turn, feedback to stimulate further inputs into policy-making and the cycle continues. An adaptation of this model is outlined in Figure 2.2.
Easton views the political system as being stable and subject to continual stress from the environment. He comments, "What is happening in the environment affects the political system through the kinds of influences that flow into the system. Through its structures and processes the system then acts on these intakes in such a way that they are converted into outputs." (Easton 1965: 111). At its core the political system model simply conceptualises how and why certain kinds of inputs are converted into outputs. The outputs return to other systems that exist in the political environment, or they may return directly back into the system itself. There is an exchange, or 'reciprocity' in the relationship between the system and the political environment within which it operates. The inputs of the environment are the outputs of the political system. As Easton notes,

"... there is a continuous flow of influences or outputs from the political system into and through the environments. By modifying the environments, political outputs thereby influence the next round of effects that move from the environment back to the political system. In this way we can identify a continuous feedback loop."
(Easton 1965: 111).
Easton’s model is not a theory of policy-making, instead it provides a heuristic device to conceptually the food regulatory system so as to assist with testing theories of the policy-making process within this system. The significance of Easton’s model is that it illustrates policy as a process and enables the analyst to identify elements of that process for insightful analysis. Specifically, the political system can be disaggregated into a number of different levels, each of which is then amenable to more detailed analysis. It was the nature of the relationships among the various levels within the system with which Easton was particularly interested.

Easton’s systems model is not without criticism. Some commentators argue that the linear sequence of demand initiation → conversion → outputs for the political system, as conceptualised in the model, rarely occurs so smoothly in practice (Ham and Hill 1993). Also, the systems framework is criticised for placing detailed consideration on systems analysis aspects of the model at the expense of exploring the dynamics of the ‘black box’ of decision-making (Ham and Hill 1993). Finally, the model has been criticised for not being able to adequately account for structural influences on the decision-making process (Palmer and Short 1994).

By gaining a theoretical understanding of the use of evidence in the policy-making process, this thesis will contribute to Easton’s plea to explain the nature of the relationships between the levels of the model. Also, such understanding will help address some of the criticisms of the model.

2.7 The analytical levels of the food regulatory system

The setting of food standards by the NFA was governed by legislated procedures and objectives set down in the NFA Act 1991. The present policy analysis adapts Easton’s model of a political system to conceptualise the food regulatory system as operating at three interrelated levels. In adapting Easton’s systems model the analysis of the case study aims to illuminate what happens at each of the system’s levels and test theory of how and why they interact within the policy-making process of the food regulatory system in Australia.
2.7.1 The decision-making process level

When assessing a food standard matter, the NFA was required to take into account any submissions received from the public in response to its public notices. Also, the food regulatory system set out objectives for developing and varying food standards to provide a common basis for decision-making when assessing applications and proposals and to give guidance as to the relative weight the NFA should attach to conflicting demands made on the regulatory system. The governing objectives were set out in section 10 of the NFA Act 1991. At the time of the review of Standard A9, the objectives in descending order of priority were:

i) The protection of public health and safety.

ii) The provision of adequate information relating to food to enable consumers to make informed choices and to prevent fraud and deception.

iii) The promotion of fair trading in food.

iv) The promotion of trade and commerce in the food industry.

v) The promotion of consistency between domestic and international food standards where these are at variance.

2.7.2 The procedural level

The NFA Act 1991 prescribed the procedures for varying and setting food standards. Any person or organisation could make an application to the NFA to amend an existing standard or develop a new standard. Food standards were set and a subsequent amendment to the Food Standards Code was made by a process that responded to an application that could be made by anyone or by the preparation of a proposal by the NFA. The procedure that the Authority followed when it received an application, or generated its own proposal, involved the following four step process:

i) Preliminary assessment (not relevant to a proposal)

When the NFA received an application, a preliminary assessment was made to ensure the application fell within the NFA’s area of responsibility, that it did not duplicate other existing applications and that there was sufficient information to proceed. The NFA was required either to reject the application citing reasons for the rejection, or accept the application. If the application was accepted, the NFA then invited public submissions through notices in newspapers and on its website. Any external application made to the NFA had to be processed within 12 months. Proposals had no time constraint.
ii) Full assessment
After considering any submission that has been received, the Authority undertook a full assessment based on the policy objectives set out in the NFA Act 1991. Following the full assessment, if the NFA supported the application or proposal, it then prepared a draft standard or variation to the standard before it conducted an inquiry. The Authority was then required to give notice of its intention to conduct an inquiry and again invite written submissions within a specified time. If the Authority did not support the application, it was required to give the reason and information on appeal rights.

iii) Inquiry
After an amendment is drafted, a second round of public consultation usually was instigated. Following consideration of public submissions the amendment to the Code was fine tuned, for example, refining the wording, and any issues raised were addressed.

iv) Recommendation to the NFSC
The final stage in the process was when the NFA made a recommendation to the NFSC to adopt a draft standard. The NFSC was responsible for deciding whether an amendment recommended by the NFA should become law.

The Authority also was required to make a recommendation to the NFSC within 12 months after the receipt of an application. The NFSC could adopt, amend or reject the Authority’s recommendations or return them for reconsideration. Should any minister have disagreed with a recommendation of the NFA, dispute procedures were in place to ensure other ministers were aware of the minister’s views and the matter was resolved.

If and when the Council adopted a draft standard the Authority was required to cause a copy to be published in the Commonwealth of Australia Gazette and the New Zealand Gazette specifying the date it was to come into effect. Food standards were published collectively in the Food Standards Code.

2.7.3 The political environment level
The political environment within which the food regulatory system operates exerts a profound influence over the system’s governance, powers and functions (Roemer 1991).
At the time of the case study the political environment within which the food regulatory system operated was characterised particularly by two interrelated policy agendas. Firstly, there was a microeconomic reform agenda that through a series of regulation reviews and reforms was shaping the future direction of public health law (Bidmeade and Reynolds 1997). Secondly, the political environment had become increasingly focussed on engaging with the global marketplace and fostering the export competitiveness of Australian food products.

**Microeconomic reform agenda**

In response to political and industry perceptions that food regulation administration in Australia was impeding food trade, several government inquiries were conducted into food regulation in the late 1980s. The Victorian Business Regulation Review Unit (Business Regulation Review Unit 1988) and the Commonwealth Industries Assistance Commission (Industries Assistance Commission 1989) conducted inquiries that concluded that the existing food regulation system was a significant impediment to the development of an efficient and competitive food export industry. These inquiries recommended the need to harmonise food laws and regulations across Australia. These two inquiries were instrumental in setting up a Special Premiers' Conference in October 1990 where it was agreed to establish an independent statutory authority with responsibility for maintaining and developing national food standards as "... an essential piece of microeconomic reform" (National Food Authority 1992: 6). It was these inquiries, therefore, that were directly responsible for the replacement of the NHMRC system with the NFA.

The impact of this microeconomic reform agenda upon the Australian food regulatory system continued throughout the 1990s, both during and beyond the period of the case study being analysed in this thesis. Specifically, the Commonwealth, State and Territory Governments adopted programs of legislative and regulatory review endorsed by the Council of Australian Governments (COAG) (Food Regulation Review Committee 1998). Under the auspices of COAG major regulatory reviews have included the *Competition Policy Reform Act 1995* and the development of a set of 'Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting Bodies' (Council of Australian Governments 1997).
The latest food regulation arrangements, introduced in mid-2002, represent the culmination of a series of reviews and reforms into the food regulatory system throughout the 1990s. The most notable review during this period was the Food Regulation Review that commenced in March 1997 as part of the reform statement ‘More Time for Business’ announced by the Prime Minister that was itself prepared in response to the Commonwealth Government’s Competition Principles Agreement and with the key objectives, that while protecting public health and safety, to (Food Regulation Review Committee 1998):

i) Reduce the regulatory burden on the food sector, and examine those regulations which restrict competition, impose costs or confer benefits on business.

ii) Improve the clarity, certainty and efficiency of food regulatory arrangements.

The Food Regulation Review coincided with the review for and subsequent gazettal of the Joint Australia New Zealand Food Standards Code, in December 2000. The major aim of the new Code is to reduce and simplify existing regulations covering food manufacture and handling. It is intended that the new regulations will enhance industry innovation, competition and trade.

These regulatory reforms and reviews were and are being driven by a microeconomic reform agenda within a neoliberalism approach to governance that has emerged since the 1980s as the dominant political ideology in Australia (Baum 1998). Neoliberalism is characterised by new theories of management that call for ‘small’ government and increased reliance upon the ‘invisible hand’ of the market working through consumer choice and entrepreneurial competition (Stretton and Orchard 1994). According to Hancock, the basic tenets of neoliberalism are (Hancock 1999):

i) The commitment to a limited role for government in creating the legal and institutional setting for the efficient functioning of the laissez-faire economy.

ii) The freedom of individuals from government coercion, except where individual rights are under threat.

iii) That there are benefits of unregulated voluntary market transactions to optimal wealth creation, distribution and efficiency.

The regulatory reforms draw directly on an ideology that the most efficient way to organise economic activity, in order to maximise the output of the economy, is through a
competitive market system that is subject to minimum government regulation. This approach is claimed to be free of values regarding what consumers or producers should or should not do. Indeed, this ideology claims that adequately informed individuals are the best judges of their own wellbeing.

Global trade in food

Although, historically, security of food supplies has been a national priority, global trade in food is becoming analogous to that of any other business and not necessarily a fundamental priority for each nation (James 1993). For example, the American food manufacturing industry is the largest industry in the world (Forbes 1994). It has been estimated that the global agri-food industry (comprising farming, processing, manufacturing, distribution, and associated chemical and pharmaceutical interests) will develop into an industry worth approximately US$10 trillion, or approximately half of the world economy, by 2028 (Goldberg 1991). As a significant component of the global political economy, food plays a role across a range of national and international political agendas. It will be increasingly difficult for individual countries to remain isolated from international developments and national food legislation will be expected to conform with standards harmonised through international consensus (Jukes 1995).

The Australian domestic food market is relatively small, stable and saturated with product (Lester 1994). Australia’s food trade is predominantly international. During the period of the case study for this thesis, food policy-making had become increasingly directed at fostering opportunities to expand export food trade. Consequently, the domestic market was inextricably linked with global trade. For example, in July 1992, the Ministers for Industry, Technology and Commerce, and Primary Industries and Energy announced the federal government’s Agri-Food Strategy (Department of Primary Industries and Energy and Department of Industry Technology and Commerce 1992). The Agri-Food Strategy and its accompanying Agri-Food Council were established to provide a focus for policies to enhance the international competitiveness of the Australian agri-food industries. The ultimate objective of the Strategy was to improve the international competitiveness of Australian agri-food industries. The Strategy’s philosophy was “...a focus on facilitating market-driven growth, removing impediments and minimising regulation, with the onus of proof lying with those advocating intervention.” (ACIL 1993: i).
Whereas Australia has historically been an exporter of primary food products, prices are falling in commodity markets and there is increasing competition from developing countries, consequently it is value-added processed food products that are being actively promoted by government and industry. During the 1980s and 1990s there was an increasing focus by the Commonwealth government, regardless of which party has been in power, towards increasing exports of processed foods as an essential contributor towards export earnings. The government's emphasis on export performance for food is highlighted by reviews of the role of the food processing industry (Industries Assistance Commission 1989; Prime Minister's Science Council 1991) and the establishment of the Prime Minister's Supermarket to Asia Council in 1996 to promote Australian food products in Asia (Food Regulation Review Secretariat 1997).

Many countries have entered into international agreements that impose obligations on them with respect to how they trade in food in the global marketplace. These developments set a broad political framework both for minimising regulation and interventionist policies, especially where these may be judged to restrict trade or competition, and for harmonisation of standards internationally. As a consequence, international obligations exert a powerful influence over the way in which food regulation policy is developed and implemented at national and international level.

In 1995 the World Trade Organization (WTO) came into force establishing rules on international trade in all goods, including food and agricultural products. As the umbrella intergovernmental organization for international trade the WTO administers the WTO Agreement and associated Multilateral Trade Agreements. Annexed to the WTO Agreement are various legal instruments, two of which are relevant to food regulation:

i) The Agreement on Technical Barriers to Trade (TBT)
This agreement aims to improve the efficiency of production and to facilitate international trade. It stresses that technical regulations should not create an unnecessary obstacle to trade or discriminate against imported goods. A court can determine if a standard is protecting people from a real danger and threat to wellbeing or is simply a protectionist measure. The practical significance of the TBT Agreement in the context of public health policy is with respect to measures intended to prevent consumer deception, e.g. whether nutrition labelling and claims are a disguised trade barrier.
ii) The Agreement on Sanitary and Phytosanitary measures (SPS)

Sanitary measures are those that relate to the safety of food for human consumption and include the rules that specify the permissible levels of pesticide residues, additives, toxins and disease-carrying organisms in food and beverages. Phytosanitary measures relate to protecting plant health, including quarantine controls. This agreement is concerned with minimising the potential use of SPS measures as barriers to trade. The SPS Agreement provides that sanitary and phytosanitary measures must be based on sound science and risk assessment principles. Also, these measures must be aligned with Codex standards. Ostensibly, Codex has become the world body responsible for setting food standards.

Codex standards are advisory and not enforceable internationally and as such Codex standards do not present a direct threat to national food standards. Nevertheless, the WTO dispute resolution structure allows governments to refer to Codex and other international standards when trade disputes arise at the WTO (Eldred and Coffield 1997). The WTO rules are legally binding on Member countries even if it means that domestic legislation must be changed. Australia is a member of the WTO and the parent Food Act addresses the obligations imposed upon Australia as a signatory to international Agreements, so that Australian food laws are in harmony with international laws (Lindenmayer 1999).

2.8 Challenges in using food regulation as a policy instrument to achieve public health outcomes

The previous section in this chapter described the structure and procedures of the food regulatory system within which food regulation policy is made. In order to understand how and why public health policy is made in a food regulation setting, policy analysis needs to extend beyond the structural features and technical procedures of the food regulatory system to consider its policy processes. The analysis of policy processes needs to be cognisant of the following challenges for using food regulation as a policy instrument to achieve public health outcomes.
2.8.1 Conceptual challenges - The interpretation of the 'protection of public health and safety' policy objective

Food regulatory systems are governed by the powers set out in the parent Food Act. In Australia, the *NFA Act 1991* does not make mention of the role of food regulation as a policy tool to achieve public health outcomes. Instead, food regulatory systems have been established to respond to demands from stakeholders and to reconcile competing interests to develop the food supply, rather than having any inherent goal of their own or a long term vision for the development of the food supply. The legacy of this 'responding' orientation is reflected in the profile of the food regulatory system's governing objectives as outlined in the previous section. Specifically, the objectives refer to the 'protection' (as distinct from the 'promotion') of public health and safety and are potentially conflicting in the sense that they incorporate trade considerations, albeit as a lesser priority.

Despite the priority accorded to the protection of public health and safety objective, no food regulation agency either in Australia or internationally has explicitly defined this objective and how it applies to the practical development of food regulation policy. For example, when making public health policy in a food regulation setting, what is the difference between protecting public health and promoting public health? What is the difference between protecting public health and protecting safety? The lack of an explicit definition for the protection of public health and safety objective, means that it is especially vulnerable to being interpreted and applied ambiguously.

There is difference of opinion regarding the nature and scope of the interpretation of the protection of public health and safety in the setting of food standards. On the one hand there are those who believe that the interpretation should be confined to technical safety measures associated with microbiological and toxicological studies, e.g. setting the acceptable maximum residue limit for the presence of cadmium in peanuts. On the other hand there are those who believe the interpretation should be inclusive of broader nutrition and public health principles associated with the relationship between food and health, e.g. social, ethical, cultural and environmental considerations.

In May 2001 ANZFA published a position paper outlining its role in health promotion (*Australia New Zealand Food Authority 2001*). According to the position paper,
"The protection of public health and safety will vary according to the nature of the work undertaken by ANZFA. For example, food regulatory measures dealing with microbiological issues tend to have an immediate safety aspect or health protection role. Alternatively, nutritional considerations often have a more significant public health focus and hence health promotion function. ANZFA’s role, in terms of health promotion, is to support, complement and strengthen existing public health initiatives." (Australia New Zealand Food Authority 2001: 9).

This general interpretation affirms the nature and scope of the protection of public health and safety in terms of microbiological and toxicological measures. Broader public health and nutrition measures are positioned as being of a health promotion nature and therefore beyond the scope of the objective.

The nature and scope of the interpretation of the protection of public health and safety has a direct bearing on the use of scientific evidence in public health policy-making in a food regulation setting. ANZFA emphasises that scientific principles and approaches underpin its work in developing, varying and reviewing food standards, by "Using the best scientific evidence available, ANZFA uses risk analysis procedures to determine the most appropriate strategy to address food related issues of public health and safety significance." (Australia New Zealand Food Authority 2001: 4). There are relatively well developed risk analysis procedures available to process scientific evidence from microbiological and toxicological studies regarding the potential safety impact of food standards. From this perspective, the causal factors and risk outcomes are often well defined, quantifiable and there are relatively short term and linear relationships to measure in individuals. Conversely, the broader nutrition and public health consequences of food standards are not so amenable to the collection and analysis of evidence as they can be multifactorial, cumulative and take decades to emerge as population-wide impacts.

2.8.2 Scientific uncertainties
Advances in food science and technology are increasing our knowledge of food ingredients and creating an unprecedented rate and extent of change in the development
of novel food products\textsuperscript{11} and opportunities for food policy interventions. Whereas there are well developed risk analysis principles in place to determine risks and benefits of an intervention, by definition, novel foods and ingredients have no history of use and it is not possible to access evaluative evidence to predict with certainty their public health effectiveness and/or safety in the longer term. As a consequence of these scientific uncertainties food regulators invariably need to rely on value judgments in their interpretation and application of the available scientific evidence. When commenting upon the US experience in food regulation, Miller lamented that, "Scientific knowledge is accumulating at such a rate that we know almost too much and understand too little about the substances we are attempting to evaluate and regulate." (Miller and Taylor 1989: 23).

In a food regulation setting the relationship between science and the legal aspects of policy-making is particularly challenging due to the contrasting styles of resolving issues (Nyhart and Carrow 1983). Legal and policy-making institutions are intended to decide issues and resolve uncertainty to increase confidence in the process. However, part of the rigour of the scientific evaluation process is to highlight areas of uncertainty and the limitations of different processes. As Somogyi observes,

"Knowledge is hardly ever complete and never a static state. It is rather a dynamic concept, constantly in the process of development and refinement ... regulation based on science must invariably be considered as a transitory stage reflecting current knowledge at a given point in time." (Somogyi 1999: 2).

These scientific uncertainties raise questions about principles for when it is appropriate to act upon scientific evidence and make policy, ie at what point is there a sufficient quantity and quality of evidence of efficacy and safety to proceed to policy formation (the 'precautionary' principle)? Alternatively, if there is no evidence of harm should policy be opposed regardless of whether there is any evidence of benefit (the 'no-harm' principle)?

\textsuperscript{11} Standard 1.5.1 of volume 2 of the Australian Food Standards Code defines a novel food as meaning "... a non-traditional food for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented"
2.8.3 Ethical dilemmas

Public health interventions invariably have moral underpinnings and frequently engage ethical dilemmas (Cole 1995). For example, when formulating policy decisions in the setting of food standards to effect public health outcomes policy makers face an ethical dilemma that is inherent in all law, that of balancing the interests of the individual and the interests of society (Roemer 1991). From a public health perspective, law has been described as a process by which individuals living together in a society meet their common problems and solve them to promote the collective interest (Wing 1985). Yet, there are ideological differences as to whether the collective interest is best achieved by protecting individual rights within the society or protecting the collective rights of the society as a whole. Debates associated with the dialectic between individualism and collectivism often reveal irreconcilable differences, and there may be no consensus on the ‘correct’ ethical response to a policy matter. However, there are ethical principles to provide guidance in policy-making.

According to Beauchamp and Childress 1994, (cited in Last 1998: 35), modern ethical theory is founded on four principles: respect for autonomy; non-maleficence; beneficence; and justice, which are defined as:

i) **Respect for autonomy** – is the concern about human dignity and freedom and the rights of individuals to make choices and decisions for themselves;

ii) **Non-maleficence** - is the principle of not harming, derived from the ancient medical maxim, *primum non nocere* (first do no harm);

iii) **Beneficence** - is the principle of doing good; and

iv) **Justice** – is concerned with fairness, equity, and impartiality.

The individual versus collective rights dichotomy illustrates there are occasions when the principles can conflict. The role of the state in intervening in individual rights is widely supported when there is an identified need to protect individuals from acute food safety concerns (Wikler 1983). However, when the state intervenes either to protect common goods, eg conserving the characteristic nutritional qualities of food, or to manipulate the nutrient profile of a food to effect a public health outcome, it can impose costs and benefits on stakeholders and it leaves itself open to accusations of impeding the interests of society as a whole or of being paternalistic. Dworkin defines paternalism as “...interference with a person’s liberty of action justified by reasons referring exclusively to
the welfare, good, happiness, needs, interests, or values of the person being coerced” (Dworkin 1983: 20). Downie and others see no contradiction with government’s role in regulation. They suggest that government does have a duty because the preamble to the WHO Constitution states that there is a fundamental right to the highest standard of health for everybody i.e. acceptance of the WHO Constitution commits states to health policies focused on the collective good. Health legislation may diminish the freedom of some in society but extends the freedom of the majority and improves their quality of life, i.e. rather than removing individual autonomy, it is enhancing it (Downie et al. 1992).

The resolution of this ethical challenge depends to a large extent on how to define and measure both a collective interest and the level of harm to an individual that might result from a public health intervention. These definitions and measurements, themselves depend on answers to questions such as how many individuals, or what proportion of the population, should benefit from an intervention before it is considered a public health intervention? and what level of harm to the collective interest is considered tolerable before a state intervention is justified that might restrict an individual’s rights?

2.9 Conclusion

This chapter has presented a description of the food regulatory system in Australia as a political setting to analyse how and why scientific evidence is used in the making of public health policy. The inherently political nature of using food regulation as a policy instrument makes the food regulatory system a rich setting to analyse and test theory of the use of scientific evidence in the public health policy-making process. Easton’s model of a political system has been adapted to provide a conceptual base for analysing the policy-making process associated with the political setting within which food regulation is developed and from which to gain a theoretical understanding of its operation.

The public health policy-making process in a food regulation setting is governed by legislated procedures and objectives. A former Director of the FDA and Carson have argued that the procedures and policy objectives of the food regulatory system guide the, “… development of food science and technology by providing signposts, in the form of scientifically sound regulatory decisions” (Shank and Carson 1994: 207). The analysis
presented in this chapter argues that scientific evidence notwithstanding, public health policy-making in a food regulation setting faces complex challenges. Generally, public health policy in a food regulation setting is made in response to the demands of stakeholders. Conceptually, it lacks a clear definition of what is meant by protecting public health and safety. Moreover, it confronts scientific uncertainties and ethical dilemmas when being used as a policy instrument intended to effect public health outcomes. Extending Shank and Carson’s signposts metaphor, it could be argued that the signposts are erected after the road has already been laid out by car manufacturers and engineers, the message on the sign is open to interpretation and it is not clear where the road, along which the signposts are placed, is heading.

The food regulatory system is the unit of analysis for this thesis. The challenges associated with using food regulation as a policy instrument for achieving public health policy outcomes identified in this chapter provide the key issues to guide the investigation. It is to these issues that the findings from the analysis of the case study will be generalised in the thesis discussion. In the next chapter a review of different theories of the use of scientific evidence in the policy-making process is presented.
CHAPTER 3

A review of theories on the use of scientific evidence in the making of public health policy

3.1 Introduction

The previous chapter presented a description of the food regulatory system in Australia as the political setting for analysing the use of scientific evidence in the making of public health policy. The use of food regulation as a policy instrument for achieving public health outcomes was described as an inherently political process involving competing rationalities among stakeholders and confronted by conceptual challenges, scientific uncertainties and ethical dilemmas. An understanding of how and why scientific evidence is used in the policy-making process requires theories that explain the processes by which the conceptual challenges, uncertainties and dilemmas are resolved.

Elsewhere, it has been noted that there exists a limited well-articulated and empirically verified body of theory to underpin the policy-making process within this subfield of policy science (Sabatier 1991; Nutbeam and Harris 1998). Moreover, there are no theories that are dedicated to explaining the use of scientific evidence in a food regulation setting. A major challenge in reviewing theories of the policy-making process is its nebulous nature, or as Lindblom comments, policy-making "...is a complex analytic and political process to which there is no beginning or end, and the boundaries of which are uncertain." (Lindblom 1968: 4). The available policy-making theories have been categorised into those that take a 'macro-view' and those that take a 'micro-view' (Walt 1994). Macro-view theories of policy-making are those theories that explain how and why power is distributed and exerted over the political system. Micro-view theories focus on the political environment, stakeholders and procedures associated with the political system and within which decision-making occurs. This thesis confines its investigation to micro-view theories of policy-making and the patterns of interaction between factors involved in shaping the operation of the political system.
The present chapter provides a literature review of theories of how and why scientific evidence is used in the making of public health policy. The purpose of this review is to synthesise the theoretical framework against which the findings from the policy analysis will be interpreted. The policy and social science literature refer to two broad areas of theory that in combination can help guide research into the use of scientific evidence in policy-making. Firstly, there are theories of the policy process that are concerned with explaining activities and procedures associated with problem definition, agenda setting, how individuals and groups affect what governments do and politics comes into practice. Secondly, there are theories of the decision-making process that are concerned with explaining how and why choices are made from among competing policy alternatives (Carroll and Johnson 1990). This literature review is structured into three sections that view policy-making as:

- A rational-linear process.
- A process involving political and social factors.
- The strategic resolution of competing core values.

These sections correspond with an increasingly sophisticated conceptualisation of the policy process and the accompanying decision-making process.

3.2 Policy-making as a rational-linear process

Since the 1950s, when Lasswell first enunciated the policy sciences as scientific disciplines, many theories of the policy-making process have been derivative of Lasswell's rational-linear approach to explaining the public policy process (Lasswell 1951). In this section a review of models and theories that explain the policy-making process as a rational-linear process is presented.

3.2.1 Theories of the policy process consistent with the rational-linear approach to policy-making

Lasswell and his peers viewed the policy sciences as focussed on investigating and explaining policy-making as a process that occurs through a sequence of stages. The stages are also depicted as operating as components of a policy cycle. The sequence begins with problem identification and agenda setting and moves on to policy formulation, adoption, implementation, evaluation and then the process feeds back to
either identify new problems or refine policy formulation and the policy sequence continues. This model is exemplified by Anderson's 'sequential pattern of action' an adaptation of which is illustrated in Figure 3.1 (Anderson 1975).

Figure 3.1 Key stages in the health-policy-making process (Adapted from Anderson 1975: 26)

Problem identification and agenda setting
↓
Policy formulation
↓
Policy adoption
↓
Policy implementation
↓
Policy evaluation

This relatively simple explanation of the policy process provides a convenient model around which many policy textbooks and courses have traditionally organised their representation of public policy phenomena and processes.

3.2.2 Theories of the use of evidence in the decision-making process consistent with the rational-linear approach to policy-making

The implicit assumption of policy theorists who subscribe to the rational-linear model of policy-making is that the use of evidence in decision-making involves systematic, policy-relevant research being conducted by disinterested scientists and then translated in a linear fashion to inform public policy. This use of evidence in the making of public health policy is depicted in Figure 3.2. Three principles adapted from evidence based medicine have tentatively been accepted by the NHMRC to complement the rational-linear approach to evidence based practice in a public health setting (Rychetnik and Frommer 2000):

i) It is important to know whether public health interventions are effective and do more good than harm.
ii) The benefits and costs of public health interventions should be described and evaluated, so they can be weighed against other options for the use of resources.

iii) People who make (or are affected by) evidence based decisions about public health interventions should be aware of the strengths, limitations and gaps in the available evidence.

Figure 3.2 The rational-linear approach to the use of evidence in policy-making

Evidence → [translation process] → Public health policy

The theory of the decision-making process that captures this rational-linear conceptualisation of the use of scientific evidence in policy-making is the rational-deductive theory. The rational-deductive theory explains the decision-making process as starting with the identification of a problem and then proceeding to work through sequential steps to its solution. The process involves clearly articulating the goals, values or objectives guiding policy makers and the various options for dealing with the problem are considered and their costs and benefits evaluated and compared. The approach assumes a realist view of the natural world and its phenomena and has its origins in the early part of the twentieth century when modernism held that scientific approaches and technology would lead to rational policy-making (Hogwood and Gunn 1984). The main features of this approach are that it relies heavily on scientific evidence and a commitment to rational choices. Policy-making tries as far as possible to follow a deductive approach to decision-making to achieve the best possible policy outcome.

Ideally, policy-makers complement their policy decisions with adequate and timely monitoring mechanisms in place that can be employed to obtain data of the policy decision to inform further research that in turn can be used to inform further refinement of the policy-making process. An example of this interrelationship between policy-making, monitoring and research is represented by that conceptualised in The Operational Plan for the US National Nutrition Monitoring System, as adapted in Figure 3.3, (US Department of Health and Human Services and US Department of Agriculture 1991) (cited in Sims 1993: 17).
3.2.3 Critique of the rational-linear approach to policy-making

The rational-linear model of policy processes has been widely criticised as being an unrealistic explanation of the use of evidence in policy-making (Ham and Hill 1993; Black 2001). The model is challenged for assuming that research is conducted rigorously, comprehensively, timely and then applied to policy-making in a non-controversial, consensual, accurate and linear way. If public health policy-making occurred as a result of a rational-linear relationship with evidence, policy-makers would have the opportunity to draw upon a progressively expanding store of epidemiological information. It would then be expected that public health policy would become increasingly formidable in addressing the health problems of society (Levine and Lilienfield 1987). However, this outcome has not occurred. Understanding why this outcome has not occurred requires an analysis of the processes involved in constructing evidence and then translating it into policy and the relationship between the two.

i) Constructing the evidence
There is an inherent contradiction in a policy-making process that relies on evidence obtained from the evaluation of a policy intervention that itself must first have had available evidence for its development, i.e. it is a ‘chicken and egg’ situation. For
example, by definition food policy innovations such as the introduction of novel foods, have no historical precedent and in the absence of a priori evidence it is not possible for policy-makers to have access to evidence that provides certainty of their safety or public health impact. Instead, policy decisions must be made on the best available evidence. Evidence tends to accumulate to a point where a decision is made that an observed association between a public health problem and a variable can be inferred as causal. Inevitably, judgement is needed in interpreting the quality and quantity of the evidence and balancing risks versus benefits and then applying to policy decisions (Benson and Hartz 2000; Sommer 2001).

As Hawkins observes,

"Understanding the decisionmaking process in regulatory agencies, however, is no simple matter, partly because regulatory tasks by their nature can involve highly technical problems. Such tasks may also be clouded by high levels of uncertainty yet demand the application of value judgements about the probability of harm and the degree of acceptable risk.‖ (Hawkins and Thomas 1989: 5).

Crandall and Lave also highlight the influence of agency discretion and policy-making under conditions of scientific uncertainty, "With few scientific constraints, regulators find themselves driven by political forces, using an intuitive decision-making process.‖ (Crandall et al. 1981: 16-17).

ii) Translating the evidence

Rather than a rational-linear relationship between evidence and public policy, Barker and Peters argue that it is more accurate to perceive the relationship as being one that is closed and circular (Barker and Peters 1993). They describe the relationship between research and policy as being mutually complementary and self-perpetuating. The question becomes does research drive public policy or does public policy drive research? Some practitioners describe the atemporal motivation for scientific evidence and the input of scientific experts as a process of ‘policy legitimation’ (Topf 1993). For example, research generates scientific evidence that can be used to inform public health policy decisions and public health policy can stimulate certain research to be conducted that, in turn, can be used to legitimise certain policy outcomes and the cycle continues. As Levine comments,
"... changes in health policy occur for reasons quite separate from the acquisition of new knowledge. Particular economic, political or ideological factors may stifle any policy reforms or, when circumstances are propitious, give birth to new specific regulations, laws or policies without any impetus from new epidemiological data ... Changes in health policy, in turn, may determine the research priorities and questions that command the attention of epidemiologists. For their part, policymakers may seek to justify their new policies by making use of established or 'rediscovered' epidemiological findings. They may also support funding for studies that are likely to generate data that are relevant for the new health policies." (Levine and Liliensfield 1987: 2).

The factors associated with the construction and the translation of evidence illustrate the political nature of using evidence in policy-making. Although governments may be concerned about obtaining rational solutions to public problems, they work in a political environment in which opinions matter and 'facts' and 'opinion' are frequently closely intertwined (Peters and Barker 1993). According to Peters and Barker,

"... a greater degree of influence over policy can be gained by those offering advice to government about solutions to problems than can be gained by those offering a deeper understanding of the problem itself. ... It may be that governments ultimately are problem-solving organizations and anything that can be made available to assist them in finding solutions will be more valued than abstract understandings of cause and effect. ... producing some solution - even an ineffective one which is, in fact, no solution - may be better, at least in the eyes of the public, than doing nothing at all." (Peters and Barker 1993: 18).

The stages model is a heuristic device that provides an idealised structure for representing the policy process in an ordered sequence. It prescribes the way policy ought to be made. The model is not a causal theory in the sense that it cannot offer an explanation of how and why evidence is used in progressing public health policy from one stage to another, nor can it be tested on an empirical basis. In order to build a theoretical framework for studying the use of evidence in policy-making there is a need to move beyond such heuristic devices to explanatory theories. Moreover, there is a need to conceptualise the
decision-making process as operating in alternative non-rational and non-deductive ways. In the next section of this chapter, theories that account for the political nature of the use of evidence in policy-making are reviewed.

3.3 Policy-making as a process involving political and social factors

The impetus, intention and objectives for policy-making can be rational and comprehensive, but invariably the development and implementation of policy is subject to political and social influences that reduce the rational components and lessen its comprehensiveness (Gardner and Barraclough 1992). The making of public health policy involves competing interests and competing demands being placed upon policy-makers and is therefore an inherently political process, based on human values and ultimately inspired by political philosophy (Seedhouse 1997). As Walt comments, “… public policy making is a political process, not simply an analytical problem-solving process: it is a process of negotiation, bargaining, and the accommodation of many different interests which reflects the ideology of the government in power.” (Walt 1994: 73). In this section a review of theories that explain policy-making as a process that involves political and social factors is presented.

3.3.1 Theories of the policy process consistent with the conceptualisation of policy-making as a process involving political and social factors

In the publication of early empirical studies of policy phenomena it was reported that policy decisions were made in response to convenient solutions when they first arise, rather than systematically considering all available alternatives and making rational choices. To explain these observations Cohen, March and Olsen proposed the ‘garbage can theory’ of organisational choice as a behavioural model of decision-making (Cohen et al. 1972). The garbage can theory posits that in the policy environment, some issues will have solutions attached to them, others will not, other solutions may be waiting for an issue to which to attach themselves. The model conceives these issues, problems and solutions as being messy and their attention from policy-makers will depend on the time they are picked up and the availability of ‘cans’ to put them in. The model assumes that
when it comes to decision-making, values are complex, knowledge is uncertain and rules are confusing.

In his investigation of major policy issues undertaken by the US federal government Kingdon analysed how issues come to be issues, how they come to the attention of policy-makers, how agendas are set and why ideas ‘have their time’ (Kingdon 1995). He based his agenda setting analysis on the garbage can theory. Kingdon conceptualised policy-making as involving three major policy ‘streams’. The three streams are a:

i) Problem stream, consisting of information about real world problems that is derived from data, events, or feedback from past interventions.

ii) Policy stream, consisting of a policy community of researchers, advocates and other specialists who analyse problems and formulate possible alternatives that must be technically feasible and compatible with dominant values.

iii) Political stream, that sets the governmental agenda and consists of such factors as elections and leadership contests.

Kingdon’s theory is that these three major policy streams tend to be omnipresent during the day-to-day operations of the government and operate independently of each other. At critical times the three streams come together, i.e. a problem is identified and brought to the government’s attention, a solution(s) is proposed and the political climate is receptive and a window of opportunity is opened during which time major policy changes can occur. Conversely, a strong evidence base, represented by the problem stream, in isolation, is unlikely to stimulate the policy-making process. Kingdon’s model offers a clear alternative to models that portray policy-making as occurring as a series of stages or steps. Agenda setting theories of the policy-making process are not unique to Kingdon. Other theorists who have proposed a model of agenda setting in the policy-making process include Cobb and Elder (Cobb and Elder 1983) and Hall and colleagues (Hall et al. 1975). The Hall model in particular, with its emphasis on the need for the existence of the three concepts of ‘legitimacy’, ‘feasibility’ and ‘support’ for an issue to receive policy attention, shares common features with Kingdon’s streams model.

Richmond and Kotelchuck have devised a health policy model that also conceptualises three necessary components that must be present for health policy to occur, as depicted in Figure 3.4. These three components are the (Richmond and Kotelchuck 1991):
i) Knowledge base, consisting of the scientific and administrative database upon which to make decisions.

ii) Political will to support change, involving the desire and commitment to develop and fund new programs or to support or modify existing programs.

iii) Social strategy to accomplish change, consisting of the plan by which we apply political will to improve or initiate programs.

Figure 3.4 Health policy model (Source: Richmond and Kotelchuck 1991: 450)

As with the three streams in Kingdon's model (and the three concepts in the Hall model), the three components of the health policy model are insufficient in isolation and all must be present for the model to be complete and for the political setting to be predisposed to bring about policy change. From this perspective the likely success of policy-making depends on 'striking a balance' between the scientific evidence and the values, priorities, needs and concerns of stakeholders through the establishment of a 'positive political climate' (Sims 1993). Unlike the Kingdon and Hall models, Richmond and Kotelchuck stress the interdependent nature of the components in their model, e.g. new knowledge creates political will and vice versa.

Atwood and her colleagues have applied the health policy model to different public health issues to assess the relative balance of the three components in scientist's work in supporting public health policy. Their assessment is that "... the magnitude of risk posed by a public health problem often bears little relation to the amount of political will (and
resources) generated by the issue." (Atwood et al. 1997: 1604). The practical implication of this finding is that a disproportionate amount of effort is directed towards establishing the knowledge database for policy-making to the detriment of gaining commensurate political will and an acceptable social strategy.

In response to consistent observations of the problematic relationship between research and policy of the type reported by Atwood and her colleagues, policy analysts sought to explain their empirical observations of the research-policy interface with 'research utilisation' theories. Research utilisation theories were generally predicated on the notion that researchers and policy-makers exist in two different 'communities' each with its own separate priorities and language. In 1986 Weiss proposed seven uses of social science research in policy and this has become a standard reference for all subsequent investigations attempting to understand the research-policy nexus (Weiss 1986). The seven uses are captured in the following models:

i) The knowledge-driven, or engineering model
   A linear sequence model where knowledge and information from basic research leads to applied research that leads to developmental research and application.

ii) The problem-solving model
    Starts with the existence of a problem and policy-makers search for research to solve the problem.

iii) The interactive model
    Policy problems give rise networks of consultation and communication between decision-makers and stakeholders, including researchers, through processes involving the interaction of ideology, interests, and information.

iv) The political model
    Research is used as a political resource to support positions that are politically derived by various interests.

v) The tactical model
    Political actors use research to manipulate policy processes, e.g. the act of commissioning or conducting research might be a tactic to delay decision-making.

vi) The enlightenment model
    Research influences policy by framing the way that problems are thought about through theories and concepts that diffuse into the everyday discourse and thinking of policy-makers circuitously through multiple channels over time.
The intellectual enterprise model

Research is not an independent variable acting on policy but a dependent variable alongside policy with both interacting with wider social factors.

Weiss's seven models, and the research utilisation literature in general, are concerned with the processes by which research and policy interact, and the relationships between researchers and policy-makers. These models conceptualise evidence as a separate entity to the political process of policy-making and the notion of evidence based practice is focused on understanding the various political motivations that explain the translation process between the two communities. Solutions based on the two communities conceptualisation emphasise the need for improved channels of communication and mechanisms of collaboration between researchers and policy-makers to improve evidence based practice (Samet and Lee 2001).

Short undertook case study research to test research utilisation models (Short 1998). Short's findings indicated that research is more likely to be used when it is congruent with the core values of the decision-maker and is likely to provide an ethical foundation and justification for the intended course of action. For example, in her analysis of community development policy she concluded,

"... the research reports supported and justified policy directions that had already been articulated ... or put in place... [and] made recommendations that were consistent with broader political and economic considerations ... research is more likely to affect policy development when it reinforces the values and goals of policy-makers, and when the outputs of the research process are compatible with policy-makers' perceptions of the pragmatic realities of the policy-making process."

(Short 1998: 79).

Short's assessment is supported by Rutten, who observes that scientific evidence is more likely to be used by policy-makers when it contributes to preconceived ideas of actions and policy, "... information and analysis are highly valued by policy makers when it is 'good', meaning that it can be assimilated into the stock of knowledge with which policy makers already make sense of the policy world" (Rutten 1995: 1632).
3.3.2 Theories of the use of evidence in the decision-making process consistent with the conceptualisation of policy-making as a process involving political and social factors

There are two theories of the use of evidence in the decision-making process that reflect the dynamics characterised by the policy process theories consistent with this policy-making process, the incrementalist theory and the mixed-scanning theory. The incrementalist theory of the decision-making process subscribes to the view that all implications are never known at the outset and so there is a constant need to reflect and amend decisions. A leading proponent of incrementalism, Linblom, described this approach to policy-making as one of 'muddling through' (Lindblom 1959).

According to Lindblom, policy decisions are never the definitive option but the ones that make the most sense at a particular point in time (Lindblom 1968). Policies need to be adapted to suit new or changed circumstances. The approach relies heavily on the judgements of key players and reflects a pluralistic society in which there are multiple influences. Interest groups play a key role in shaping and reshaping the policy environment. Incrementalism is essentially remedial and conservative as it focuses on small changes to existing policies usually in response to pressure from interest groups. As such, Ziglio claims that incremental policy making will tend to be reactive and likely to reinforce the status quo, rather than lead to innovation and change (Ziglio 1987). Moreover, incremental decision-making tends to lack a long-term focus and is particularly vulnerable to influence by the broader social and political contexts. Governments tend to be reactive in initiating policy. For example, rather than commissioning basic research and proactively collecting evidence, they react in short time frames to the limited available evidence (Peters and Barker 1993).

The mixed-scanning theory of the decision-making process represents a compromise between the rationalist and incremental principals and aims to combine the best features of each by balancing the use of scientific evidence with political realities (Etzioni 1967). Etzioni based his analysis on the assessment that the rational-deductive theory does not pay sufficient attention to the politics and values of any policy environment and that the incremental theory tends to be overly reactive. The mixed-scanning theory divides policy decisions into a macro (fundamental) and micro (small) classification and involves the policy-maker in undertaking a broad review of the policy field, rather than engaging in
the detailed exploration of all policy options as suggested by the rational-deductive model.

3.3.3 Critique of the conceptualisation of policy-making as a process involving political and social factors

The models and theories of the policy process that are consistent with this policy-making process contribute valuable insights into why certain policies are likely to be made and predicting when other policies are bound to fail to get onto the political agenda. They identify the policy-making process as being a political activity that engages various factors in mediating the process of constructing evidence and then translating it into policy. Also, they share the explanation that politics, not scientific evidence, serves as the ultimate arbiter when selecting between policy alternatives (Hancock 1997). Specifically, they all concur that decision-makers are constrained to selecting from among a stock of available alternatives and the policy alternative most likely to be selected is the one that 'resonates' with characteristics dictated by the broader political environment.

The multidisciplinary nature of policy science presents challenges for reviewing and building theories and explanatory frameworks of the policy-making process. A starting point for much modern policy analysis is to be mindful of Lasswell’s observation that the primary task of policy analysis is to understand how problems and processes are contextualised (Lasswell 1951). Policy is located in the context of prevailing political, economic and social trends. Contexts determine the rules and parameters within which the policy system operates and thereby shape the political debate in terms of how public health issues are conceived and addressed.

The influence of contextual antecedents and the actions of stakeholders in advocating for a specific public health policy has led some policy scientists to question whether there is a more systematic pattern to the policy process than the relatively haphazard conceptualisation portrayed by the garbage can theory and its derivative theories. Public health policy is about the government’s values and intentions for the health of the population. These values and intentions will affect the interests of individuals, groups and organisations with a particular stake in the public health policy in different ways. Frequently, the making of a public health policy involves competition between different stakeholders for their particular interests to prevail. It is this competition between
different stakeholders that is central to conceiving policy-making as a political process. Policy analysts suggest that traditional conceptions of the policy process be extended to take into account contextual factors shaping modern forms of governance (Pal 1997). It is argued that there is a dynamic interaction among stakeholders, processes and the broader contextual factors shaping the nature and scope of the political system within which policy is made.

Moreover, with analysis of further cases of public health policy-making the utility of the research utilisation theories has been questioned and the two communities paradigm alone has been challenged as being an inadequate basis for conceptualising the dynamics of the relationship between research and policy (Gibson 2002 (In Press)). In particular, the models have been criticised for treating research and knowledge as a black box and decision-makers as a ‘monolithic conglomerate’ (Lin 2002 (In Press)). This assessment asserts that the models fail to capture the problem of what constitutes evidence and for whom and so are unable to adequately explain how and why scientific evidence is used in policy-making.

The need to account for both the role of contexts in shaping the governance of the political setting and the advocacy of stakeholders in pursuing policy outcomes consistent with their interests, has resulted in policy scientists seeking a more sophisticated theory(s) to explain the policy process and the use of evidence in the decision-making process. Theories that are based on a broader conceptualisation of the policy-making process and that seek to explain what constitutes evidence and for whom are reviewed in the next section of this chapter.

3.4 Policy-making as the strategic resolution of competing core values

Public health policy does not appear of its own volition. As Walt notes, "... since processes do not have a life of their own, but are dependent on actors to give them expression, analysis of the policy process is interwoven with an exploration of which actors are involved, and how far each may be exerting influence on policy." (Walt 1994: 6). Therefore, in analysing policy it is crucial to ask process-oriented questions regarding whose interests will be served or threatened by a policy change, how they were involved,
what resources and strategies they used, and their success in shaping the policy in their favour (Milio 1988).

Policy outcomes reflect different stakeholders’ ability to harness governmental action to respond to their organised and articulated needs (Sims 1998). From this perspective, the use of evidence in public health policy-making is confronted by the often contradictory demands of competing economic, ideological, and bureaucratic interests (Austin and Overholt 1988). Stakeholders deploy their resources to influence the policy-making process and outcomes that will either enhance, or minimise harm to, their interests. As McAlister muses,

"Democracy, as we know it, proceeds through compromises between conflicting public, private, collective, and individual interests. Thus modern history abounds in irony, not the least being the way in which private corporations, public institutions, communication media, and clinical professions absorb vast resources in contrary activities influencing the health of human populations." (McAlister et al. 1991: 3).

Stakeholders’ effectiveness in promoting their interests during the policy-making process will depend on their influence, resources and skills relative to stakeholders with competing interests. For example, generally food producers possess a greater amount of resources than consumers to advocate for their interests (Nestle 1993). Indeed, Walt cites the case of the pressure that can be exerted on governments by transnational corporations with, "... their ultimate weapon being to remove their investment." (Walt 1994: 39). Davis et al describe the policy process as the "... complex interplay of values, interests and resources that are guided through institutions and mediated by politics" (Davis et al. 1993: 15). In this section a review of theories that provide insights into interest groups that seek to influence government policy-making and the processes that they employ to exert this influence is presented.

3.4.1 Theories of the policy process consistent with the conceptualisation of policy-making as the strategic resolution of competing core values

It was Milio’s early work that made a significant contribution to theoretical understandings of policy-making in a food and nutrition setting. During her evaluation of Norway’s innovative national food and nutrition policy and later comparison with policy-
making in the US (Milio 1991), Milio identified factors that were important to the success of food and nutrition policy-making. These factors provided the basis to Milio’s ‘ecological framework’ of policy-making (Milio 1988). In the framework, Milio identifies four main players who are regarded as being crucial to shaping the policy-making process: policy holders (usually politicians and bureaucracies); policy influencers (who can be groups inside and outside government); the public; and the media. She also identifies a number of determinants that can influence policy development: the social, economic, and political context in which action is proposed; the interests of those players wishing to influence policy development; and the capacity of those players wishing to influence policy to put in place strategies to represent their interests.

Milio’s conclusions regarding the integral role of certain players in the policy-making process illustrates an application of the broad approach of group theory to a food and nutrition setting. Group theory conceives policy-making as being about the interactions and struggles among groups (Anderson 1975). Political interest groups form on the basis of shared interests. Interests then become the basis for interest groups and lobbyists’ attempts to influence policy outcomes in their favour (Hancock 1999). At any given time, public policy will reflect the interests of dominant groups. From this perspective, the policy-making process involves struggles between groups to ensure their desired policy interests are achieved in preference to those put forward by other groups.

The manipulation of information is a component of the struggles between interest groups. As Milio comments, stakeholders “… filter information from factual reality through lenses tinted by their judgements of what is best for the success or survival of their own group. … [These interests] … offer a better explanation of their policy actions than the public rationale.” (Milio 1988: 267). Similarly, de Leeuw argues that whereas epidemiological research provides the foundation for informing policy-making and much evidence has emerged from this work, the traditional models of policy-making are failing to explain how and why this evidence is actually used in the policy-making process. She proposes that the use of evidence in public health policy-making is explained by an interaction between three determinants:

i) A bias acquired by policy-makers stemming from sets of causal (cause-effect), final (intervention-effect), and normative (underlying values) assumptions and beliefs
that relate to notions of effectiveness, efficiency, acceptability and appropriateness of policy instruments.

ii) Interest webs of groups in certain domains that determine the formulation and implementation of policy based on vested interests. In this context, data are not information, they become information through meanings imposed by the users of data. Information is subsequently not enough to act, it has to appeal to already existing domain definitions, and perceived interests.

iii) The power of organisations to monitor and communicate as this interacts with the assumptions and interest determinants (Leeuw 1993).

According to Leeuw, "... these mechanisms in policy making have little or nothing to do with the 'truth content' of epidemiological work, and everything with the way this work is deployed in the policy-making game." (Leeuw 1993: 52). Austin and Overholt share Leeuw's assessment when commenting that scientific evidence is but one of many inputs into the policy-making process and in addition to not necessarily being the most significant input, "... scientific evidence becomes a tool of politics rather than the determinant of policy." (Austin and Overholt 1988: 5). From this perspective of the policy process, the use of evidence in policy-making is perceived as a political act that is part of a larger social and political process. Theories of the policy process seek to explain the contexts, stakeholders and processes associated with this political act.

The 'policy subsystem' approach has been developed as a means to systematically examine and analyse the policy process by which interest groups seek to influence government policy-making. The policy subsystem approach builds on the earlier understandings captured by group theory. The significance of the notion of policy subsystems is that stakeholders can form informal alliances with other stakeholders to increase their leverage in the policy-making process. Policy subsystems have been described as 'decentralised power structures' that are characterised by their shared knowledge base and core values directed toward a specific public policy issue (Sims 1998). An analysis of the policy-making process from a subsystem perspective focuses on studying processes associated with informal alliances rather than processes associated with formal institutions.
One of the more comprehensive reviews of subsystem characteristics and the interaction between subsystem participants is the essay by Hamm examining research on the patterns of influence among legislative committees, executive agencies and other interest groups (Hamm 1983). Among the explanatory factors associated with the functioning of subsystems identified by Hamm are the commonality of interests among committees, agencies and interest groups, the recruitment of certain individuals to occupy strategic decision-making positions on committees, and the ‘overrepresentation’ of a particular interest on a committee.

A well-developed example of the policy subsystem approach is the Advocacy Coalition Framework (ACF) proposed by Sabatier and Jenkins-Smith and depicted in Figure 3.5 (Sabatier and Jenkins-Smith 1993). The ACF builds on the basic concept of subsystems by explaining policy change as the product of competition between several ‘advocacy coalitions’. An advocacy coalition is formed with the coming together of individual policy actors who share a common belief system, that is, a set of basic values, causal assumptions and perceptions, and who seek to manipulate the rules of various governmental institutions to achieve their core beliefs. Scientific evidence is perceived to influence policy through the beliefs of advocacy coalitions who are able to sponsor research and accept or reject data based on how it aligns with their core beliefs. Policy change is explained as an outcome of fluctuations in the dominant belief systems within a given policy subsystem over time. These fluctuations are a function of three sets of processes:

i) The interaction of competing advocacy coalitions within a policy subsystem.

ii) Changes external to the subsystem, such as changes in socioeconomic conditions, changes in governance and decisions from other policy subsystems.

iii) The effects of ‘stable system parameters’ such as basic social structure and constitutional rules – on the constraints and resources of various actors.

The strength of the ACF in explaining the use of scientific evidence in policy-making is its inclusion of factors such as advocacy coalitions and the attention it pays to exogenous factors. Although the framework has been successfully applied in explaining policy-making in a number of areas, including food and nutrition policy (Sims 1998), the applicability of the framework to a food regulation setting is untested.
Figure 3.5 The Advocacy Coalition Framework
(Source: Sabatier and Jenkins-Smith 1993: 229)

Relatively Stable Parameters
1. Basic attributes of the problem area (good)
2. Basic distribution of natural resources
3. Fundamental socio-cultural values and social structure
4. Basic constitutional structure (rules)

External (System) Events
1. Changes in socioeconomic conditions
2. Changes in systemic governing coalition
3. Policy decisions and impacts from other subsystems

Policy Subsystem
Coalition A
a) Policy beliefs
b) Resources
Strategy A1 re guidance instruments
Decisions by Sovereigns
Agency Resources and General Policy Orientation
Policy Outputs
Policy Impacts

Coalition B
a) Policy beliefs
b) Resources
Strategy B1 re guidance instruments

Constraints and Resources of Subsystem Actors
3.4.2 Theories of the use of evidence in the decision-making process consistent with the conceptualisation of policy-making as the strategic resolution of competing core values

The policy process models provide a structural representation of the contexts, stakeholders, processes and their pattern of interaction in policy-making. Theories of the decision-making process consistent with the conceptualisation of the policy-making process as the strategic resolution of competing core values provide explanations of how and why scientific evidence is used in supporting the integrity of the policy process models. According to Tesh, science, politics, and ideology all interact with one another, "This interaction, neither lamentable nor corrigeable, is the cardinal fact about policy making. Understanding policy arguments requires a conception of this interaction." (Tesh 1988: 132).

Post positivists believe that in evaluating scientific evidence, facts cannot be divorced from theory and by the particular measurements of the observer and are inherently value-laden. Facts have little meaning outside of a system of theories and conventions and possibly cannot exist independent of theory, ie facts are facts only within some theoretical framework (Hesse 1980). From this post positivist perspective, scientific inquiry and evidence based practice are viewed as inherently normative concepts. For example, Daly et al argue, "... when a given problem is studied, different approaches to research will ask different questions, collect different data and use different frames of analysis" (Daly and McDonald 1992: 5). The values of scientists permeate the planning, collection and interpretation of evidence during the policy-making process (Longino 1990; Kreiger 1992; Labonte 1998). As Kreiger observes,

"Epidemiology is, like any science, at once objective (using defined, rigorous, and replicable methods to assess refutable propositions) and partisan (reflecting underlying values and assumptions guiding conceptualization, choice, and analysis of research problems)" (Kreiger 1999: 1152).

Syne argues that the making of public health policy usually relates to a body of scientific evidence, but rarely do the ‘facts’ lead irrevocably to policy. His explanation for this phenomenon is that the same facts often are seen quite
differently by people with different perspectives, experiences, and priorities (Syme and Guralnik 1987). This explanation is consistent with the assessment of Kuhn that science is itself an ideology, partially dependent upon agreed theories to generate its ‘facts’ (Kuhn 1962). Scientific facts are, for the most part, socially constructed (Zuckerman 1988). In commenting on the social construction of epidemiological evidence, Petersen and Lupton argue that epidemiology constructs patterns of causation for a public health issue through the way investigations are conducted and the selective use of evidence (Petersen and Lupton 1996).

Policy-makers need to be cognisant of what sorts of data provide scientific evidence for particular types of policy decisions (Davey Smith et al. 2001). There exists a tension among public health practitioners about accepting the legitimacy of data obtained from one research method relative to another from different ontological, epistemological and methodological positions. For example, McKinlay argues that the prevailing methodological perspective that informs health research is positivist, emphasising the collection of quantitative information at the level of the individual and this invariably privileges a medical perspective towards public health (McKinlay 1993). Baum concurs with this assessment when she comments,

"In much public health research the epidemiological tail has wagged the public health dog. It is the early medical domination of public health that has meant epidemiology has been the preferred discipline with randomized controlled trials and (at a pinch) quasi-experimental designs as the preferred method. An undue concentration on these methods has limited the scope of public health inquiry." (Baum 1995: 461).

The dominant influence of evidence based medicine to inform public health policy practice presents a double-edged sword for public health policy-makers. Firstly, the appraisal process of evidence based medicine may provide information of limited relevance to a public health setting. Secondly, the evidence obtained from a public health inquiry may not be amenable to the evidence based medicine appraisal process.
i) The appraisal process of evidence based medicine may provide evidence of limited relevance to a public health setting.

In the absence of effectiveness evidence from the evaluation of a public health policy, decision makers tend to use aetiological and efficacy evidence from clinical trials. Clinical trials rely on a ‘reductionist’ view of science in which direct cause and effect correlations are measured and quantified. Reductionism is a process that seeks to reduce the complexity of real world phenomena to relatively simple cause and effect relationships that can be delineated and measured. Reductionism involves controlling for potential confounding factors to enable linear multivariate statistical methods to identify very precise associations between variables.

However, there is a contradiction in applying evidence obtained from individuals in a controlled clinical setting to inform public health policy intended for the whole population. The reductionist approach inherent to the experimental design to achieve internal validity collects data from specific individuals under controlled experimental conditions by abstracting these individuals from socio-environmental contexts. This ‘context-stripping’ limits the generalisability of any associations established under these controlled experimental settings to the real world where people engage in many contexts that explain or moderate causal associations with health outcomes. This introduces plausible rival hypotheses and threats to the external validity of experimental evidence.

As the rigour of the methods to generate aetiological and efficacy evidence increases the generalisability and relevance of the research findings to public health policy tends to diminish. Inevitably there is a trade-off between internal and external validity. Where,

"Internal validity refers to the approximate validity with which we infer that a relationship between two variables is causal or that the absence of a relationship implies the absence of cause. External validity refers to the approximate validity with which we can infer that the presumed causal relationship can be generalised to and across alternate measures of the cause and effect and across different types of persons, settings, and times" (Cook and Campbell 1979: 37).
ii) Data from the evaluation of public health interventions may not be amenable to 
the appraisal process of evidence based medicine.

The utility of the experimental research design to the evaluation of public health 
policy interventions is problematic. From a practical perspective it is difficult to 
randomise two groups within a defined population (Campbell and Fiske 1959), e.g. 
to avoid ‘contamination’ in access to the intervention. Also, strategically 
investigations must assess multifactorial ‘webs’ of disease causation that tend to be 
cumulative and develop over relatively long time periods (Nutbeam et al. 1990; 
McKinlay 1993). These difficulties are especially pronounced in attempting to 
measure dietary change. In practice, RCTs are at best only able to detect and measure 
the relationship between the addition or removal of single nutrients on health 
outcomes and usually only over relatively brief time periods. Moreover, the 
conventional measurement techniques are not sensitive to the longer term impact of a 
policy on public health indicators such as environmental sustainability. Advocates 
for policy interventions aligned with these broader public health outcomes complain 
that they are disadvantaged because they are expected to measure outcomes and 
demonstrate effectiveness in evidence-based terms defined by methodological 
orthodoxy (Nutbeam et al. 1990; Naidoo and Wills 1994; Speller et al. 1997; Legge 
1999).

There has been an acknowledgment that evidence based practice may have been 
dominated by evidence based medicine to the detriment of public health policy 
decisions in Australia (Health and Medical Research Strategic Review Committee 1999). In recognition of this limitation a report including a schema to evaluate 
research-based evidence on public health interventions and to determine the potential 
applicability of the evidence to public health decision-making has been published 
(Rychetnik and Frommer 2000).

The outcome of social constructionism is that those who define public health and the 
scientific evidence that is legitimised to identify a public health issue also control the 
planning, implementation and evaluation of policy interventions to address public 
health issues. Drawing boundaries around ideas and concepts to control agendas and 
legitimise decisions and actions is referred to as the politics of definition (Conrad and 
Schneider 1985). Factual claims are frequently accepted as true not because they
accurately reflect reality, but because they have been certified as true by certain individuals or committees who are considered expert to pass judgement upon the truth and falsity of such claims (Jasanoff 1990). From this perspective the use of evidence in policy-making is explained by struggles over "... the legitimacy of certain kinds of knowledge and the rules according to which that legitimacy is adjudicated." (Labonte and Robertson 1996: 433).

One approach used by policy makers to increase the perception of objectivity in the policy-making process is to defer sensitive public policy matters to expert advisory committees to prepare policy recommendations. However, the way experts use their knowledge invariably involves judgements based on values they bring to decision-making (Crotty 1995). With controversial issues, value judgements need to be made about the risks and benefits of various approaches and their costs relative to other priorities. These decisions cannot be made on the basis of science alone and technical experts cannot be expected to be expert on public policy decisions. Yet, often the role of technical experts is not confined to factual information and instead they are asked to make judgements for policy in areas such as evaluating risk and benefits and in the process impose their personal values on society because they fail to distinguish their own value judgements from their technical expertise (Yankelovich 1991). Veatch argues, "... it is wrong to presume that ... by the very process of becoming a technical expert in an area, one also acquires some special skill in making ethical and other value judgements about what one ought to do in that area." (Veatch 1991: 430).

In her publication of the findings from case studies of advisory committees Jasanoff argues that there is a need to expose the scientific advisory process to greater scrutiny because such committees "... occupy a curiously sheltered position in the landscape of American regulatory politics. In an era of bitter ideological confrontations, their role in policymaking has gone largely unobserved and unchallenged." (Jasanoff 1990: 1). The role of scientific and technical experts frequently extends beyond advising on policy to directly exerting influence on the parameters of political debate, political agendas and making political judgements on policy issues (Baggott 2000).
Others extend their criticism of expert panels to the way such panels are established and experts selected. Citing his observation of the establishment of US expert panels to address coronary heart disease Skrabanek has claimed that expert panels can be undemocratic and ineffective because participating experts are carefully selected for their views and only token dissidents are selected (Skrabanek 1990). Drawing on his analysis of expert advice giving in the area of public health nutrition, Mills has noted that there is a disincentive for expert advisers to be bold and challenge the orthodoxy as they can readily be replaced by more cautious advisers (Mills 1993).

Evidence based practice in the policy-making process can be explained by the meaning evidence acquires in the context of argument that is ideologically driven. Boudon and Bourricaud define ideology as “A system of ideas which offers a justification for the values that are assumed to form the basis of consensus. … a system of beliefs which contributes to determining both the ends of action and the selection of means” (Boudon and Bourricaud 1989: 204). Whereas ideology is a stable system of beliefs that are resistant to empirical challenge, theories are constantly subject to modification in the light of evidence. As Baum observes, “The values and politics within a society help people to interpret and make sense of seemingly objective facts. Recognition of these values is important and their role in public health policy should be openly debated.” (Baum 1998: 63-64). According to Parsons, “Decision analysis therefore requires that we understand the way in which facts and values interact, and the way in which ‘beliefs’, ‘ideas’, ‘interests’, on the one hand, interplay with ‘information’, ‘facts’, ‘reality’, and vice versa.”(Parsons 1995: 246).

The public health policy-making process is influenced by stakeholder’s competing arguments that are based on competing value systems of public health. The relationships between stakeholders determine who initiates, frames and drives the process, how and why certain evidence is legitimised and ultimately what policy is decided. That policy-making is a political process means that policy analysts need to analyse how and why stakeholders frame a problem and then how social and political contexts and processes privilege and/or obscure the arguments of stakeholders to determine whose values prevail and therefore shape the meaning acquired by scientific evidence.
Lomas suggests that rather than focusing on decision-making as an event or product, analysts need to look at process, i.e. it is more appropriate to analyse the "... ethereal nature of that diffuse, haphazard, and somewhat volatile process called decision-making." (Lomas 1997: 10). He has proposed a framework for understanding the context of decision-making (Lomas 1997). The framework divides the policy-making world into three interrelated domains: the institutional structure for decision-making including the formal structures of the executive, legislature and bureaucracy, and the informal structure of stakeholders and coalition; the core values that mediate the selection and interpretation of evidence; and the information production process including the interaction between researchers and the media. Lomas' framework is depicted in Figure 3.6.

Figure 3.6 A schematic of the contextual influences on the decision-making process (Source: Lomas 1997: 13)

Lomas describes the values that influence a decision as emerging from a complex interaction of three factors:

i) Interests – how one would like the world to work.
ii) Ideologies – declare a view of how the world ought to work.

iii) Beliefs – knowledge of how the world is thought to work.

According to Lomas, interests and ideology are resistant to change in the face of new information and beliefs is the only factor receptive to change based on knowledge from research findings, though such findings compete with other sources of persuasion and the influence of interests and ideology (Lomas 1997).

Information comprises research, anecdote, experience and propaganda and is turned into ‘common knowledge’ by various individuals and organisations including interest groups and the media. This common knowledge serves as both an input into the institutional structure for decision-making and as a persuasive force acting on the beliefs embedded in values (Lomas 1997). Within this conceptualisation, research and policy are ‘processes’ that are continuous and evolving components contributing to the integrity of the framework rather than static ‘products’.

3.4.3 Critique of the conceptualisation of policy-making as the strategic resolution of competing core values

The work of Milio, de Leeuw, Sabatier and Jenkins-Smith, and Lomas provide models and theories to offer insights into how and why scientific evidence is used in the public health policy-making process. They challenge the implicit assumption that the interpretation and application of scientific evidence arises as an independent, albeit necessary, component in the policy process. Instead, these policy analysts view public health policy as the outcome of competition among stakeholders regarding contested core values relating to public health. From this perspective the use of scientific evidence is itself an integral component of the political process of policy-making.
3.5 Conclusion

This chapter has reviewed the policy and social science literature to present a theoretical framework of how and why scientific evidence is used in the making of public health policy. Theoretical explanations of the use of scientific evidence in policy-making have become progressively more sophisticated. Initially, the policy sciences operated to an optimistic, albeit idealistic, conceptualisation of evidence based practice in policy-making as a rational-linear process. Then, the mitigating influences of political and social factors on the translation of evidence into policy were incorporated into various models and research utilisation theories. Finally, evidence based practice is being conceptualised as a more strategic political act. The political nature of the public health policy-making process is reflected in the competing rationalities among stakeholders in terms of contested core values towards public health. Scientific evidence is perceived as not just informing policy decisions but an integral component of the process to privilege and/or diminish the arguments of different stakeholders.

The competing core values among stakeholders towards public health policy play a critical role in determining the use of scientific evidence. They influence the legitimacy of different interpretations of public health policy objectives in a food regulation setting and the rules by which it is adjudicated. Several theories have been proposed to explain this legitimation and rule adjudication in shaping the policy process. Each of these theories tells a plausible story and provides insights. Given the complex nature of public health policy-making, it may be unrealistic to expect one all encompassing theory to be able to account for the diversity of the potential mechanisms and phenomena associated with the policy-making process in general, or in a food regulation setting in particular (Ham and Hill 1993).

This theoretical framework can be used to interpret empirical findings from the case study to explain phenomenon and gain theoretical understandings. The policy analysis that follows focuses on investigating how and why the complementary policy objectives of using food regulation as a policy instrument to achieve public health outcomes while upholding the protection of public health and safety, acquire meaning. This requires identifying the pattern of processes and interactions that
determine how and why the contested core values are resolved. As a first step towards identifying the pattern of political processes there is a need to order the different core values associated with public health in a food regulation setting. A typology of these characteristics is outlined in the next chapter.
CHAPTER 4

A typology of public health models in a food regulation setting

4.1 Introduction

The description of the food regulatory system outlined in Chapter 2 highlighted that there are competing expectations among stakeholders regarding the use of food regulation as a policy instrument to effect public health outcomes. The food regulatory system employs policy objectives to adjudicate the competing expectations of stakeholders. Policy makers face conceptual, scientific and ethical challenges in interpreting and applying policy objectives when using food regulation to achieve public health outcomes. For example, the primary policy objective in the setting of food standards, which generally is that public health and safety is protected (Australia New Zealand Food Authority 1996; Joint FAO/WHO Food Standards Programme 1997), has not been clearly defined (Lawrence 1998; Lawrence 1999). Therefore, what is the difference between protecting public health and protecting safety? And between protecting public health and promoting public health?

The literature review presented in the previous chapter highlighted that the construction and translation of scientific evidence in policy-making is a normative process. Stakeholders form their arguments for how and why scientific evidence should be used in making public health policy by drawing on their different core values of public health. The testing of theory of the use of scientific evidence in the policy-making process involves analysing how and why the competition between the contested core values of different stakeholders is resolved and public health policy objectives take on meaning. The first step towards analysing the use of scientific evidence in public health policy-making is to identify the different interpretations and applications of public health policy objectives.

---

12 An earlier version of this chapter, entitled "What is the relationship between food regulation and public health?", was presented at the ANZFA Public health professional’s forum 'Exploring ANZFA’s Health Promotion Role', Canberra, June 2000.
This chapter presents a typology as a classification scheme for ordering the different core values associated with the different ‘types’ of meanings ascribed to public health policy objectives in a food regulation setting. The typology has been developed from a review of the public health literature. After explaining the typographical contribution to policy analysis, the chapter presents the characteristics of three public health models that have been constructed as conceptual units, or types, that in aggregate represent the proposed typology. Principles for then applying the typology as a whole to the public health policy-making process are outlined.

4.2 The typographical contribution to policy analysis

A central premise to this thesis is that public health is a socially constructed concept (Kelman 1980). From an epistemological perspective, the notion of reality and public health meaning as a social construct can be traced back to Kant the founder of critical philosophy (Reiss 1991). The social construction of public health means that there is no one best definition of effecting or protecting public health in a food regulation setting. Public health policy objectives in a food regulation setting are subject to interpretation and take on meaning depending on arguments made by stakeholders based on their different core values towards public health. As Parsons comments,

"A problem has to be defined, structured, located within certain boundaries and be given a name. How this process happens proves crucial for the way in which a policy is addressed to a given problem. The words and concepts we employ to describe, analyse or categorize a problem will frame and mould the reality to which we seek to apply a policy or ‘solution’. The fact that we may share the same data, or at least believe that we share the same data, does not mean that we shall see the same thing. Values, beliefs, ideologies, interests and bias all shape perceptions of reality" (Parsons 1995: 88).

The interpretive approach to policy science relies heavily on the concept of type because socially constructed meanings generally appear as ‘typifications’. That is meanings of public health (and therefore the interpretation and application of public
health policy objectives) tend to take on a various, more or less agreed, typical forms. Typifications describe both social meanings and also social reality, since that reality is structures of meaning. According to Steinberger, the identification of contested policy alternatives and the need to understand social meaning “... tends to locate the policy process more squarely within the social world generally, helps to specify the mechanisms by which contexts are manipulated, and suggests a particular research agenda, viz., the empirical examination of typifications.” (Steinberger 1980: 190).

The first step in the policy science process is classification. It is a necessary precursor to advanced policy analysis. Policy analysis has had a ‘typographical tradition’ that provides conceptual insights and a basis for theory testing and development to understand the relationship between process and policy outcomes (Steinberger 1980). By proposing that different types of public health policy exist in a food regulation setting and the types have different politics and characteristics associated with them, there is a scheme in which linkages between process and policy can be analysed.

A typology is a classification scheme that extends beyond description to elucidate and group the otherwise disparate characteristics associated with the phenomena under investigation. The typology that has been constructed for this study orders core values that characterise the different socially constructed meanings ascribed to the relationship between food and public health. These meanings are critical in explaining the collection, analysis, interpretation and application of scientific evidence in the making of public health policy. According to Tiryakian, “... a typological classification creates order out of the potential chaos of discrete, discontinuous, or heterogeneous observations. ... it also permits the observer to seek and predict relationships between phenomena.” (Tiryakian 1968: 178).

A typology of the different meanings associated with public health in a food regulation setting is developed in this chapter as a coherent base intended to serve two functions:

i) Retrospectively, it can be applied to analyse an existing policy to assess consistency between theory and practice. As Gardner observes, “Policy analysis usually proceeds by drawing on theoretical frameworks, perspectives,
models and concepts. They order the material being studied and conclusions can be drawn about the extent to which a particular policy is consistent with the framework, model or ‘ideal type’” (Gardner 1998: 2).

ii) prospectively, it can help inform food regulation policy decisions intended to promote public health while ensuring that public health and safety is protected. In this capacity it contributes to the need identified by Davis and Howden-Chapman, “... to embed research within a conceptual framework that will facilitate its ready translation into policy” (Davis and Howden-Chapman 1996: 868).

4.3 Public health models as the conceptual units of the typology

In the present chapter public health ‘models’ are constructed as the conceptual units of the proposed typology to organise the core values associated with the different types of meanings regarding what public health is and the way it can be promoted and protected in a food regulation setting. The term model is adopted from that defined by Tones and Tilford as, “... a theory driven construct which, ideally, encapsulates the essential elements of the theoretician’s formulation of a particular aspect of reality.” (Tones and Tilford 1994: 12).

Many public health practitioners have developed schema that distinguish the values, ideologies, beliefs and interests associated with public health policy interventions by characteristics including the way health is defined and the purpose and the target of the intervention (Downie et al. 1992; Frenk 1992; McKinlay 1993; Palmer and Short 1994; Tones and Tilford 1994; Seedhouse 1997; Baum 1998; Labonte 1998). Although these practitioners place differing emphasis on their description of the technical detail, they broadly agree on the need to construct conceptual units to analyse the way that scientific evidence is interpreted and applied to public health policy development, implementation and evaluation.

Policy interventions intended to effect public health outcomes can be categorised into three distinct models of public health in accordance with the values, ideologies,
beliefs and interests with which they are associated. These three models of public health are the:

i) ‘Medical’ model

ii) ‘Disease prevention’ model

iii) ‘Health promotion’ model

These models are broad constructs that capture many different perspectives of public health. It is beyond the scope of this analysis to review all perspectives that might relate to each model. Instead, the purpose is to describe the way health is defined and public health is conceptualised and the purpose and the target of policy interventions that characterise the core values that distinguish each model. Although there is an attempt to delineate models on the basis of these characteristics, in practice the models are not necessarily mutually exclusive, that is, there is a need to keep the boundaries between the different models ‘permeable’ (Labonte 1998).

The core values that are peculiar to each public health model provide a focus for analysing how and why evidence based practice is used for making public health policy in a food regulation setting. The public health model defines the nature and scope of the epidemiological evidence that informs food regulation policy decisions intended to both promote and protect public health and safety. Selected characteristics of each model are described in the following section. Each public health model is illustrated with an example of a food standard policy intervention for food labelling and food composition with which it is aligned. In aggregate the public health models form a coherent typology that is outlined in Table 4.1.

4.4 Selected characteristics of the different public health models

4.4.1 Medical model

The socially constructed meaning of health
Health is defined as the absence of biological abnormalities and symptoms that might lead to disease and disability. Health is regarded as being an asymptomatic state
(Morgan et al. 1985). In this context diseases are perceived to be abnormalities in the structure and function of the body organs and the biological or physical malfunctioning of the body (Kleinman et al. 1978).

The medical model of public health emanates from an atomistic view of public health in which the individual is the unit of analysis for planning, implementing and evaluating an intervention. Public health is conceptualised as the sum of the health of individuals within the population rather than the health of the collective whole. Public health is informed by an ideology of ‘individualism’ and the development of resources, technologies and treatments that enable professionals to provide increased treatment choices to individuals.

Health problems experienced by individuals are explained by deviations from biological norms. These deviations may be detected in individuals as pathological disturbances or by screening for clinical indicators of specific causal agents, e.g. raised levels of risk factors for a disease, or genetic abnormalities. This notion implies that universal norms exist against which an individual can be assessed. The purpose of interventions aligned with the medical model is to repair the body when it ‘malfunctions’ and to keep it in good running order by changing an individual’s physiological functioning. These interventions focus on controlling potential disease exposure and genetic predispositions to disease, restoring ‘abnormal’ risk factor levels to normal or treating disease symptoms via the administration of drugs or by surgical intervention (Aggleton 1990).

The medical model encourages increased investment in medical research, the development and provision of interventions and individual responsibility to address diagnosed disease rather than advocating political change to society as a whole. As the 21st century unfolds, technological advances in intervention treatments and services aligned with the medical model are providing an unprecedented level of health care choices to an individual. This need for treatment provision and curing has fostered a rapid growth in industries and professional associations established to meet this demand.
Scientific evidence used to inform policy decisions intended to promote public health

The medical model emerged in the late 19th century from the 'germ theory' of disease that postulated that microbes cause disease. The germ theory supplanted the miasma theory of disease causation that had prevailed throughout the 19th century. Diseases were individualized and linked to causal organisms and then diagnostic categories were constructed so that problems of a social group were presented in terms of clinical entities (Bartley 1985). Epidemiology became a key scientific discipline and it was effective at classifying infectious diseases in terms of their causes, e.g. water-, food-, air-, vector-borne diseases. Epidemiologists sought to relate the cause of specific diseases to single agents as exemplified in Koch’s classic work on tuberculosis (Evans 1976).

The medical model is informed by a positivist-reductionist approach to the way health is investigated. The aetiology of disease is ascribed to single causal factors. These relationships are unidirectional between a specific cause and a specific disease outcome. It is believed that phenomena can be reduced to their basic components and direct cause and effect relationships measured and quantified under controlled clinical conditions. The benchmark of medical research is the experimental design in which only the experimental variable is allowed to vary. In epidemiology the RCT is generally ranked as the ‘gold standard’ for experimental design because the process of randomisation enables the infinite number of potential confounding variables to be controlled, thus eliminating most threats to internal validity (Armitage 1972; Last 1988; Clark and Oxman 2000).

Food composition and food labelling policy interventions consistent with this model

Food standards interventions consistent with the medical model position food as a commodity the composition of which can be manipulated to affect an individual’s physiological functioning in accordance with each of the following three prevention approaches:
i) Primary prevention

Primary prevention has also been described as ‘prophylactic medication’ (Doll 1983). It is characterised by anticipating where diseases might occur and intervening to increase the ability of physiological systems to resist insult from potential disease causes. With the completion of the mapping of the human genome, there is a burgeoning interest in potential gene-nutrient interactions and scientific evidence derived from investigations that combine genetics and nutritional science. Nutrition can influence both the expression and stability of the genome. The existence of variations in the genomic profile between individuals means that genetics can predetermine nutrient requirements at the individual level. Taken to its extreme, primary prevention would involve establishing scientific evidence of nutrient–gene interactions and applying the findings to the tailoring of an individual’s diet regimen, taking into account variation with different lifestages, to maximise genotype benefits.

The term functional food has been coined to describe food products anticipated to act as primary prevention agents. The concept of functional foods was discussed in Chapter 2. The fortification of staple foods with folic acid in Australia has been recommended and implemented as a primary prevention approach to reduce the risk of NTDs. Effectively, folate fortified foods are the first and only functional foods in Australia (Anon. 1997). The term ‘functional’ health claim has been proposed to describe the food label information that is consistent with this example. A functional health claim has been defined as the information that describes the relationship between an ingredient present in a food product and the prevention of a disease in an individual (Lawrence and Rayner 1998).

ii) Secondary prevention

Secondary prevention approaches are characterised by intervening in the causal chain for disease at an early stage before the individual is aware of the disease, e.g., restoring an ‘abnormal’ risk factor level to ‘normal’. Traditionally, therapeutic agents have been developed as secondary prevention aids, e.g., to lower blood cholesterol levels. From a nutrition perspective, the concept of functional food may evolve to be another form of secondary prevention agent. For example, food products resulting

---

13 The relationship between folic acid and the reduction in risk of NTDs is discussed in detail in Chapter 6.
from the interesterification of plant sterols and stanols with margarine have been reported to exhibit a cholesterol lowering effect when a specified 'dose' was consumed on a daily basis by individuals with mild hypercholesterolaemia (Miettinen et al. 1995). A functional health claim would be the food label information consistent with this example.

iii) Tertiary prevention
Interventions consistent with a tertiary prevention approach aim to treat and control the effects of an existing disease. Products consistent with this approach include:

- Nutrient supplements to treat malnutrition in individuals.
- Foods for special dietary uses, such as a gluten-free food suitable for individuals with coeliac disease.
- Naso-gastric feeds and enteral feeds for individuals with diseases that prevent the consumption of a normal diet.

Technological developments that have demonstrated a benefit for individuals in the controlled environment of clinical trials cannot be expected necessarily to extrapolate to population-wide benefits. The public health impact of so-called functional foods needs to be kept in perspective. For example, if a feeding trial for a product containing a special fibre indicates that it will reduce cholesterol levels in hypercholesterolaemic men, can we assume that this benefit will also apply to men with normal cholesterol levels? for women? for children? (Preston and Lawrence 1996). The products may provide benefits for specific individuals who suffer from the particular risk factor or genetic predisposition for which the functional food has been developed and also have the resources to purchase the relevant food product.

The interpretation of the policy objective to protect public health and safety
The interpretation of protecting public health and safety for food standard interventions aligned with the medical model relates to the potential risk of food components to have an adverse impact on the physiology of individuals. Interventions that focus excessively on nutrient fortified foods or nutrient supplements have the potential to create the risk of dietary imbalances. For example, foods such as fruits and vegetables that are sources of β-carotene are protective
against lung and other cancers (Steinmetz and Potter 1996). However, when the β-carotene is isolated from the food matrix and provided in supplemental form it has been reported to show no protective effect and instead to exacerbate adverse effects including excess lung cancer incidence and overall mortality in smokers (Albanes et al. 1995; Omenn et al. 1996). Similarly, products resulting from the interesterification of plant sterols and stanols with margarine, for the purpose of reducing cholesterol absorption, have been reported to reduce an individual’s plasma carotenoid levels by 19% (Westrate and Meijer 1998). The unknown long-term consequences of consuming novel foods and novel levels of food components requires risk analysis procedures to monitor potential cumulative side effects and toxicological impacts of these components on individuals over extended time periods.

4.4.2 Disease prevention model

_The socially constructed meaning of health_

Health is defined as for the medical model and is achieved by preventing the onset of disease, i.e. it is a state to be preserved (Labonte 1998). Proponents of the disease prevention model adopt a mechanistic view of health that regards the human body as a machine and that the role of interventions is to prevent the parts of the machine from breaking down and thereby reduce the incidence of disease.

Whereas the purpose of interventions aligned with the medical model is to prevent disease in high-risk individuals, the unit of analysis for interventions aligned with the disease prevention model is populations. The conceptual foundation to the disease prevention model draws heavily on the ‘population strategy’ to preventive medicine espoused by Sir Geoffrey Rose (Rose 1. J2). Rose argued that the incidence of morbidity and premature mortality can be reduced for an entire population only by changing risk factor distributions at the population level, not by concentrating on the upper end of the risk distribution, i.e. the causes of individual cases are not necessarily the determinants of incidence among populations.

Rose’s explanation assumes that most disease within a population occurs in individuals at moderate risk. Interventions that aim to shift the mean exposure to risk
factors of the whole population are therefore likely to achieve a greater impact on public health than those restricted to high-risk individuals. According to Rose, relative risk may be used as aetiological evidence but it “... is no measure at all of aetiological outcome or of public health importance” (Rose 1985: 32). The public health benefit depends not only on the benefit that each individual receives but also on the prevalence of the risk factor (Rose 1981). The application of the disease prevention model to public health nutrition policy is illustrated by the concept of population nutrient goals that are defined as “... the population average intake that is judged to be consistent with maintenance of health in a population. Health in the population is, in this context, marked by a low prevalence of diet-related diseases in the population.” (World Health Organization 1990: 106). These goals are not intended to be applied to the diets of each and every individual in the population as this aggregate change would be substantially greater than that intended for the population as an entity.

The corollary of the population approach to disease prevention in comparison with the high-risk individual approach of the medical model is that many people within the population to which the intervention is applied will not suffer from the disease. The challenge is to persuade large numbers of individuals to change their behaviour in accordance with population recommendations despite many not realising any significant benefit from such a change (Davison et al. 1991). Rose termed this phenomenon the ‘Prevention paradox’, “A preventive measure which brings much benefit to the population offers little to each participating individual” (Rose 1985: 38). Others have criticised Rose’s population strategy for presuming the population is ‘sick’ and claims that this thinking leads inexorably to policy interventions that perpetuate a ‘medicalization’ of human life (Charlton 1995).

The rationale for interventions aligned with the disease prevention model is that the population’s exposure to risk factors is the consequence of inappropriate lifestyle behaviours that, in turn, are regarded as being the responsibility of individuals in the population. Therefore, it is believed that policy interventions should be targeted at changing an individual's behaviour to change exposure patterns to risk factors at the population level. This belief is consistent with an ideology of individualism with the individual being held responsible for behaviour change with some support for the
development of resources and structural change to help make healthy choices easy choices. The focus on personal attributes has led to this model being termed the ‘lifestyle approach’ to health policy (Terris 1980; Green and Raeburn 1988).

*Scientific evidence used to inform policy decisions intended to promote public health*

By the late 1950s several epidemiologists had begun to question the relevance of models of infectious disease aetiology in relation to the study of chronic disease aetiology. Rather than question the assumptions implicit in epidemiological thinking, arguments presented in the scientific literature sought to redefine the concept of aetiology and to create more complex models of disease causation (Lilienfeld 1959; Yerushalmy and Palmer 1959; Sartwell 1960). The relationship between risk factors and non-communicable diseases came to be described in terms of a ‘web of causation’ to reflect the multifactorial aetiology of chronic disease (MacMahon et al. 1960; Susser 1973).

In common with the medical model, the disease prevention model takes a positivist-reductionist approach to inquiry. However, the experimental design common to the medical model does not translate well to the identification of causal factors for chronic diseases. Individual risk factors for a disease prevalent in a population need to be identified from among a potential multitude of risk factors. From a logistical and ethical perspective it is problematic to randomise populations precisely and so it is difficult to isolate specific explanatory variables using the RCT experimental design. The term ‘quasi-experimental design’ was introduced by Campbell and Stanley (Campbell and Stanley 1963) to describe research that shared the feature of non-random assignment of groups, but approximated experimental design in the scheduling of data collection procedures, e.g. case-control and cohort research designs. The quasi-experimental design is the common approach for ‘risk factor’ epidemiology that informs interventions aligned with the disease prevention model.

From a nutrition perspective scientists draw on evolutionary theory to hypothesise that a major explanation for the prevalence of diet related chronic disease is that certain modern behaviours are not compatible with the way the human body has evolved (Eaton et al. 1988; McKeown 1988). The principles of evolutionary
adaptation suggest that the physiological and biochemical processes necessary to metabolise and synthesise the energy and nutrients in foods are controlled by a genetic profile programmed through the process of natural selection over millions of years. Over these millions of years of evolution, human beings (and their primate predecessors) have adapted progressively to a wide range of naturally occurring foods (World Health Organization 1990). Relative to the pace of modern change in culture and society, the process of biochemical and physiological evolution is slow and humans are still biologically adapted to a hunter-gatherer lifestyle as this represents the conditions under which they have spent the vast majority of their existence. Thus, contemporary human nutritional requirements are not dissimilar from those that existed during the palaeolithic period as 99% of modern humans genetic profile is the same as that of humans from this period (Eaton and Konner 1985).

Agricultural and technological developments have resulted in humans now having the capacity to make available a great diversity of food items many of which bear little resemblance to those present in the environment that ended approximately 10,000 years ago with the agricultural revolution (Leakey and Lewin 1992). Relative to the modern diet, the palaeolithic diet contained a greater amount and variety of fruits and vegetables, legumes, seeds, roots, nuts, meat and fish and a smaller proportion of cereal grains and fats and oils (Eaton et al. 1996; Eaton et al. 1997; Cordain et al. 2000). In response to the prevalence of chronic disease McMichael comments,

"The public health problem arises from the dissonance between human culture and human biology. ... [therefore] ... it is desirable to shift the population distribution of consumption and of biological risk markers (e.g. blood cholesterol) to levels that approximate to our nutritionally sufficient evolutionary past, and that are associated with lower risks of various chronic diseases." (McMichael 1991: 9-12).

Some scientists have questioned the presumptions on which the evolutionary theory to developing dietary recommendations is based. They ask where is the evidence that humans are now maladapted to their environment and diet? For example, Nestle
acknowledges that the existence of humans today indicates that paleolithic diets must have provided sufficient energy and nutrients to at least support growth and reproduction. However, she argues that satisfying these minimal requirements to ensure the continuation of human existence is not necessarily the same as optimally determining adult health and suggests that this is unlikely as human life expectancy has increased dramatically during this century (Nestle 2000). It is difficult to draw conclusions on the relationship between diet and longevity by comparing paleolithic and modern time periods. Critical factors that influence longevity varied between these periods, eg infant mortality rates were substantially higher during the paleolithic period.

Many commentators concur that the primary driver of evolution is for the human body to survive to reproductive age so as to propagate the next generation. They argue that there is no evolutionary advantage for the body to survive beyond reproductive age. Other scientists argue that there is an evolutionary advantage for women to live beyond menopause so that they can advise their children on survival, e.g. grandmothers can promote infant survival and nurturing (O'Connell et al. 1999). Rather than being a direct influence via genetic profile, grandmothers offer an a priori affect via cultural influence. Also, men can still reproduce into old age.

**Food composition and food labelling policy interventions consistent with this model**

Food standards interventions consistent with the disease prevention model position food as a commodity the composition of which can be manipulated to modify an individual’s exposure to dietary risk factors. It is intended that manipulating the composition of certain food products in accordance with the dietary guidelines, e.g. fat-reduced products, will assist individuals within a population to change their dietary intake and thereby contribute towards the achievement of a population dietary profile congruent with nutrition goals and targets.

The term ‘dietary guideline’ health claim has been proposed to describe the food label information that is consistent with this intervention. A dietary guideline health claim has been defined as the information that relates a modified food, or nutrient in a food, to a dietary guideline recommendation (Lawrence and Rayner 1998).
addition, foods belonging to food groups the consumption of which is encouraged by the dietary guideline recommendations, e.g. fruit and vegetables, would also qualify for a dietary guideline health claim.

The challenge for linking the regulation of individual food products or groups of foods with public health in this setting is two-fold:

i) It is the total diet profile not that of individual food products that is the relevant exposure variable, thus many assumptions need to be made in extrapolating the composition of individual food products to a contribution to the total diet. This may explain the paradox whereby the increased availability and consumption of energy- and fat-reduced food products for individuals in the US has coincided with an increase in the prevalence of obesity across the US population (Allred 1995).

ii) The scientific evidence is based on the association between the population’s dietary intake and chronic disease prevalence, not the dietary intake of specific individuals within the population. In this context Trostle has described dietary guidelines as medical ideology at work (Trostle 1988).

The interpretation of the policy objective to protect public health and safety

The interpretation of protecting public health and safety for food standard interventions aligned with the disease prevention model relates to the potential for modified food composition to have an adverse impact on the dietary intake profile of population sub-groups. For example, dietary imbalances in groups of young children arising from an excessively low fat intake.

Rose suggests distinguishing two types of preventive measure by their mode of action and potential risk and benefit. The first consists of the removal of an unnatural factor and the restoration of ‘biological normality’, which he describes as the conditions to which presumably we are genetically adapted, e.g reducing severe obesity, for which there should be a reasonable presumption of safety and benefit. The second involves leaving the cause of incidence and imposing some unnatural factor, in the hope of conferring protection. Rose regards these measures as increasing biological abnormality from the conditions to which we are genetically adapted and long-term safety cannot be assured (Rose 1981). For example, the
emphasis on substituting polyunsaturated fats for other fats in the diet as an intervention to help prevent heart disease has been challenged because this dietary manipulation may create alternative problems as polyunsaturated fats are ‘fertile substrates’ for free radicals (Roberts 1993).

4.4.3 Health promotion model

The socially constructed meaning of health

The evolution of contemporary health promotion can be traced through a series of events coordinated by the WHO during the last quarter of the 20th century. These events have sought to shift the theoretical framework for health from a focus on individuals towards a focus on the structural influences that create health opportunities. The publication of the WHO’s ‘Global Strategy for Health for All by the year 2000’ (World Health Organization 1981), provided guiding principles for a series of health promotion conferences that the WHO organised at the end of the last millennium. The first International Conference on Health Promotion was held in Ottawa in 1986 where the Ottawa Charter for Health Promotion was proclaimed (World Health Organization 1986). The Ottawa Charter emphasised that, “Health should not be seen as the prime objective of living but rather as a resource for everyday life which permits all people to lead an individually, socially and economically productive life.” (World Health Organization 1986: 1).

From a health promotion perspective it is society as a whole that is the unit of analysis for public health. Health differentials within and among populations have their origins in class and social relationships. Populations with lower socio-economic status suffer a disproportionate burden of ill-health and disease (Blanc et al. 1996). Socially and economically disadvantaged populations and communities generally have reduced opportunities to 'control' their environment. The determinants of the health of populations are regarded as being the social, economic, ecological and cultural circumstances in which people live and it is at these determinants that interventions are targeted. The values, beliefs and interests captured in the health promotion model reflect a ‘collectivist’ approach to public health interventions in which the focus is on preserving environmental resources and promoting social justice so that all individuals have opportunities for making informed choices.
The scope of the Health for all agenda is inclusive of an ecological perspective to public health (Kickbusch 1989; Catford 1991). The Ottawa Charter stated, “The inextricable links between people and their environment constitutes the basis for a socio-ecological approach to health” (World Health Organization 1986: 2). The ecological dimension to the health promotion model has been reaffirmed at WHO’s health promotion conferences in Adelaide (World Health Organization 1988), Sundsvaal (World Health Organization 1991) and Jakarta (World Health Organization 1997). This ecological dimension brings special criteria to bear on food policy considerations that involve the need to protect food as a common good.

*Scientific evidence used to inform policy decisions intended to promote public health*

There is a contemporary debate about the utility of clinical and risk factor epidemiology to provide a sufficient knowledge base for public health policy (Kreiger 1999; Schwartz et al. 1999). Epidemiologists acknowledge that traditional epidemiological approaches have contributed understanding of the aetiology of chronic diseases such as coronary heart diseases and some cancers, however, these studies are now operating on ‘diminishing returns’ and failing to achieve a significant influence on public health outcomes (Levine and Lilienfield 1987; Editorial 1994; Krieger 1994; Schwartz 1994; Skrabanek 1994; Wing 1994; Mackenbach 1995; Taubes 1995; Susser and Susser 1996; Shy 1997). For example, Syme highlights that there are three limitations with the way risk factor epidemiology thinks about heart disease (Syme 1996):

i) When all risk factors are considered, they explain only about 40% of the coronary heart disease that occurs (Marmot and Winkelstein 1975).

ii) Even when we do identify risk factors, it is difficult to get people to change and few large scale community health intervention programs have been able to demonstrate effectiveness in changing behaviours or improving population health outcomes (McCormick and Skrabanek 1988; Grundy 1990; Erben et al. 1992).

iii) Even when interventions are successful in changing behaviours in individuals the population’s health will not necessarily improve. This lack of population health improvement arises because the elimination of one disease such as
coronary heart disease is not reflected in reduced aggregate mortality levels (Oliver 1988). Moreover, new people continue to enter the at-risk population because the social forces that are creating the problem are not being modified and ultimately these interventions are not sustainable.

From a methodological perspective, simply detecting the statistical effect of a factor that remains after other influences are removed does not provide the mechanistic information needed for understanding the connection between the two variables. Susser and Susser refers to the epidemiological evidence informing the disease prevention model as being characterised by the 'black box' of causality, i.e. "...related exposure to outcome without any necessary obligation to interpolate either intervening factors or even pathogenesis." (Susser and Susser 1996: 670). As such, the risk factor model of disease has been criticised for lacking a theoretical logic for transferring statistical correlations into causal processes (Stallones 1980; Skrabanek 1994). Others argue that to understand the determinants of population health in terms that extend beyond proximate, individual-level risk factors, epidemiologists must learn to apply a social-ecologic systems perspective when conducting public health research (McMichael 1999).

Some critics argue that the extent of the desire for investigations to be 'scientific', to be grounded in demonstrable relationships between measurable variables, and to eliminate uncontrollable factors, may well misinterpret the social reality that is sought (Dolbeare 1975). Reductionist approaches enable known potential confounding influences to be controlled. However, in controlling for these influences they may strip away the underlying social and environmental contexts that explain the relationship and which are the very issues that need to be addressed by public health policy (Dean 1996).

Leading epidemiologists have expressed concern that there is a lack of epidemiologic theory to explain patterns of disease causation in populations, as distinct from what makes an individual ill (Kreiger and Zieler 1996; Pearce 1996; Susser and Susser 1996). Epidemiological studies that treat populations as a collection of individuals rather than as a unit for investigation in its own right may ignore the dynamics associated with people in their social role where the collective whole can be more
complex than the sum of the individual parts (Koopman and Lynch 1999). As Shy states,

"By essentially assuming that risk factors for disease in individuals can be summed to understand the causes of disease in populations, academic epidemiology has limited itself to a narrow biomedical perspective, thereby committing the biomedical-fallacy of inferring that disease in populations can be understood by studying risk factors for disease in individuals." (Shy 1997: 479).

The health promotion model operates from the premise that the etiology of health opportunities is not distributed randomly within the community and instead is located within the social and environmental settings within society. The model is characterised by multiple cause – multiple outcome (holistic) relationships. Baum argues that, just like the microbes of the 19th century, the (social-environmental) forces responsible for contemporary public health problems are largely invisible and the task of public health is to use research to make the forces visible (Baum 1999). Kreiger has proposed an ‘eco-social’ theory of epidemiology that integrates social and biologic understandings of influences on public health (Krieger 1994). Similarly, Susser and Susser (Susser and Susser 1996) and Schwartz et al (Schwartz et al. 1999) have suggested the need for an eco-epidemiology paradigm that addresses the interdependence of individuals and their connection with the biological, physical, social and historical contexts in which they live.

Proponents of the health promotion model perceive the relationship between food and health in a holistic context that focuses on the food supply in total, rather than individual foods or nutrients, as relevant to health. For example, a synergistic relationship between food components in the total diet has been demonstrated by Trichopolou and colleagues who report that the Greeks’ diet contribution to survival is greater than the sum of its parts (Trichopolou et al. 1995). Moreover, eating a varied diet provides a secure foundation for consuming an adequate amount and appropriate combination of essential nutrients (Hodgson et al. 1994; Wahlqvist 1999) and is the basis for the first dietary guideline (Commonwealth Department of Health 1992). The evidence for this dietary guidance has been derived, in part, from
prospective studies that have reported an inverse relationship between diets comprising foods from a diverse biological base and mortality in men and women (Kant et al. 1993) and women only (Kant et al. 2000). Similarly, evidence is emerging of positive associations between the broader food, cultural and lifestyle context associated with various cuisines, such as the Mediterranean diet, and public health outcomes (Nestle 1995; Trichopolou and Lagiou 1997). This holistic approach to dietary guidance has been recommended by the WHO and FAO who jointly developed Food Based Dietary Guidelines to encourage culturally sensitive, affordable and sustainable approaches to nutrition and health (World Health Organization 1998).

Food composition and food labelling policy interventions consistent with this model

Food standards interventions consistent with the health promotion model position food as a public health resource, or common good, that needs to be available in a sufficient amount and variety to meet the energy and nutrient requirements of the population. The RDIs have been developed as the reference standards of intake of essential nutrients considered to be adequate to meet the known nutritional needs of practically all healthy people (National Health and Medical Research Council 1991). Population-wide nutrient deficiencies may arise when there is an inadequate amount of one or more nutrients in the food supply to meet the nutritional requirements of the population. From a health promotion perspective, food fortification can be used to increase the amount of a nutrient(s) in the food supply to reduce population-wide nutrient deficiencies. Globally, folate deficiency arising from inadequate amounts of folate in the food supply is one of the most common nutrient deficiencies and is associated with megaloblastic anaemia. The fortification of staple foods with folic acid as a primary prevention intervention is common in many developing countries where there is an inadequate amount of folate in the food supply. In Australia, there are two examples of food fortification to address inherent nutrient deficiencies in the food supply: the fortification of staple food products with thiamin to help reduce the risk of Wernicke-Korsakoff syndrome; and salt iodisation to reduce the risk of goitre. Nutrient content claims and nutrient function claims are the food labelling initiatives consistent with the health promotion model.
The interpretation of the policy objective to protect public health and safety

From a health promotion perspective, the interpretation of the objective ‘to protect public health and safety’ in the setting of food standards is grounded in principles that recognise the ecological basis to the relationship between food and health. Specifically, protecting the inherent nutrient profile and the sustainability of the food supply as an ecological resource (World Health Organization 1991). The philosophy behind interventions aligned with the health promotion model is that there is a need to protect the viability of the food supply and its biodiversity as biological capital to sustain its capacity to promote human nutritional needs.

The relationships between food and health are mediated through a variety of biochemical processes. Knowledge regarding the actual requirements for and the complexity of the relationships of food constituents to health is still unfolding. Many factors affect the bioavailability and interaction of vitamins and minerals in foods, and often it is difficult to predict accurately the impact of compositional changes on public health (Tummlund 1994). No nutrition intervention is completely risk free because all have the potential to disturb dietary balance in some way (Mertz 1994). Consequently, “… the delicate balance of nutrients that is conducive to health can be disturbed not only by deficiencies but also by excesses of individual nutrients which, without being toxic by themselves, can adversely affect the bioavailability and function of others.” (Mertz 1984: 770). An excess of one nutrient may interfere with the bioavailability of another, for example, excessive calcium intake has been reported to interfere with iron absorption (Hallberg et al. 1992).

However, it is known that the consumption of many different combinations of naturally occurring foods has been consistent with human survival. According to Eaton et al, it is not so important in what form the building blocks necessary for proper metabolism and biochemical function enter our body, what is important is that “… the foods we eat provide the same spectrum and proportion of nutrients ... as were eaten by our hunting and gathering ancestors, the nutrient pattern for which our genes were originally selected.” (Eaton et al. 1989: 88). Historically different foods have had a characteristic nutrient profile. The protection of the characteristic nutrient profile of individual food products provides a secure foundation for maintaining the appropriate spectrum and proportion of nutrients in the diet (Gussow 1993). The
indiscriminate addition of nutrients to a food product alters its characteristic nutrient profile and has the potential to disturb the biological relationship between food and health. The cumulative and long-term consequences on public health and safety of nutrient manipulation are unknown.
Table 4.1  An overview of selected characteristics of the public health models

<table>
<thead>
<tr>
<th>Public health model</th>
<th>Medical</th>
<th>Disease prevention</th>
<th>Health promotion</th>
</tr>
</thead>
<tbody>
<tr>
<td>Definition of health</td>
<td>An asymptomatic state</td>
<td>A state to be preserved</td>
<td>A positive resource</td>
</tr>
<tr>
<td>Unit of analysis</td>
<td>Individual</td>
<td>Population or groups of people</td>
<td>Society</td>
</tr>
<tr>
<td>Target of intervention</td>
<td>Physiological processes</td>
<td>An individual’s behaviour(s)</td>
<td>Social and ecological setting</td>
</tr>
<tr>
<td>Purpose of intervention</td>
<td>Control potential disease exposure and genetic predispositions to disease</td>
<td>Prevent risk factors exceeding normative limits</td>
<td>Promote social equity and environmental integrity and sustainability</td>
</tr>
<tr>
<td>Values, ideology, beliefs and interests</td>
<td>Belief in individualism and the development of resources, technologies and treatments that enable professionals to provide increased choice to individuals</td>
<td>Belief in individualism with the individual assuming responsibility for behaviour change with some support for the development of resources and structural change to help make healthy choices easy choices</td>
<td>Belief in the collective interest and the protection of common goods by preserving environmental resources and promoting social justice so that all individuals have opportunities for making informed choices</td>
</tr>
<tr>
<td>Scientific evidence used to inform public health policy</td>
<td>Direct cause and effect relationships</td>
<td>Multiple cause - single effect relationships</td>
<td>Multiple cause – multiple effect (holistic) relationships</td>
</tr>
<tr>
<td>Role of food</td>
<td>A commodity whose composition can be manipulated to affect an individual’s physiological functioning</td>
<td>A commodity whose composition can be manipulated to modify an individual’s exposure to risk factors</td>
<td>A public health resource (common good) for growth and development for all people in society</td>
</tr>
<tr>
<td>Focus of food regulation</td>
<td>Food composition</td>
<td>Diet intake</td>
<td>Food supply</td>
</tr>
<tr>
<td>Food composition policy</td>
<td>Modify nutrient composition in accordance with the findings of clinical trials</td>
<td>Modify nutrient composition in accordance with dietary guidelines (nutrient goals and targets)</td>
<td>Restore nutrients lost in processing</td>
</tr>
<tr>
<td>Food labelling policy</td>
<td>‘Functional’ health claim</td>
<td>‘Dietary guideline’ health claim</td>
<td>Fortification when inherent nutrient deficiencies arise in the food supply</td>
</tr>
<tr>
<td>Interpretation of the protection of public health and safety</td>
<td>Avoiding the toxicity impact of a food product ingredient on an individual’s physiology</td>
<td>Nutrient content claim Nutrient function claim</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Protecting the sustainability and integrity of the food supply</td>
</tr>
</tbody>
</table>
4.4 Principles for applying the models to public health policy practice

In the previous section the scientific evidence associated with establishing efficacy and safety for interventions aligned with each public health model was described. The challenge for practitioners is putting these models into practice. As Nutbeam states “One of the greatest challenges for practitioners is to identify how best to achieve a fit between the issues of interest and established theories or models which could improve the effectiveness of a program or intervention.” (Nutbeam and Harris 1998: 16). In this section, principles for applying the conceptual models to the development, implementation and evaluation of public health policy are described.

4.4.1 Policy development

It is not the intention of this review to imply that one public health model is inherently preferable to another. Rather it is argued that each model has a legitimate role in the development of public health policy in a given circumstance and the policy-making process needs to be inclusive of all models. The critical principle is to match a policy response to the actiology of the problem, i.e. a ‘horses-for-courses’ approach. However, the public health cause and ‘appropriate’ policy response can be difficult to ascertain. The different ways that the cause of a public health issue can be conceptualised is illustrated by the policy response to the endemic appearance of pellagra in the South of the US during the early 20th century. The three different conceptualisations of cause are:

i) The proximal cause of pellagra was identified as niacin deficiency in individuals (Goldberger et al. 1918). From this perspective niacin fortification of food products was recommended so as to increase individual’s exposure to niacin.

ii) The interim cause of pellagra was attributed to the removal of niacin from maize as a consequence of the manufacturing process (Park et al. 2000). From this perspective niacin restoration of maize was recommended to replace the amount of niacin lost during the processing of that food.

iii) The distal cause of pellagra was attributed to socioeconomic conditions and its disappearance may have been as much to do with economic recovery as fortification programs (Mertz 1997). From this perspective scientists argue that
the incidence of pellagra were declining well before the introduction of mandatory niacin fortification in the US and this policy was an inappropriate ‘techno-fix’ approach (Nestle 1994).

According to Rose, “If we consider screening a population to discover those with high serum cholesterol levels and advising them on dietary change, then that intervention is appropriate to those people in particular: they have a diet-related metabolic problem.... The 'high-risk' strategy produces interventions that are appropriate to the particular individuals advised to take them.” (Rose 1985: 35). In this instance an appropriate food regulation role may be to promote the development of either potential functional food products that can demonstrate efficacy in lowering serum cholesterol levels or fat-reduced products to complement a low-fat diet regime for these high-risk individuals. However, there is no logical basis for recommending these food regulation initiatives to non high-risk individuals, or the population in general (Dean 1996).

There is a disjunction between theory and policy practice when scientific evidence aligned with one public health model construct is extrapolated to inform policy practice intended to address a problem aligned with another public health model construct. Threats to the effectiveness and ethics of a policy intervention arise when the scientific evidence to support the intervention is derived from a unit of analysis that differs from that for the public health problem being addressed. Associations observed at the aggregate, or group, level do not necessarily translate to associations at the individual level and vice versa. The abstraction of risk factors from population statistics to intervene at the individual level has been described as ‘ecological fallacy’, i.e. “... a logical fallacy inherent in making causal inference from group data to individual behaviours.” (Schwartz 1994: 819). Conversely, focusing on evidence of associations from studies at the individual level to design and implement group or population interventions has been described as the ‘individualistic fallacy’, in which information about the environment is incorrectly inferred from data on individuals (Scheuch 1969).
4.4.2 Policy implementation

Public health problems can result from a complex mix of social, political, economic, biological and environmental causes. There is a need to be inclusive in choosing interventions to address a public health problem. In certain circumstances the coexistence of interventions aligned with different models may be advantageous. As mentioned in the introduction to this thesis, the WHO define public health as “... a social and political concept aimed at improving health, prolonging life and improving the quality of life among whole populations through health promotion, disease prevention and other forms of health intervention.” (Nutbeam 1998: 352). Interventions aligned with the different models represent different, potentially complementary, preventive strategies (McMichael 1989). In public health nutrition the complementary nature of the different models to combat micronutrient malnutrition has been emphasised (Darnton-Hill 1999).

Many commentators express concern that in practice undue emphasis can be placed on interventions aligned with one or other model when an alternative or a combination of interventions may be preferable for addressing the public health problem. For example, an undue emphasis on interventions aligned with the medical or disease prevention models may have the potential to deflect attention away from broader social structures and relations where health is created and onto individual responsibility for lifestyle and ‘health choices’ (Crawford 1980), or medical solutions (Illich 1976; Navarro 1980). Interventions that are directed exclusively at changing an individual’s behaviour without consideration of the individual’s environment have been accused of inappropriately presuming that the actions of individuals essentially are rational decisions involving freedom of choice and instead exacerbating a ‘victim blaming’ mentality (Ryan 1976). Doyal and Pennell acknowledge that medicine provides help for the ill but, by concentrating on individual body pathology, they believe that it hides and exonerates the role of structural factors in society in determining health (Doyal and Pennell 1979).

The ideal policy approach to maximise public health status may be a combination of interventions derived from each of the three public health models implemented in such a way as to complement each other. Health promotion interventions aim to protect the ecological resource base and strengthen social cohesion across the
population. These outputs will contribute to providing a secure foundation for all people to achieve their health potential. Disease prevention interventions might be targeted at population groups to prevent potential risk factors exceeding normative levels. The medical approach will account for those individuals who are vulnerable to a specific disease or are suffering a disease. As Frenk states

"... in order to fully understand and act upon a health problem it may be necessary to integrate the information on the subindividual level (through biomedical research), the individual level (through clinical research), the population level (through epidemiological research) and the societal level (through health systems research)" (Frenk 1992: 1401).

4.4.3 Policy evaluation

The methodology and indicators for evaluating a policy need to be consistent with the public health model with which the policy is aligned. For a given public health policy there are characteristic indirect, intermediate and outcome indicators, units of analysis (individuals, population or society) and time frame. The evaluation design and measures must be sensitive to these characteristics. Applying an evaluation design that is appropriate to one model to evaluate a policy that is aligned with another model may be conceptually flawed, ethically dubious and epistemologically irrelevant. McKinlay stresses the importance of the concept of ‘appropriate methodology’ that emphasises the need to match the level of intervention with the most suitable research approach (McKinlay 1993). For example, while not advocating that one methodology is intrinsically superior to another, McKinlay suggests that the quantitative methods of experimental designs are particularly appropriate to research aligned to the medical and disease prevention models. However, the utility of these methods diminishes for the health promotion model where the phenomena to which they are applied are not amenable to rigorous experimental control and manipulation (McKinlay 1993). Conventional mortality and morbidity measures have been described as ‘blunt instruments’ for evaluating health promotion interventions (McGinnis 1989).

In addition to selecting the appropriate methodology and indicators to assess the effectiveness of a policy in achieving its objectives, an evaluation procedure needs to
be able to detect outcomes that expose inconsistencies between policy practice and theory. For example, if aetiological evidence aligned with the medical model is inappropriately applied to develop a policy aligned with the health promotion model then the evaluation should be sensitive to potential adverse outcomes. This entails examining the impact of a policy over the longer term and on population and environment indicators, rather than on immediate clinical outcomes. If an evaluation design is restricted to assessing medical indicators then it will not have the capacity to measure the broader impact of an intervention including potential adverse outcomes.

The appropriate selection of evaluation criteria or endpoints are critical to determining whether a policy intervention will be correctly evaluated as having been effective and safe. For example, interventions aligned with the medical model might be judged against their impact on physiological pathways in individuals as the endpoint. Evaluations based on behaviour and assessing change in diet composition would be inappropriate. The use of endpoints inconsistent with the nature of the issue under investigation is scientifically and ethically flawed. As Berk and Rossi comment “… evaluation research may validate a particular view of social problems by emphasizing certain outcomes as opposed to others. Evaluation research methodology contributes to the definition of social problems; virtually all technical issues have an ideological side” (Berk and Rossi 1976: 339).

4.5 Conclusion

The use of food regulation as a public health policy instrument engages competing rationalities among different stakeholders. These competing rationalities are based on contested meanings of public health in a food regulation setting. Thus, the policy process is, at least in part, a struggle to get one or another meaning established as the accepted one. It is the resolution of these contested meanings with which the policy-making process for the food regulatory system must contend. Theory needs to explain how and why the public health policy objectives either to promote public health or to protect public health and safety within this system take on meaning.
This chapter has proposed a typology to order the different meanings that stakeholders ascribe to public health policy in a food regulation setting. It has been argued that given the contested core values associated with the concept of public health it is not possible to devise a simple formula for translating scientific evidence into public health policy. Public health models were constructed to organise and bring order to the different core values associated with public health and thereby impose meaning on how and why the protection and/or promotion of public health is interpreted in a food regulation setting. The typology is a necessary precursor to theory testing as it provides a classification scheme against which findings from the policy analysis can be assessed.

The public health models are value-laden constructs and this inevitably shapes their application to policy-making. The choice of any particular model is a political statement. It has been suggested that core values might conceivably be used not only to justify adoption of a given model but also serve as a basis for vigorously attacking competing models and associated practice (Tones and Tilford 1994). With the typology in place, the case study can be analysed to identify factors that influence the selection and application of public health models in policy-making, especially where there is a departure from that predicted by the typology. Explanations for policy-making can then be sought by identifying patterns of causal factors associated with the core values of the different models. In the next chapter the research method used in this thesis to identify these patterns of causal factors is described.
CHAPTER 5

Method

5.1 Introduction

The multidisciplinary nature and diversity of theories and models associated with the policy sciences, as presented in the literature review, highlights the challenges confronting the policy analyst proposing to test theory of the policy-making process. Policy analysis is not a discipline in its own right, instead, it has been described as being "... an applied sub-field whose content cannot be determined by disciplinary boundaries but by whatever appears appropriate to the circumstances of the time and the nature of the problem" (Wildavsky 1979: 15). As Parsons observes,

"... public policy and the problems with which it is concerned do not exist in neat, tidy, academic boxes. ... the aim of the policy approach is not to pull these issues apart, so much as to recognize how problems come to be addressed and structured by the way in which knowledge is organized and deployed ... consequently and inevitably the study of policy-making and policy analysis is essentially multiframed." (Parsons 1995: 64-65).

A multidimensional and multidisciplinary policy analysis method was employed in this investigation. The policy analysis method involved collecting, organising and assessing information to identify the pattern in the policy-making process that led to the folate fortification policy. The pattern was then interpreted against the theoretical framework to test the plausibility of different theories to explain how and why scientific evidence was used in the case study.

The present chapter provides a description of the procedures followed and activities conducted in undertaking the policy analysis for this thesis. The chapter describes the: research design; data collection; data analysis; data reporting; and procedures, that were implemented to ensure a high standard of rigour throughout each stage of the research process to strengthen the credibility and integrity of the investigation.
5.2 The research design

The research design is the logic that links the research method, the data to be collected, and the conclusions to be drawn, to the initial question of the study (Yin 1994). The aims of the research design used in this investigation were to:

i) Focus the nature and scope of the data collection prior to the commencement of the fieldwork.

ii) Establish objectivity in the analysis of the data.

iii) Achieve methodological rigour.

The rationale for selecting the research method for the policy analysis of this thesis was the nature of the research aim. As stated in the introduction to this thesis, the research aim is to test theory to gain a theoretical understanding of the use of scientific evidence in the making of public health policy in a food regulation setting. The research method selected to enable the research aim to be achieved was based on an adaptation of the case study method that has been effectively used in previous policy analysis investigations (Hamel et al. 1993; Yin 1994; Davis 1998).

Policy analysis requires data that provide insights into explanatory contexts, the technical nature of the policy-making agency and the values of interested parties (Milio 1991). The case study method possesses distinctive qualities that enabled the investigation to retain the holistic characteristics of the real-life events that were critical to understanding the political phenomena associated with the policy-making process. Case studies can be exploratory, descriptive or explanatory. The research design for this thesis extended beyond description to obtain data that were analysed and interpreted to test theory of the public health policy-making process in the food regulatory system. In this investigation an explanatory case study design was used in order to generate new knowledge through the extension of existing theory.

The research design for this inquiry used qualitative and quantitative methods and naturalistic approaches to inductively and holistically understand the policy-making process of a single case study. A naturalistic inquiry is concerned with capturing processes and studying real-world situations as they unfold naturally, it is non-
manipulative and open to whatever emerges with a lack of predetermined constraints on outcomes. With a holistic perspective the whole phenomenon under study is understood as a complex system that is more than the sum of its parts and the focus of inquiry is on investigating complex interdependencies (Patton 1990).

The logic to the research design was that if policy-making is constructed by social and political forces, it follows that policy-making can equally be deconstructed to identify these forces and then reconstructed to build theory of how and why these forces operate. Making sense of the whole requires breaking it down into its parts and looking at the patterns that connect these parts to each other.

The conventional case study method was adapted for the policy analysis research design of this thesis to reflect the ontological, epistemological and methodological perspectives of the constructivist approach to inquiry. The ontological, epistemological and methodological perspective to this policy analysis research design drew on Guba and Lincoln’s description of the social constructivist approach (Guba and Lincoln 1994). The ontology of the research design was that the reality of the way the public health policy was made, is a socially and experientially based construction. Knowledge and truth were viewed as being socially constructed, or created, rather than being discovered. Therefore, policy-making processes are understood through interpretation and as such constructions are attempts to make sense of or to interpret experience.

Constructions are not more or less true, rather they are more or less informed. From an epistemological perspective, myself, as the policy analyst, and the object of investigation, the case study, were assumed to be linked so that the ‘findings’ were created as the investigation proceeded. The methodological perspective to the constructivist approach of the policy analysis was hermeneutical and dialectical. The investigation unfolded through a ‘dialectic’ of iteration, analysis, critique, reiteration and reanalysis, that led to the testing of theory. The aim of this constructivist approach to the policy analysis was understanding. The criterion for progress is that over time, everyone formulates more informed and sophisticated constructions of the use of scientific evidence in the policy-making process and thereby knowledge accumulates.
The case study chosen for the present thesis was the policy-making process that led to the policy of folate fortification of staple food products in Australia in response to epidemiological evidence that folic acid consumed during the periconceptional period helps to reduce the risk of NTDs. The case is defined temporally from the establishment of the NFA (19 August 1991) through to the gazetted of revised Standard A9 on 14 June 1995.

The case study provided a rare opportunity to analyse how and why scientific evidence was used in the making of public health policy in a food regulation setting. Moreover, the peculiar nature of the circumstances associated with the case study captured issues identified in Chapter 2 as being directly relevant to the unit of analysis and this added to its richness and ability to build theory to make analytic generalisations (Davis 1998). This richness is essential because the research findings in this thesis were based on the evaluation of this single case, rather than multiple cases, and as such the case needed to provide a powerful illustration of the critical issues under investigation (Hamcl et al. 1993). According to Yin, a single case study design can be a legitimate approach to gain theoretical understandings if it satisfies any one of three rationales: it represents the critical case associated with a theory; it is a revelatory case; or it is an extreme or unique case (Yin 1994). As I discuss in Chapter 6, the case study was both revelatory and unique and enabled critical aspects of public health policy-making to be analysed and explained. The unit of analysis for the thesis was the policy-making process in the food regulatory system (this is the level to which the study findings are generalised).

The research design for this study is summarised in Figure 5.1 and involved the following series of steps:

i) The review of the case study, presented in Chapter 6, was used to illustrate the conceptual, scientific and ethical dilemmas relevant to evidence based practice in a food regulation setting that had been identified in Chapter 2.

ii) Data collection focussed on examining these conceptual, scientific and ethical dilemmas.
iii) The case study was deconstructed into the three levels of the food regulatory system: the decision-making process level; the procedural level; and the political environment level.

iv) Data were organised and coded to describe what happened at each of the three levels of the food regulatory system.

v) Themes relating to the policy-making process were identified from regular patterns of data that emerged in the description for each level of analysis.

vi) An assessment was made of the themes at each level of analysis to determine the contribution of that level of the food regulatory system to explaining the case study. Potential logic gaps and clues were identified for directing a deeper level of analysis into the policy-making process.

vii) The themes of the policy-making process from each of the descriptive analyses were assessed iteratively to gain a progressively deeper insight into what happened with the policy-making process. The insights were synthesised to reconstruct one coherent assessment of the case study.

viii) The assessment was interpreted against theory to test the plausibility of different theories to explain the use of evidence in the case study.
Figure 5.1 The research design for the study

Research aim

Review of case study

Data collection

Focus nature and scope of data collection.

Select research method to achieve research aim.
Select case study that captures issues raised in the review of the unit of analysis.

Deconstruct case study in accordance with the three levels in the food regulatory system and code data against each of the levels.

Description

Description

Description

Grouping of regular patterns of data to identify themes of the policy-making process

Themes

Themes

Themes

Analysis of themes to assess the contribution of each level of the food regulatory system to the case study and to identify potential logic gaps in description

Assessment

Assessment

Assessment

Progressively deeper analysis across levels to reveal what happened.

Reconstruct one coherent assessment of the case study

Test theoretical explanations of the use of evidence in the policy-making process associated with the case study

Interpretation of assessment to explain how and why process happened.
5.3 Data collection

The purpose of the data collection was to obtain an accurate and comprehensive detail of the events, the stakeholders, the issues, the processes and the arguments involved with the case study. The review of the case study presented in Chapter 6 identified relevant conceptual, scientific and ethical dilemmas that focussed the nature and scope of the data collection. As Milio observes, “In effect, an attempt is made to view the policy-making process from the outside, through the documents of organizations and other groups, and from the inside, through the eyes of participants.” (Milio 1988: 269). Data for this investigation were collected from four sources. These data sources were the three types of qualitative data defined by Patton, namely, in-depth, open ended interviews with individuals, direct observation consisting of detailed descriptions of people’s activities and behaviours and written data in the form of documentation yielding excerpts and quotations (Patton 1990). In addition, quantitative data were collected. The data collection was conducted with explicitly developed protocols and instruments. A description of the four data sources and their relevance to the research method follows.

5.3.1. Field notes

Field notes were a primary data source for this study and involved recording detailed descriptions of my direct observations of events, meetings, processes and people’s (including self) activities, behaviours, quotes, actions and interactions. Field notes have a particular validity and reliability as a research method when the research focus is human behaviour and is concerned with identifying what people actually do, rather than what they say they do (Quine 1998). The writing and management of the field notes as textual data followed the procedures recommended by Bernard (Bernard 1994).

During the period of the case study I was employed as an NFA staff member and directly participated in events and processes associated with the making of the folate fortification policy. When the NFA began considering policy recommendations in response to the folate-NTD evidence, the present policy analysis had not been envisaged and my role as an observer actively recording field notes of the policy process as a structured component of a research study was not planned. Generally,
the recording of many field notes arose either from professional diary excerpts or opportunistically in response to an unrelated professional requirement to keep a file note of all relevant telephone conversations, meetings and events associated with the policy-making process. The review of Standard A9 was adversarial and it was not uncommon for staff working in the Nutrition Section of the NFA during the review period to be challenged about the policy-making process both personally and professionally in public meetings. Food Authority staff working in the Nutrition Section were advised by NFA management to keep file notes documenting the circumstances associated with the policy-making process for Standard A9.

My role in being immersed in the phenomena being investigated approximates the role defined by Bernard as that of an ‘observing participant’ (Bernard 1994). As I discussed in the introduction to this thesis, the PhD study began after the folate fortification policy had been launched and as such I had not contrived a research method during the case study. Nevertheless, my involvement in the case study afforded me distinct advantages to gain insights into many events, documents, processes that then significantly aided the retrospective data collection phase of the research, e.g. increasing my awareness of and access to information.

The collection period for the recording of field notes extended from the May 1992 meeting of the NFA, which included an agenda item to discuss the review of Standard A9, through to the time that I left ANZFA at the end of 1996. Field notes were intermittent and took the form of jottings, annotations to agenda papers and other documents circulated in meetings, and diary inserts or file notes. The original data for each field note predominantly were recorded on separate pieces of looseleaf paper or a word document in a computer file and usually the note was less than one page in length. Generally, notes were recorded on the same day of the observation. The original notes were ‘cleaned’, e.g. duplicated information was removed, and transcribed into a format that was more accessible to data analysis. Each field note was recorded with a unique identifier number and the date and event with which it was associated, e.g. a field note (FN) from 19 May 1994 regarding the third meeting of the NHMRC’s Expert Panel on Folate Fortification (Expert Panel) would be cited as ‘[FN008-19/5/94, 3rd Expert Panel meeting]’. The list of field note sources is provided at Appendix 2.
5.3.2. Documents
A range of documents was collected to provide a secondary data source of technical, historical and contextual information about the study. The legitimacy of using written documents as text for data analysis has been described by Richters (Richters 1998). The strengths of the documentary data are that they are stable and can be repeatedly reviewed, the collection process was unobtrusive as the documents were not created as a result of the research and they are exact in the sense that they contain exact names, references and details. Data obtained from documentary sources were used in this study to:

i) Outline the sequence of events, the procedures and stakeholders associated with the case study.

ii) Corroborate and augment evidence available from other data sources to enable inferences to be drawn about the policy-making process.

iii) Provide ideas about important questions to pursue through observations and interviewing.

Relevant documentary data were identified using a data collection search strategy that aimed to achieve a comprehensive coverage of document sources associated with the case study. Documentary data were collected using three approaches:

i) Maintaining records of working documents prepared before the study
My work at the NFA meant that I had had access to many of my own working documents relevant to the policy-making process for food regulation in general and the case study in particular. These documents were invaluable in mapping the various stages in the development of the case study and providing insights into those events and the motives and behaviours of stakeholders that shaped this development. These documents included drafts and memos recording the incremental development of the policy arguments and recommendations, agenda papers and minutes of meetings. Only personal working documents from this period were collected and included in the database for subsequent analysis. Internal NFA working documents were not collected unless they were available on the ANZFA archives files and therefore were not confidential.
ii) Searching official files and records

During the course of the study systematic searches were conducted of files located at both ANZFA (as the NFA had become) and the Nutrition Section of the then Commonwealth Department of Human Services and Health (DHSH) that contained documents associated with the case study. The rigour of this search process was complemented by my previous involvement with the NFA as I was aware of the existence of many potentially obscure documents on file that were relevant to the case study, e.g. internal memoranda, that may have been overlooked if a search had been conducted by a researcher not intimately familiar with the case study.

The search of ANZFA files involved a formal application procedure to view (and photocopy) documents on the Authority’s public register at its Canberra office. The search was conducted by requesting all files that related to the review of Standard A9, the NFA’s review of folate and NTDs, the NFA’s involvement with the Expert Panel on Folate Fortification and ANZFA’s subsequent involvement with the implementation of the folate fortification policy. The documents on ANZFA files included public submissions to the ANZFA policy review process, launch materials, media releases, letters, internal memoranda, correspondence between various stakeholders, agendas items, public announcements, minutes of meetings, administrative documents, formal studies, newspaper clippings, and government reports.

The search of the DHSH files involved a less formal procedure. Although the Nutrition Section of the DHSH was intending to establish a public register for its documents, at the time of the data collection all information was maintained on existing working files. Following a verbal request to Senior officers of the Nutrition Section of the DHSH I was granted permission to visit the Nutrition Section and view (and photocopy) documents on the working files that related to Standard A9, the establishment of the Expert Panel on folate fortification, the conduct of this Expert Panel and the DHSH’s involvement with the implementation of the folate fortification policy. The documents on the DHSH files included background papers related to the DHSH watching brief and submissions to NFA’s review of Standard A9, internal memoranda, letters, correspondence between various stakeholders,
preliminary drafts of policy documents, informal file notes related to the policy-making process, agenda papers and minutes of meetings.

iii) Documents made available in the public domain

Official documentation available in the public domain also was collected. This documentation included the policy document, annual reports, newspaper clippings, records in Hansard, media releases and Ministerial speeches, as well as progress reports and policy implementation proposals published by NFA/ANZFA and the DHSH. The relatively haphazard nature of the release of this documentary data meant that it was not possible to undertake a systematic search for this data collection approach. Attempt was made to achieve a thorough coverage of historical and current documents released into the public domain by placing myself onto relevant agencies' mailing lists, regularly viewing these agencies' websites and maintaining regular contact with colleagues to inform me of any relevant documentary data of which they were aware or themselves had a copy.

The quality and comprehensiveness of the data collection process for documentary sources must pay regard to the potential for selectivity in those documents made available for retrieval and reporting bias within the document. I did not assume that all documentation associated with the case study would be available or accessible nor did I assume that those documents that were collected would necessarily provide a comprehensive, accurate and unbiased record of events. Indeed, the more revealing, and potentially sensitive documented accounts of the policy-making processes may have been withheld without my awareness.

I implemented several approaches to achieve as comprehensive coverage of relevant documents as possible. The collection of documents was an iterative process. The information contained in certain documents led to the identification of information gaps and the existence of, or need to locate, additional documents. Also, the interviews with key informants provided insights into the existence and location of additional documents. All collected documents were read. Each piece of data from a document was recorded with a unique identifier number and the date and source from which it was obtained, e.g. on the 3 June 1994 there was a newspaper article document (D) in the Telegraph Mirror that reported on the NHMRC's policy
recommendations, this is cited as '[D113-3/6/94, Telegraph Mirror ‘Baby food may get vitamin additive’]'. The list of document sources is provided at Appendix 3.

5.3.3. Key informant interviews

Key informant interviews were the major source of primary data for the study. They were conducted as semi-structured interviews. The process of conducting the interview was flexible and open-ended to allow for additional information and discussion by the informant. The purpose of the interview questions was to elicit information against themes that emerged from the literature review, case study description and the field notes recorded during my involvement in the case study as an observing participant. The flexibility of the semi-structured interview is a particularly suitable characteristic for collecting data for policy analysis (Yin 1994). The informant’s opinions and insights were used alone and in conjunction with the other data sources to corroborate facts associated with:

i) The description of the events, issues and stakeholders involved with the folate fortification policy-making process.

ii) Critical steps in explaining how and why the policy was made.

iii) Interpreting the overall process.

Non-probability sampling was used in the selection of the key informants. The power of non-probability sampling is not statistical, but comes from the purposeful selection of informants that can provide in depth and rich information on the study issue for greater insights (Patton 1990). The purposeful sampling was based on the informants satisfying specified criteria ('criterion sampling'). The selection criteria for the key informants were that the informants had been or were involved in:

i) Public health policy-making in food regulation in Australia.

ii) The policy-making process that led to the folate fortification policy.

iii) Circumstances that could provide particular insights into aspects of the study.

My prior knowledge of the policy process contributed to the construction of the sampling frame and the selection of key informants. Given this prior knowledge and the need to obtain opinions from several perspectives, including the government, academia, consumer representatives and food manufacturers, the initial sample frame extended to 24 key informants. This sample frame was flexible and had the capacity
to evolve, through a ‘snowballing’ technique, as the study developed. For example, key informants were asked to recommend other key informants where appropriate (and data sources in general). As a consequence of this procedure two additional informants were included in the sample frame, making a total of 26 key informants (see Appendix 4). The sampling continued until no new information was being gained, i.e. the ‘saturation point’ was achieved. The sampling included a search for ‘negative cases’, i.e. informants who represented a diversity of opinions were included in the sampling frame. Twenty two of the 26 key informants who had been invited to participate in the study made themselves available for interview. Sixteen of the interviews were conducted in a face-to-face setting, usually in the informant’s work environment. The remaining six interviews were conducted over the telephone.

The data obtained from key informant interviews offered advantages over the other data collection methods. Questions were targeted to focus directly on the case study topic and the answers were insightful in providing perceived causal inferences. Opportunity was provided for the informants to expand on their answers in recounting their experiences. The interviews focussed on motivating the informant to respond freely and honestly to questions, exploring an issue fully, probing further into responses including beliefs, feelings and attitudes, and adapting questions to each informant. The questions were structured and asked using an open and ‘naïve’ approach in order to avoid ‘leading’ the informants in delivering their responses. The duration of the interviews ranged from 30 minutes to 3 hours. All interviews were taped to allow greater rapport and more natural conversation¹⁴. Also, the raw data were available for later analysis as an accurate record because the questions and answers were recorded.

A generic theme list with indicative questions was drawn up in preparation for the interviews and to guide the questions to be asked of the informant (see Appendix 5). The theme list was developed around a list of topics that were discussed, but neither the wording nor the order of questions was fixed. This enabled the interview to be conducted in a flexible manner to allow the interviewee to elaborate on certain topics. Also, a particular line of questioning could be pursued where appropriate to

¹⁴ One informant requested the tape recording be paused for a five minute period during which a response to a particularly sensitive issue was provided.
elicit deeper perspectives and explanations of specific issues that may not have been anticipated prior to the interview. For example, the emphasis of the interview was modified in accordance with the selection criteria for particular informants to enable a particular line of questioning to receive greater attention. The data were partly processed during the course of the interview so questions could evolve and be expanded upon dependent on the response of the informants. A separate theme list was used for each interview so that notes could be written onto each list.

Potential problems with the key informant interview data collection component of the case study were bias due to poorly constructed questions, response bias due to poor recall and reflexivity in the sense that the informants reconstructed or rationalised responses to what they thought sounded best or to what they believed I wanted to hear. The research strategies engaged to strengthen the data collection were to pilot test the theme list, the interview questions and my interview technique on colleagues at Deakin University. Also, during the interview I attempted to achieve a conversational tone and to maintain a sense of neutrality. Generally, my questions were worded in an open-ended way to encourage the informant to express opinions and to have the opportunity to elaborate on their views and perceptions of issues associated with the case study. I attempted to build trust and rapport by phrasing questions relating to sensitive topics in such a way as to suggest that I had heard it all before and in a dissociated style to stress a non-judgemental role on my behalf.

All key informant interviews (n=22) were transcribed verbatim from tapes by a transcriber and myself. The tapes were cleaned in the sense that words and utterances such as ‘ums’, ‘ahhs’ and ‘you know’ were not transcribed, but otherwise were not edited. The transcriptions were then swapped and the transcriber and myself checked each others transcripts for accuracy15. At the conclusion of each interview I recorded my immediate impressions and noted relevant methodological and technical observations related to the way the interview had been conducted and the responses of the informant. Each piece of data from an interview was given a unique informant number and the page number of the transcript from which it was selected, e.g. a

15 Except in two instances where the informants specifically requested that I was to be the only person to listen to the tape recordings
quote from key informant 7 that appeared on page 12 of the transcript would be
given the unique number ‘[7/12]’.

The management of the interview process involved setting up and recording the
interview and was determined by procedures that had been approved prior to
commencing the data collection by the Deakin University Ethics Committee. The
ethics approval and plain language statement sent to informants are attached at
Appendix 6. Participants were given a clear account of the aim of the interview in a
covering letter of invitation and again at the start of the interview when I provided an
opportunity to ask any questions. To ensure that the identity of the informants
providing the comments and opinions was not traceable, I adhered to the following
procedures:

i) No identifiable information was recorded on the transcription documents.

ii) Tapes were stored in a secured cabinet.

iii) The reporting of information maintained anonymity at all times.

iv) Any information that could be attributed uniquely to one person was
deliberately reported in a generic manner, e.g. ‘Expert Panel member’.

5.3.4. Quantitative data
Quantitative data were collected to contribute information to assess assumptions
associated with the decision-making process within the broader policy-making
process. The specific objectives of collecting quantitative data from primary and
secondary sources were to assess assumptions regarding the:

i) Dietary intake of the target group and potential at-risk groups.

ii) Efficacy of the policy option of nutrition education to increase folic acid-
containing supplement use and whether such supplement use would deliver a
sufficient dose of folate to the target individuals.

iii) Implementation of the policy recommendations.

The assessment of assumptions regarding the dietary intake of population groups and
the efficacy of nutrition education to increase folic acid intake from nutrient
supplements involved collecting data from the 1995-96 National Nutrition Survey
(NNS) and the 1995-96 ‘Nutrient supplement survey’. 
The NNS collected data on food and nutrition from the Australian population and was conducted during the period from February 1995 to March 1996. Approximately 13,800 people aged two years and over from urban and rural areas in all Australian States and Territories participated in the survey. The 24-hour recall method was used as the main indicator of food intake in the NNS. The NNS survey method is described in detail elsewhere (Australian Bureau of Statistics 1998).

The Nutrient supplement survey was designed, coordinated and analysed by myself under the auspices of ANZFA and has been reported elsewhere (Lawrence et al. 2001a; Lawrence et al. 2001b)\(^\dagger\). The purpose of this survey was to obtain accurate data quantifying the contribution of nutrient supplements to the intake of folate and vitamin B\(_{12}\) and awareness of the term folate and knowledge of the folate-NTD relationship, among a random sample of Australian adults at the time of the gazettal of Standard A9. Data on nutrient supplement intake were obtained from a randomly selected sample of Australian adults from 5422 households by including several additional questions in two Australian Bureau of Statistics' population survey monitor surveys conducted during August 1995 and February 1996. Both surveys took place during the data collection period for the NNS. In each survey questions about nutrient supplement intake and knowledge regarding folate were asked of a randomly selected member of the household aged 18 years or over. Nutrient supplements were defined as supplements that contain one or more vitamins or minerals. Interviewees were asked: ‘Yesterday, did you take any vitamin or mineral supplements in tablet, capsule or drop form?’ Data on knowledge about folic acid were obtained from the responses to two questions. Interviewees were asked: ‘Have you ever heard of folic acid or folate?’ If they answered ‘yes’, they then were asked to select one of the following responses in answer to the question: ‘Do you know why it is important for women of child-bearing age to consume foods or supplements containing folic acid or folate?’ ‘To help them get pregnant’; ‘To help prevent birth defects’; ‘Other reason’; or ‘No or don’t know’.

Determination of nutrient intake from vitamin and mineral supplements requires a detailed knowledge of the ingredient and nutrient composition of specific

\(^\dagger\) The description of the nutrient supplement survey and its findings was published in two journal articles attached at Appendix 10 and 11.
supplements. In Australia, vitamin and mineral supplements are classified as therapeutic goods and regulated under the auspices of the Therapeutic Goods Administration. Most of these products, with a small number of exemptions, must be included in the Australian Register of Therapeutic Goods (ARTG). Products included in the ARTG have an 'AUST L' (listed), or an 'AUST R' (registered) number which depends on the ingredients as listed on the package. These numbers provide a unique identifier for more than 25,000 dietary supplement products in the ARTG and can, therefore, be used to determine their ingredient and nutrient profile. The availability of the AUST L and AUST R numbers provided the opportunity to collect, for the first time, quantitative as well as qualitative data on nutrient supplements in a representative sample of Australian adults.

If the person interviewed reported having taken one or more vitamin or mineral supplements during the previous day they were asked, if possible, to provide the supplement container(s) so that the interviewer could record the AUST L or AUST R number of the product(s) on the survey form. For products without an AUST L or AUST R number on the container, the brand name and other relevant product information were recorded. If the container was not available the interviewee was asked to describe the brand and name of the product. Subjects were then asked how many tablets, capsules, drops or spoons of the supplement that had taken yesterday.

An assessment of the implementation of the policy recommendations involved collecting data from a 'store survey'. The store survey was designed, coordinated and analysed by myself under the auspices of ANZFA and is reported elsewhere (Lawrence et al. 1999)\textsuperscript{17}. The purpose of this survey was to evaluate the implementation of the folate fortification policy by assessing the number and profile of food products fortified with folate in stores across Australia. The collected data was used to contribute to the assessment of the implications of the folate fortification policy in Australia.

The selection of stores was based primarily on achieving a broad geographical coverage in all states and territories. Two stores in each capital city (from one low

\textsuperscript{17} This paper is attached at Appendix 12.
and one high socio-economic status area) and at least one store in a regional city (population greater than 10,000), a rural town (population approximately 1,000 to 10,000), and remote area (population centre of less than 1,000 and at least one hour by car to the nearest rural town) in each state or territory were identified. Sixty stores in total were involved in the survey. Woolworths (Safeway in Victoria) was selected randomly as the supermarket chain for data collection in each location.

The baseline for the store survey was conducted from late 1995 to early 1996 in the period between the release of the folate fortification policy and before any available food products were fortified with folate. The survey was then repeated four times at approximately eight-monthly intervals. Products included in the survey were from those categories listed in Standard A9 as being permitted to be fortified with folate.

The quantitative data collected from the nutrient supplement survey and the store survey during the course of the present study were made available to policy-makers to provide feedback throughout the lifecycle of the policy evaluation. For example, the findings from the store survey data were made available to decision-makers at ANZFA and used to inform the decision-making process for the approval of the pilot folate-NTD health claim trial (see Chapter 10). The collection of quantitative data to evaluate the impact of the policy on knowledge, dietary folate intake, biological markers and ultimately the prevalence of NTDs was beyond the scope of the study.

5.4 Data analysis

The data collection generated a substantial amount of rich and thick information. The purpose of the data analysis was to impose meaning on the various data that had been collected to achieve the research aim. The result of the analysis was a higher level of synthesis of the data that went beyond description to meanings and consequences to explain the policy-making process associated with the folate fortification policy. It was these meanings that then were used to inform the testing of theory. There were several challenges for the analysis. The analysis was attempting to identify patterns that connect the data and to make sense of these patterns to explain a policy-making process that was complex, truncated and adversarial. The analysis was required to
combine data that were mainly textual and unstructured with quantitative survey data.

Easton’s model of a political system, outlined in Chapter 2, was adapted as a heuristic device for analysing the policy-making process within the food regulatory system. The case study was deconstructed into the three levels of the food regulatory system: the decision-making process; the procedural; and the political environment (Chapters 7-9 respectively). A dual purpose was served by deconstructing the case study into these three levels. Firstly, the complex interactions among the various events, processes and stakeholders associated with the case study were unravelled so that they could be more readily described and the contribution of each level of the food regulatory system to the policy-making process assessed. Secondly, once the case study had been unravelled it enabled the identification of themes that could then be interpreted against existing theory to reconstruct the links that bind the different levels of the food regulatory system.

An explanation testing approach was used as the analytical strategy to the research. Explanation testing meant that the final explanation was not fully stipulated at the beginning of the process. The purpose was to develop insights about the policy elements and then test theory of the policy-making process while rival explanations (which were not tenable) were excluded. The analysis was not confined to the last phase of the research process, it was a continuous and iterative enterprise that consisted of concurrent flows of activity and was based on strategies for an inductive and interpretive case study. The following sequence of analytical abstractions adapted from Miles and Huberman (Miles and Huberman 1994) formed the analytic strategy for the case study.

5.4.1 Description
The complexity of the policy-making process in the food regulatory system presented challenges in attempting to analyse the substantial amount of collected data. The first task in the analysis was description to organise the data for subsequent assessment and interpretation. The descriptive analysis aimed to answer basic questions including what were the events? the processes? and who were the stakeholders associated with the case study? Description was about making the complex story of
what happened in the policy-making process for the folate fortification policy understandable.

In preparation for the description stage of the data analysis, data organisation began during data collection when the raw data were cleaned and transformed to create a text to work with and the data were then collated. Data from interviews, documents and field notes were entered onto individual word document files. Two hardcopies were made of each file. One copy became the master copy from which other copies were made for marking and cutting up and pasting. The other copy was stored. The entire data set then was read several times to gain a sense of the whole.

The data from the field notes, documentary sources and interview transcripts were coded in two stages in preparation for the description. Firstly, the data were coded with the number 1 (decision-making process), 2 (procedural) or 3 (political environment) according to the level of the food regulatory system with which they aligned. Secondly, code names consisting of words and letters (non-hierarchical, alpha codes) were assigned to the data in accordance with the event, process or stakeholder within each level with which the data were associated. The data from the various data sources were then combined and presented in such a way as to provide a detailed description of what happened at each level of the food regulatory system.

5.4.2. Identification of themes
Themes relating to the policy-making process were the main patterns that gave order to the set of data for each level of analysis. Thematic analysis was the first step in gaining a sense of the whole, of the regularities and patterns across the three levels of analysis. This step was essential for the development of a more specific and detailed analysis of the explanatory processes that bound the three levels of analysis and therefore to test theory of the links within the food regulatory system. The qualitative data were subjected to thematic analysis based on the method outlined by Gifford (Gifford 1998). This analytical process involved a series of steps in which themes were identified and the data were linked within an explanatory framework. In this section I describe the analytical process by which themes were identified for later assessment and interpretation.
The data were not broken down into themes until the whole story, or description, at each level of analysis was looked at and read several times. Themes were identified through the stories that emerged rather than through specific words or actions. On a blank sheet of paper, regular patterns of data and issues began to be grouped into themes relating to aspects of the policy-making process. The criteria for grouping the patterns into specific themes were identified. This involved developing clear descriptions of the characteristics that patterns had in common and what criteria excluded them from being put in a given theme category. The data were subjected to a second round of coding and the coded segments extracted and condensed. This exercise resulted in a draft coding manual that, for coding each theme, included a description of what the items aligned with a theme had in common and what characteristics exclude items from being aligned with a theme. Code names consisting of words and letters (non-hierarchical, alpha codes) were assigned to each theme to represent the meaning of that theme.

I coded the data from the field notes, documents and interview transcripts with a coloured pen, marking off units that cohered because they dealt with the same theme and then dividing them into themes at different levels of analysis. The themes were given a name and instances of them were marked with a shorthand label (a code). The themes were more finely differentiated, clustered and relabelled with scissors and computer.

By the time I had coded the data from the field notes, documents and interviews, I had established the themes that needed to be indexed and the patterns that needed to be located. The descriptive data were classified into meaningful thematic categories. The process of classification and coding was a conceptual task that laid the foundation for assessment and interpretation.

5.4.3 Assessment of data and the search for connections

The assessment of what happened in the policy-making process that resulted in the folate fortification policy was an iterative process that involved continual comparison within and across the levels of analysis to reconstruct one coherent assessment of the case study. The main intellectual tool for this stage of the analysis was comparison.
The first step in the assessment process was to assess the integrity of each of the levels of the food regulatory system to provide a sufficient account of the case study. The assessment involved going beyond the descriptive data by interrogating these data to identify logic gaps and clues that indicated there might have been additional aspects of the policy-making process to take into account. The themes that had been identified at each level of analysis guided the assessment process and assisted in posing questions to guide a deeper level of analysis into the food regulatory system.

The second step in the assessment process was to assess the connection between the three levels of the food regulatory system to reconstruct a coherent account of the policy-making process within the system. This step of the assessment involved continually asking ‘why?’ to the individual assessments that emerged at each level of analysis and requiring myself as the analyst to immerse myself in the data and ‘peel’ back each level of analysis to pursue deeper insights into the policy-making process.

Progressively the analyses enabled the policy-making process to be probed more deeply to search for answers to questions posed in earlier analyses, to explain logic gaps and to uncover additional insights. The collected data were constantly reviewed and reflected upon to look for emerging patterns and specific meanings and to then search for new insights, patterns and discoveries. Connections entailed finding regularities in the relationships between and within themes as well as searching for variations. Therefore the search for connections involved identifying patterns and making sense of these patterns with the aim of comprehending the meanings of what had been described, classified and compared between the different levels of the food regulatory system. The possible relationships or patterns that connect the information were mapped out. As I iterated between the assessments at each level of analysis the story of the policy-making process was reconstructed and the assessment became more coherent as it withstood the scrutiny of empirical events. The assessment process ended when no new insights were generated from the data.
5.5 Data interpretation

According to Patton, "Interpretation involves explaining the findings, answering "why" questions, attaching significance to particular results, and putting patterns into an analytic framework." (Patton 1990: 375). Whereas the assessment process within and across the levels of analysis into the case study enabled the synthesis of a coherent assessment of what happened in the policy-making process, it was unable to explain how and why scientific evidence was actually used in this process. Assessment was about making this complex story understandable by reconstructing the component parts into the most plausible account of the policy-making process as a coherent whole. It was the interpretation of the themes within and between the separate analyses against existing theory to identify a pattern or linking mechanism of the coherent assessment that provides an explanation that provides theoretical understandings.

The themes that were identified at each level of analysis were interpreted against existing theory in the form of a theoretical framework outlined from the policy and social science literature to prepare the most plausible theoretical explanation of how and why evidence was used in the policy-making process that resulted in the folate fortification policy. When considering rival explanations my mind-set was not one of attempting to disprove the alternatives, rather, I looked for data that supported alternative explanations. Interpretation involved considering the weight of evidence for alternative explanations and looking for the best fit between data and analysis.

5.6 Data reporting

When reporting the findings that emerged from the data interpretation this thesis drew on the argument that theories may be understood as being like 'stories'. Theories can be compared in terms of the plausibility of the story they tell in themselves or relative to other stories (Rein 1976). Essentially, the process of undertaking the policy analysis for this thesis was similar to that associated with constructing a legal case whereby a theory may be evaluated against the quality of its arguments or how the case is made rather than establishing 'proof' or 'truth'.

128
Whereas the story that is told and the theory that is built cannot be subjected to tests that determine whether they are definitively proved or disproved as might be expected from the findings of a scientific laboratory experiment, the story can be tested for its plausibility in an approach akin to the judicial review process, whereby a lawyer attempts to cross-examine a witness to persuade a jury how and why a case occurred (Tones 1997). This thesis had adopted the position that my task has been to bring evidence and interpretation to bear on explaining how and why evidence was used in the case study and thereby to test theory that can be generalised for the public health policy-making process in a food regulation setting. I have attempted to construct the most plausible story of how and why evidence was used in the making of the folate fortification policy relative to all other explanations of the case study. The criteria and procedures against which my construct may be tested are its coherence, that is, the evidence shows that the story is logically consistent as illustrated by the links within the policy-making process of the food regulatory system and its congruence in terms of the stories ‘fit’ with the evidence. The reporting of the theoretical explanation was based around answering the following questions of the theory (Marshall and Rossman 1995):

i) Does it make sense?

ii) Is it consistent with the available evidence?

iii) How much does it explain?

iv) Does it add to understanding?

v) How can it be applied to other food regulatory issues?

vi) What more is needed for extending and testing it?

5.7 Increasing rigour and credibility

The constructivist method involves interpretation and giving meaning to observations. The method is prone to assertions of subjectivity in relation to the bias inherent in the ‘instrumentation’ or the use of researchers themselves as tools for data collection and analysis. Stone argues that policy analysis research is inherently political as “It always involves choices to include some things and exclude others and to view the world in a particular way when other visions are possible. Policy analysis is political argument, and vice versa” (Stone 1988: 306) emphasis in
original. I as the analyst was irrevocably present in the data and my ethical and moral positions came to bear on the interpretation of the data. As Gifford comments, “If the interpretation is ultimately that of the researcher(s), how believable are the results? ... [and] ... If there are no set rules or formulae for testing or assessing reliability or validity, how do we know that the findings are sound?” (Gifford 1998: 552). I instigated several procedures to address these concerns that involved striving for objectivity and attempting to interpret the data in rational terms.

A validating procedure was to have preliminary drafts of the methods and results of the thesis reviewed by fellow doctoral students and several informants in the case. The discussion and conclusion sections of the thesis were not revealed to the reviewers. The reviewers were asked to corroborate the essential facts and evidence presented in the case report. This procedure contributed to an increased confidence in the accuracy of the evidence and ultimately to increasing the rigour of the study.

I attempted to adopt a stance of neutrality with regard to the analysis of the policy-making process by being open to the multiple perspectives associated with the case study by reporting both confirming and disconfirming evidence. Also, I continually reflected on own involvement in the case study and attempted to be analytical in questioning the approach and assumptions made. There had to be sufficient weight of evidence to support the conclusions and the thesis includes all the available data necessary for the reader to reach an independent conclusion. For example, the discipline and rigor of qualitative analysis depend on presenting solid descriptive data in such a way that others reading the results can understand and draw their own interpretations.

The case study method has been challenged for a lack of:

i) Representativeness and inability to provide for scientific generalisation.

The present policy analysis yielded large amounts of detailed data about a specific case. The data interpretation created particular theoretical insights into the use of evidence in the policy-making process that resulted in the folate fortification policy. However, the validity of extrapolating from a specific case to a general phenomenon is frequently challenged from the perspective of the lack of representativeness of the
case used as a point of observation for the social phenomenon, or unit of analysis, constituting the object of the study.

In relation to representativeness, the adapted case study method was not intended to analyse the case as a random sample from which to enumerate frequencies for conducting statistical tests to make statistical generalisations about a population. Instead it was about analysing a particularly powerful policy-making story and determining whether it was possible to make theoretical generalisations that may become hypotheses for further investigation i.e. analytical generalisations. Analytical generalisation involves generalising a particular set of results to a broader theory by using previously developed theory as a template against which to compare the empirical results of the case study. The domain of generalisability of this case study's findings regarding theoretical understandings was public health policy-making in a food regulation setting.

ii) Rigour in the collection, construction, and analysis of the data

Each step of collecting, reducing, coding, and analysing data had threats to rigour. Because the case study is an empirical inquiry into contemporary circumstances over which I had no control, the need to avoid equivocal evidence and evidence that was biased was imperative. Bias could have been introduced by my subjectivity, as well as of the field informants on whom I relied to obtain an understanding of the case under investigation. This could have influenced the reconstruction of elements that defined how and why public health policy was made in a food regulation setting.

In relation to rigour, although it was my responsibility to define the object and case study - thus my subjectivity entered into the study, to the extent this intervention was clearly stated, it was accounted for by constant confrontation within the framework of the case study. My subjectivity and that of key informants was presented within the study to clearly distinguish them by comparison. The case study produced an explanation that, although based on the analysis of field information, transcended this information because the contrast shown by the constant comparison provided an understanding of the object of study from a political science perspective prevailing over the case study (Hamel et al. 1993).
These criticisms are not inherent to the case study method nor are they unique to this research as they can be conspicuous in any social science study. They can be overcome with rigorous methodology combining adequate planning and attention to research design, implementation and interpretation. There are techniques to address the criticisms regarding lack of representativeness and rigour and to minimise potential errors and bias in a study. The rigour of this case study was judged by criteria recommended in the form of case study tactics in conducting research. These tactics were applied at different stages throughout the analysis of the case study, from the research design stage through to the composition of the final thesis report.

The present study collected information from multiple sources and used multiple methods so that the information could be submitted to both data and methodological triangulation to corroborate facts and phenomenon and thereby improve rigour and strengthen the research design (Denzin 1978). Whereas methodological triangulation provided a check of the consistency of findings generated by different data-collection methods, data triangulation provided a check of the consistency of different data sources within the same method. As Patton comments,

"By using a combination of observations, interviewing, and document analysis, the field-worker is able to use different data sources to validate and cross-check findings. Each type and source of data has strengths and weaknesses. Using a combination of data types increases validity as the strengths of one approach can compensate for the weaknesses of another approach." (Patton 1990: 244).

All data items were corroborated by at least one other source and normally another method of data collection to develop convergent lines of inquiry for the purposes of cross-checking. The research strategies engaged to strengthen the rigour of the data collection also included aiming to collect and analyse all relevant data and not just those data that were consistent with what may have been anticipated, reporting all valid contradictory data, and using official channels and informal professional contacts wherever possible to improve access to the most comprehensive amount of available data.
Various procedures to enhance the rigour of the data were put in place during the data collection phase and all interpretation phases. Nevertheless, the data analysis ultimately depended on my own interpretive judgement. One technique to make these judgements open and transparent was to reproduce much of the textual information directly into the three levels of analysis, for example, quotations were used extensively to represent the informants' views of their experiences in their own words. This technique will assist the reader of the study to trace the process used to piece the different data together and appreciate the emerging internal logic to the understanding of the policy-making process.

Reliability refers to the degree to which the results obtained by a measurement procedure can be replicated. Several strategies were used to increase the reliability of the data by allowing double checking:

i) The data collection and analysis methods and procedures were documented with the intention of enabling another investigator to repeat the analysis of the case study with the expectation of arriving at the same findings and conclusions.

ii) A case study database to organise and maintain records of all submitted data from field notes, documentary sources, interviews and quantitative surveys was assembled during the data collection phase of the research. The database is maintained separately from the thesis so that other investigators can review the evidence directly and independently from the thesis interpretations and conclusions (while protecting the confidentiality of the information where necessary). The case study database comprises the following:

a. A physical file of original and photocopied documents, participant observer field notes, transcribed key informant interviews and quantitative data.

b. An electronic file containing complete and summarised versions of all participant observer field notes, documents, key informant interviews and quantitative data.

c. An electronic (Word for Windows) and physical file of notes on research activities.

d. A bibliography of research articles and texts maintained in Endnote.
iii) The thesis contains formal presentations of the relevant evidence and data from the database in a variety of forms for examination by a reader. All interpretations and conclusions in the narrative component of the thesis then can be related directly to these data presentations.
CHAPTER 6

The case study – the policy-making process that led to voluntary folate fortification of staple foods in Australia

6.1 Introduction

The use of food regulation as an explicit public health policy instrument is a relatively rare event. When revised Standard A9 was published as Amendment No. 27 to the Australian Food Standards Code on 14 June 1995 it contained a special provision that for the first time permitted folic acid to be added to food products in Australia on a voluntary basis at up to a claimable level of 50% of the RDI per reference quantity (Department of Human Services and Health 1995). This provision was included in food Standard A9 as a primary prevention strategy to help reduce the risk of NTDs in Australia. In a letter to the editor reporting on this policy development and published in an international journal, two Australian government officials declared boldly that, “Australia is proud to be leading the world in its attempt to address this important public health issue (NTDs)” (Adams and Jeffreson 1996: 593-594).

The policy-making process that led to the voluntary folate fortification of staple foods in Australia is the case study of the use of scientific evidence in the making of public health policy that has been selected for analysis in this thesis. The strength of the case study for analysing the making of public health policy is illustrated by the attention the policy has received both locally and internationally at professional conferences and in the scientific literature. Indeed, the editor of one international nutrition journal stated, “The relationship of folic acid to neural tube defects has

---

provided us with one of the richest case studies in nutrition science policy of this half century.” (Rosenberg 1996: 94-95).

This chapter provides a description of the issues associated with the making of the folate fortification policy in Australia. This description is structured around: the background to folate and nutrition; the public health issue; the epidemiological evidence for the relationship between folate and NTDs; the uncertainties associated with the epidemiological evidence, the dilemmas in translating the evidence into public health policy; the detail of the policy outcome; and the policy issues that the case study captures. Since the publication of the folate fortification policy, there has been ongoing research and a substantial increase in knowledge about folate and health. Moreover, the policy has stimulated its own research agenda in which technical aspects associated with its implementation, e.g. the level of food fortification, and evaluation are being continually investigated. The information presented in this chapter is confined to that which was available at the time of the policy-making process. Relevant evidence that has emerged since the publication of the policy is presented in a footnote format throughout this chapter. Information regarding the impact and implications of the policy is presented in the discussion chapter.

6.2 Background: Folate and nutrition

6.2.1 Identification of folic acid
Folate deficiency was first recorded by Biermer (Biermer 1872) when he described an anaemia among pregnant women which he called ‘progressive pernicious anaemia’. During the 1930s researchers found that cases of macrocytic anaemia in pregnant Indian women, which were distinct from pernicious anaemia, responded to a treatment with either Campolon, a crude liver extract, or Marmite, an autolysed yeast extract, the yeast preparation became known as the ‘Wills factor’ (Wills 1931). The Wills factor was isolated from spinach in 1943 and named folate after the Latin word for foliage. Folate was first synthesised in 1945 making it the second last of the vitamins to be identified. Folate is one of the water-soluble B group vitamins.
The term ‘folate’ is the commonly used group name for folic acid (pteroyl glutamic acid) and all its derivatives with similar activity. In nature folate occurs with different numbers of conjugated glutamate residues but the typical synthetic form of the nutrient used in food fortification and in vitamin supplements is the mono-glutamic acid form, folic acid. This is an important distinction because the various conjugated forms have a higher molecular weight and hence a lower vitamin activity per unit mass than folic acid. The US National Academy of Sciences has introduced (Institute of Medicine 1998) the concept of dietary folate equivalent to standardise the amount of folate in foods. The dietary folate equivalent is calculated by combining the amount of synthetic folic acid derived from nutrient supplements and fortified foods, multiplied by a conversion factor of 1.7 to adjust for the greater bioavailability of synthetic folic acid, with the amount of folate derived from food sources. This is the first time that specific recommendations have been made based on the differences in the bioavailability between the naturally occurring form of a nutrient and the synthetic form (Bailey 1998).

6.2.2 Physiological roles of folate
Folate has primary roles as a coenzyme involved in the transfer of single-carbon fragments in a wide range of biosynthetic and catabolic reactions, including many involved in the synthesis and repair of DNA and RNA, and the production of methionine from homocysteine. These roles are essential for gene expression and cell proliferation. Consequently, folate has an integral function during periods of rapid growth and cell replication, such as early in embryonic life. For more than 50 years the major clinical relationship recognised for folate has been its haemopoietic effect in the prevention and treatment of macrocytic or megaloblastic anaemia that has a significant worldwide prevalence. Folate deficiency has been described as possibly being the most prevalent vitamin deficiency in the world (Truswell 1990).

Dietary recommendations, food sources and dietary intakes of folate
In accordance with the physiological roles that have been observed for folate, the RDI for folate for population subgroups in Australia is (National Health and Medical Research Council 1991):

<table>
<thead>
<tr>
<th>Age</th>
<th>RDI (µg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-6 months</td>
<td>50 µg</td>
</tr>
<tr>
<td>7-12 months</td>
<td>75 µg</td>
</tr>
<tr>
<td>1-7 years</td>
<td>100 µg</td>
</tr>
<tr>
<td>8-11 years</td>
<td>150 µg</td>
</tr>
</tbody>
</table>
12-18 years 200 µg  
Pregnancy 400 µg  
Adults 200 µg  
Lactation 350 µg

Pregnancy is a stage of the life cycle when folate has a particularly important role. Sufficient folate is required to satisfy the cellular proliferation associated with tissue synthesis (rapidly growing foetus and placenta, the expansion of blood volume and the number of maternal red cells and the size of the reproductive organs (uterine enlargement) (Bailey 2000). During pregnancy there is a greater increase in requirements for folate than any other nutrient in Australia, except iron (Truswell 1990). However, the occurrence of any deficiencies is difficult to determine as the clinical significance of biochemical and haematological signs of folate deficiency is uncertain and may be explained by hormonal changes.

Folate is a ubiquitous nutrient in plant and animal tissues, with particularly good sources of folate (>100 µg/100 g) being yeast, liver, bran, endive, broccoli and spinach (Briggs and Wahlqvist 1984). When Standard A9 was being reviewed by the NFA the most recent national dietary intake data were those available from the 1983 National Dietary Survey of Adults (Cashel et al. 1986). Based on food composition data from United Kingdom (UK) and US food tables, the survey reported the mean folate intake for men aged 25-34 to be 304 µg/day and for women aged 25-34 to be 244 µg/day. Generally, clinical signs of folate deficiency are rare in Australia. The background paper on folate that accompanied the most recent review of the Australian RDIs concluded that folate, “... usually presents as a clinical rather than a public health problem in western countries. A reduction of the Australian recommended dietary intake for folate is proposed.” (Truswell 1990: 105).

6.3 The public health issue

Neural tube defects are specific abnormalities of development of the central nervous system and are predominantly anencephalus and spina bifida that occur in approximately equal proportions in Australia (Owen et al. 2000). Lancaster outlines the following definitions for these conditions as adopted from the International Clearinghouse for Birth Defects monitoring systems 1998 (International
Clearinghouse for Birth Defects Monitoring Systems 1998 1998): anencephalus "... a congenital malformation characterised by the total or partial absence of the cranial vault, the covering skin, and the brain missing or reduced to a small mass' and spina bifida is 'a family of congenital malformation defects in the closure of the spinal column characterised by herniation or exposure of the spinal cord and/or meninges through an incompletely closed spine" (Lancaster and Hurst 2000: 3).

The number of foetuses conceived with a NTD, i.e. the incidence of NTD, cannot be accurately measured due to problems with detecting spontaneous miscarriages of foetuses with NTDs. Instead, the prevalence of NTDs is measured by counting the number of babies born with an NTD. The birth prevalence is described as the number of affected births from 20 weeks gestation onwards plus the number of affected pregnancy terminations prior to 20 weeks gestation (Kline et al. 1989). The birth data include stillbirths, later terminations of pregnancy, neonatal deaths and surviving livebirths. Total prevalence is calculated by dividing the sum of live births, still births and terminations prior to 20 weeks with NTDs, by the sum of all live births and still births. The prevalence at birth is calculated with the same denominator, but with only live and stillborn infants with NTDs as the numerator (Owen et al. 2000).

In Australia statewide birth defects registries were not established until the early 1980s. The accuracy of the birth defect prevalence data is dependent on the quality and completeness of the reporting of birth defects on registries. Until the mid-1990s it had been difficult to obtain accurate data on the national prevalence of NTDs particularly as there has been variation among the States and Territories in ascertainment of these malformations resulting from deficiencies in notification of termination of pregnancies in some states. In the early to mid-1990s, the most complete statewide data were available from South Australia where the notification of pregnancy terminations had been mandated since 1970. Based on population data for South Australia that has been collected over several decades, the overall prevalence of NTDs (including terminations, still births and live births) in Australia was estimated to be 1.6 – 2.01 per 1000 (Chan et al. 1993). This rate is equivalent to an estimated 500 NTD cases each year in Australia, making them one of the most common forms of human congenital malformation.
6.4 Epidemiological evidence for the folate – NTD relationship

6.4.1 Descriptive epidemiology
Most NTDs are believed to be multifactorial in origin, involving genetic factors (polymorphisms) and interactions of genetic with environmental factors (Hall et al. 1988). The clearest evidence for genetic susceptibility comes from familial studies in which siblings of affected individuals have a tenfold greater risk of NTD (Campbell et al. 1986). Also, there are marked geographical variations, both between and within countries, in the birth prevalence of NTDs. However, direct comparison of reported rates of NTD among countries is affected by variable definitions for reporting fetal deaths, differences in ascertainment and notification, prenatal diagnosis, and legislation and cultural attitudes regarding termination of pregnancy. Conversely, descriptive epidemiology has identified many social and environmental factors associated with variations in the incidence of NTDs. For example, NTD rates are reported as being higher among certain minority communities, younger women and women from a relatively poor socio-demographic environment (Slattery and Janerich 1991; Elwood et al. 1992).

6.4.2 Observational and experimental epidemiology
Epidemiological studies have consistently shown a negative association between a mother’s folate intake during the periconceptional period (approximately one month prior to and three months after conception) and the risk of giving birth to a baby with a NTD. Original data on the topic are limited to 13 epidemiological studies (Smithells et al. 1980; Laurence et al. 1981; Mullinare et al. 1988; Bower and Stanley 1989; Mills et al. 1989; Milunsky et al. 1989; Vergel et al. 1990; Medical Research Council Vitamin Study Research Group 1991; Czeizel and Dudas 1992; Kirke et al. 1992; Werler et al. 1993; Friel et al. 1995; Shaw et al. 1995). The evidence for the relationship between folate and NTDs has been extensively reviewed (Slattery and Janerich 1991; Bailey 1995; Daly et al. 1995; Steegers-Theunissen 1995; Wald and Bower 1995; Bower and Stanley 1996; Botto et al. 1999; Lumley et al. 2000). An overview of the investigation process and the major findings that emerged from the key studies is presented in this section. A summary of the types of studies and trials conducted on folate and NTDs and the relative risks
associated with supplementary and dietary folate, as presented in the report of the Expert Panel, is attached at Appendix 7.

The evidence that folate can reduce the risk of NTDs evolved progressively throughout the second half of the 20th century. Evidence of the potential causative role of diet in the development of NTDs first arose from observations of the higher prevalence of NTDs among populations in Europe suffering famine at the end of World War Two (Stein et al. 1975; Elwood et al. 1992). The diet hypothesis was strengthened with the observation that use of the abortifacient aminopterin, a powerful folic acid antagonist, caused several cases of anencephaly in surviving foetuses (Thiersch 1952). This observation contributed to interest in folic acid in the research investigating the relationship between diet and NTDs. A possible association between folate and NTDs in humans was first suggested in the mid-1960s (Hibbard 1964). The observation of an inverse association between incidence of NTDs and socioeconomic status (and presumably less nutrient-dense diets) during the 1960s and 1970s led to further hypotheses about the role of nutrients in reducing the risk of NTDs (Elwood and Elwood 1980).

From the late-1970s to the 1990s a series of epidemiological studies was undertaken to investigate the hypothesis that folate was a protective factor against NTDs. Initially several intervention studies were conducted during a similar time period in south Wales and as a multicentre study in England and Northern Ireland in women with a previous pregnancy affected by a NTD. In Smithells’ multicentre study all subjects who had affected children and enrolled in the study before conception were treated with multivitamin supplements containing 360 µg folic acid while those subjects who came for care after conception, or refused to take the supplements, were used as a comparison group (Smithells et al. 1980). The key finding from the study was an 86 per cent reduction in the recurrence of NTDs among the intervention group, however there were methodological problems with the study design as the local ethics committee had prevented the trial from being randomised with a placebo group (Smithells et al. 1980). Laurence and colleagues, in south Wales, conducted several studies to prevent recurrence of NTDs. A double-blind RCT found a reduced recurrence risk 2/60 NTDs in a group supplemented with 4.0 mg/day folic acid
relative to 4/51 in unsupplemented controls, but the trial was small and the difference was not statistically significant (Laurence et al. 1981).

In the late 1980s the findings from four observational studies (three case-control and one cohort) that examined the influence of multivitamin supplementation containing folic acid and/or relatively high levels of dietary folate on the first occurrence of an NTD were reported. These studies demonstrated a reduced risk among women who took multivitamin supplements containing folic acid during the periconceptional period (Mullinare et al. 1988; Milunsky et al. 1989) and for those women who had higher dietary intakes of folate derived from foods and folic acid-containing supplements during the periconceptional period (Bower and Stanley 1989). Conversely, one study found no association for multivitamin or folic acid supplementation with reduced risk of NTDs (Mills et al. 1989). During this period a non-controlled intervention trial conducted in Cuba in which 5 mg/day folic acid supplements were consumed daily reported a statistically nonsignificant trend in the reduction of risk of recurrent NTDs (Vergel et al. 1990). Although the findings from these trials were not of themselves conclusive, e.g. the vitamin users in the case-control studies were self-selected and the definition of ‘multivitamins’ differed between studies, they did provide persuasive evidence for the folate-NTD relationship.

It was the publication of the findings from two RCTs in the early 1990s in which women were asked to take folic acid-containing supplements before becoming pregnant that provided the most compelling evidence for the folate-NTD relationship. A multicentre randomised trial conducted under the auspices of the UK Medical Research Council (MRC) investigated the affect of folic acid on the recurrence of NTDs (Medical Research Council Vitamin Study Research Group 1991). This trial used a factorial design in which groups of women were given 4.0 mg folic acid alone, multivitamins with folic acid, multivitamins without folic acid, or a placebo. Recurrence rates were significantly lower in the two groups that received folic acid compared with the two groups that did not. The relative risk was lowest in the folic acid where it was estimated that folic acid prevented 72 per cent of NTDs with a 95 per cent confidence interval 29, 88 per cent.
The following year the findings of a prospective trial in women without a history of prior NTDs who came to a preconceptional care clinic in Hungary were published. Although 4,156 pregnant women participated in the trial, the low incidence of NTD-affected births meant that the cases observed in the study emerged slowly over a 7-year period. During the period immediately before conception through to three months post-conception, the subjects were randomly assigned to a control group that consumed a trace element supplement containing copper, manganese, zinc and vitamin C, or to an intervention group that took a multivitamin and mineral supplement containing 800 µg folic acid. There were six cases of NTDs among the 2,046 pregnancies in the control group and none among the 2,104 pregnancies in the intervention group, a result significant at p=0.03. At this stage the trial was judged to provide conclusive evidence of the efficacy of folic acid-containing multivitamins in preventing the first occurrence of NTDs and was stopped on ethical grounds so that the control group was not denied access to folic acid (Czeizel and Dudas 1992).

The findings from the MRC and the Hungarian trials were then supported by two studies published within the following two years. Firstly, the findings of a randomised trial conducted by Kirke and colleagues reported a protective effect of folic acid-containing supplements for recurrence of NTDs (Kirke et al. 1992). Secondly, Werler, et al used a case-control study to report that daily periconceptional intake of a multivitamin containing 400 µg folic acid reduced the risk of recurrent NTDs by approximately 60 per cent (Werler et al. 1993). They also concluded that a relatively high dietary intake of food folate alone, approaching 400 µg, might also reduce the risk of NTDs, although not to the maximal benefit, a finding previously suggested by Bower and Stanley (Bower and Stanley 1989).

By the early to mid-1990s, the epidemiological evidence to support the hypothesis that folate supplementation during the periconceptional period helps reduce the risk of NTDs was widely regarded as being conclusive. One nutritional epidemiologist claimed that the evidence was "... stronger than that underlying almost all current dietary recommendations" (Willett 1992: 667). A decade earlier another leading epidemiologist had commented that if the results from the observational studies at that time were confirmed then the folate-NTD relationship "... is one of the great
medical advances of the century.” (Elwood 1983: 1088). At the time of the review of Standard A9, original data were available from 11 epidemiological studies. These studies had used a variety of methodological designs (case-control, cohort, non-randomised and randomised controlled trials), had been implemented in several countries and had examined a variety of sources of folate: dietary folate; supplemental folate alone and supplemental multivitamins containing folate. With one exception (Mills et al. 1989), the studies consistently found that maternal periconceptional folate helps reduce the risk of both recurrent and occurrent NTD cases by 50 – 70 per cent. Following the publication of the findings of the MRC and the Hungarian RCTs it has been considered unethical to conduct any more trials in which a control group would be denied access to folic acid.\(^{19,20}\)

With a general consensus regarding the efficacy of folate in reducing the risk of NTDs, many researchers placed demands upon policy-makers to formulate a policy response. The challenge for public health policy-makers in responding to the epidemiological evidence of the folate-NTD relationship was that there had been no evaluation of population-wide interventions to provide evidence of the effectiveness of different policy options in reducing the risk of NTDs to inform decision-making. Whereas efficacy refers to the evidence obtained when an intervention is implemented under optimal conditions, effectiveness refers to the evidence that is obtained when an intervention is implemented in the real world. As Flay comments, “Efficacy is necessary to, but not sufficient for, effectiveness.” (Flay 1986: 451).

---

19 The one aspect of the folate-NTD relationship that remained unsubstantiated at this time was whether folate alone was associated with a reduced risk of occurrent NTDs. In 1995, Shaw and colleagues published the results from a case-control study that reported that the periconceptional intake of supplemental or dietary folate reduced the risk of occurrent NTDs [odds ratio of 0.65 and 95 per cent confidence interval: 0.45, 0.94] (Shaw et al. 1995). In the same year, the findings of a Canadian case-control study were published and provided further epidemiological evidence that periconceptional dietary folate was associated inversely with the prevalence of NTDs (Friel et al. 1995).

20 In 2000, a systematic review was undertaken of the four randomised trials of periconceptional folate supplementation. The data from the trials were pooled and it was calculated that the risk of having a child with an NTD was reduced by 74 per cent, with a 95 per cent confidence interval of 46 per cent to 88 per cent. The results of the systematic review of this topic were that periconceptional folate supplementation reduces the prevalence of NTDs substantially with an odds ratio of 0.28 and 95 per cent confidence interval of 0.15, 0.53. The reduction was reported as being similar for occurrent defects and for recurrent defects (Lumley et al. 2000).
The lack of evidence of effectiveness meant that any intervention would ostensibly be a form of large-scale experiment. Policy-makers were required to make judgements in formulating their policy recommendations. In making these judgements policy-makers faced scientific uncertainties in assessing the scientific evidence and ethical dilemmas with then translating this evidence into public health policy. The scientific uncertainties and ethical dilemmas associated with the epidemiological evidence are discussed in the next two sections.

6.5 Scientific uncertainties associated with the epidemiological evidence

From a policy-making perspective, the interpretation of the epidemiological evidence for the folate-NTD relationship was influenced by scientific uncertainties regarding the preventive action of folate in reducing the risk of NTDs and the potential impact of a folate intake several times the RDI on public health and safety. These scientific uncertainties are described in this section.

6.5.1 Uncertainties associated with the preventive action of folate

At the time of the policy-making process, the main uncertainties associated with the preventive action of folate were (and are) the biological mechanism, the dose of folate required, the role of other nutrients and the prevalence trend.

i) The uncertain biological mechanism

The biological mechanism to explain the aetiology of NTDs was unknown. There was only limited evidence from animal models and in vitro studies to corroborate the epidemiological evidence and identify the biological mechanism to explain the cause and effect relationship by which folate might reduce the risk of NTDs. The scientific evidence indicated that most likely there were two possible mechanisms to explain the observed relationship between periconceptional folate supplementation and reduced risk of NTDs. Firstly, folate could have been correcting a folate deficiency arising from one or more of low levels of folate in the food supply, low dietary intake
or a defect in folate absorption. Secondly, folate supplementation could have been overcoming an intrinsic abnormality in folate metabolism.\footnote{A third mechanism has since been proposed after a secondary analysis of the data from the Hungarian RCT found a statistically significant association between folic acid supplementation and an increased prevalence of recognised spontaneous abortion (Hooke and Czeizel 1997). The authors proposed that this observation suggested that folic acid supplementation may not so much be preventing NTDs as acting via a process of teratogenesis to selectively induce the abortion of affected conceptuses. Other researchers have challenged the biological plausibility of the teratogenesis hypothesis and offer as an alternative explanation that folate may be rescuing otherwise non-viable embryos and carrying them longer into gestation to a point where they are recognised as abortions (Schorah et al. 1997).}

Studies of nutritional status during pregnancy had reported that women with an NTD-affected birth have normal serum and red cell folate levels (Scott et al. 1994), or lower, but generally not deficient levels (Kirke et al. 1993). Also, animal studies had reported that folic acid deficiency did not cause NTDs (Heid et al. 1992). The balance of evidence indicated that folic acid did not prevent NTDs by correcting a nutritional deficiency in women during the periconceptional period. It appeared most likely that the preventive role arose when folate was consumed in an amount equivalent to a pharmacological ‘dose’, i.e. an amount several times the RDI, and acted to compensate for an error in a biochemical pathway involving folate metabolism in susceptible individuals (Mooij et al. 1993). In this context folate was acting more as a therapeutic agent rather than as a conventional nutrient.

Considerable research had been undertaken to identify genetic abnormalities and subsequent biochemical mechanisms that explain the ameliorating effect of folate in preventing NTDs. For example, plasma folate and vitamin \(B_{12}\) were reported to be independent risk factors for NTDs (Kirke et al. 1993). Kirke et al have postulated that it was the malfunctioning of methionine synthase that was responsible for the majority of NTDs as the only metabolic reaction that was dependent on both folate and cobalamin is that catalysed by this enzyme. However, research had yet to identify a causal pathway and was suggestive that the genetic contribution to NTDs was complex and unlikely to be explained by any single mechanism. It may be that interactions occur among genes and between certain genotypes and environmental factors to modulate folate status sufficiently to adversely affect foetal development.
ii) The uncertain dose of folate required to prevent NTDs

There had been no definitive studies to establish the minimum effective level of folate at which the optimal protective effect against NTDs might be achieved. The preventive action of folate was consistent in epidemiological studies that used nutrient supplements containing folic acid in amounts ranging from 360 μg/day to 4.0 mg/day. The evidence from the studies of diet (Bower and Stanley 1989; Milunsky et al. 1989; Werler et al. 1993) suggest even lower levels were efficacious. Most of the studies of supplementation did not take into account the underlying contribution of diet to the total folate intake.

iii) The uncertain role of other nutrients

The results from the MRC trial showed no additional preventive benefit from adding other nutrients to the 4.0 mg dose of folic acid. However, when reporting the results of the Hungarian RCT, Czeizel and Dudas noted that they could not be certain whether the preventive effect that was observed in their RCT was due to folic acid alone or in association with the other components of the multivitamin (Czeizel and Dudas 1993). Folic acid, vitamin B₆, vitamin B₁₂, vitamin C and zinc interact with one another in many metabolic pathways and potentially may have a synergistic effect in preventing NTDs.

iv) The uncertain prevalence trend of NTDs

Declining rates in the prevalence of NTDs among births had been observed²² in many countries over several decades (Elwood and Elwood 1980; Stone 1987; Yen et al. 1992). However, caution was required in interpreting trends in NTD rates due to technological advances, usually involving maternal serum [alpha]-fetoprotein screening estimation followed by targeted ultrasound scanning, that had enabled increased antenatal diagnosis of NTDs during the second trimester of pregnancy and subsequent terminations. Because NTDs are external malformations ultrasound can readily identify over 80 per cent of affected pregnancies and this has increased pregnancy terminations. Nevertheless, Mills and Simpson argued that these trends were only partially explained by improvements in prenatal diagnosis leading to

---

²² And continue to be observed (Abramsky et al. 1999; Lancaster and Hurst 2000).
terminations, i.e. suggestive of a secular trend (Mills and Simpson 1993). In Australia it was difficult to be accurate with trend data of NTD prevalence, not just because of the increase in prenatal diagnosis and subsequent terminations, but also these terminations are incompletely reported. South Australia had the most complete ascertainment because terminations had been legal in that state since 1970 and there was a system of mandatory notification for induced abortions. South Australian data indicated that the steady decline in the prevalence of NTD births during the period 1966-1991 was entirely explained by the increase in terminations (Chan et al. 1993).

6.5.2 The potential impact of consuming pharmacological doses of folate on public health and safety

The main public health and safety uncertainties associated with consuming pharmacological doses of folate were (and are) the potential to: provide other preventive roles; promote multiple births; mask the clinical symptoms of pernicious anemia; interfere with zinc absorption and metabolism; interfere with the action of drugs; and affect longer term consequences.

i) Other potential preventive roles

During the period when the epidemiological evidence of the relationship between folate-NTDs was being assembled, evidence from observational studies suggestive of other potential health benefits of consuming pharmacological doses of folate was emerging. For example, increased intakes of folic acid were found to be associated with lowered risk of cervical dysplasia in women (Butterworth et al. 1992) and colorectal adenoma in men and women (Giovannucci et al. 1993).

---

23 International monitoring systems have since reported that some but not all of the reduction in NTD rates is attributable to an increased rate of terminations following antenatal screening (International Clearinghouse for Birth Defects Monitoring Systems 1998). Molloy and Scott report that there has been a significant reduction in the prevalence of NTDs across Europe that appears to have been a 'real' reduction after accounting for prenatal diagnosis and pregnancy termination and the reduction preceded the discovery of the folate-NTD relationship (Molloy and Scott 2001).

24 Since the publication of the folate fortification policy epidemiological evidence from observational studies has emerged suggesting a possible association between folate and reduction in the risk of birth defects such as certain congenital anomalies of the heart, face, limbs and urinary tract (Hall and Solehdin 1998; Werler et al. 1999) and Down syndrome (James et al. 1999). Other observational studies have identified a possible association between folate supplementation during pregnancy and reduced risk of common acute lymphoblastic leukaemia in the child (Fitzgerald et al. 2001) and low folate status and an increased risk for various mental disorders including Alzheimer's Disease (Bottiglieri et al. 1995) and specific epithelial cell cancers such as colorectal cancer (Duthie 1999; Kim 1999).
ii) Promotion of multiple births

Following a secondary analysis of the data collected from the Hungarian RCT, Czeizel et al reported that 93 of the 2468 infants (3.8%) born to women in the intervention group that consumed a multivitamin containing 800 μg folic acid were twins or triplets, compared with 64 of 2378 (2.7%) born to women in the control group (P = 0.03) (Czeizel et al. 1994). Although Czeizel et al suggested that periconceptional folate supplementation improved fertility by increasing the rate of conceptions and multiple births, they also acknowledged that it had not been expected when the trial commenced and represented a new hypothesis.25

It is the epidemiological evidence of a possible relationship between folate and the reduction in risk of cardiovascular disease (CVD) that is generating most interest among policy-makers. The sulphur amino acid homocysteine is a constituent of plasma arising as a byproduct of methionine metabolism. Normally the plasma concentration of homocysteine is kept within narrow limits through biochemical pathways, several of which are controlled by enzymes that require folate as a cofactor. Elevated blood concentrations of homocysteine are an independent risk factor for vascular diseases including coronary artery disease, stroke and thromboembolic disease (Wald et al. 1998; Ueland et al. 2000). Evidence now indicates that an extra 100-200 μg folic acid/day reduces plasma homocysteine concentrations (Mayer et al. 1996; Homocysteine Lowering Trialists' Collaboration 1998; Jacques et al. 1999) even in the absence of a folate deficiency (Ward et al. 1997). A meta-analysis conducted by Boushey et al concluded that there is strong evidence of a causal relationship between folate and the prevention of CVD (Boushey et al. 1995). In another review, Eikelboom et al conclude that although the association between homocysteine levels and cardiovascular disease is generally strong, the data from the prospective studies is inconsistent and until evidence of an association is available from large scale RCTs it is unclear whether blood homocysteine levels are a cause of, or a product of, the CVD process (Eikelboom et al. 1999). Presently there are more than 10 such trials being conducted (Molloy and Scott 2001).

25 In their systematic review of the randomised trials of periconceptional supplementation with folic acid, Lumley et al identified a pooled relative risk of twin pregnancy of 1.40 with 95 per cent confidence interval 0.93, 2.11, in the three trials where twinning data were collected. The authors noted that the findings were consistent in all three trials and described the results as providing "... moderate evidence of a worrying effect. ... A 40 per cent increase in multiple births could alter the relative risks and benefits of supplementation markedly." (Lumley et al. 2000: 5). These findings are consistent with those from an earlier study involving the retrospective analysis of the datasets from four of the five case-control studies (Werler et al. 1997). The interpretation of the influence of folic acid supplementation on multiple births is difficult because other factors such as increasing maternal age, increased availability of fertility treatments and improved antenatal screening techniques, that may increase or decrease multiple births, have coincided with increased folic acid supplementation.

Lumley et al suggest that a plausible mechanism for increased twinning is increased survival of multiple pregnancies rather than increased ovulation (Lumley et al. 2001). They explain that it is likely that multiple pregnancies have greater micronutrient requirements and cite an animal study that reported folate is widely used in animal husbandry to increase litter size in some farmed animals (Lindermann 1993). An alternative mechanism to explain the observed increase in twinning is that increased levels of dietary folate change MTHFR genotype frequencies and thereby overcome the common MTHFR 677C→T mutation that is associated inversely with the risk for dichorionic twin pregnancies (Hasbargen et al. 2000).
iii) Masking of the clinical symptoms of pernicious anaemia
Pernicious anaemia is a condition that results from vitamin B₁₂ deficiency that itself can arise from either low dietary intake or problems with biosynthesis. The main features of vitamin B₁₂ deficiency are macrocytic megaloblastic anaemia and neuropathy. Katz recommended against large doses (400 µg/day) of folic acid being available for self-medication, stating that it could be dangerous when given to patients with undiagnosed vitamin B₁₂ deficiency since it temporarily relieves the megaloblastic anaemia caused by vitamin B₁₂ deficiency (Katz 1973). It does not, however, prevent the irreversible damage to the nervous system that occurs in vitamin B₁₂ deficiency (Heinle and Welch 1947). Thus, folate supplementation can appear to treat the anaemia by masking its clinical symptoms, yet unless adequate vitamin B₁₂ is administered the underlying neuropathy persists leading to irreversible neurologic damage. Some scientists had raised concern that any masking resulting from pharmacological doses of folate may inadvertently increase the incidence of neurological disorders among the elderly and strict vegetarians, population groups that are particularly susceptible to pernicious anaemia (Horton 1994; Rush 1994). The prevalence of pernicious anaemia was unknown in Australia.

The practical significance of the masking influence of folate upon the anaemia resulting from vitamin B₁₂ deficiency was uncertain. Pernicious anaemia could be diagnosed by blood assays of B₁₂ deficiency rather than relying solely on observing the symptoms of the anaemia. A general practitioner who detected a vitamin B₁₂ deficiency could readily have instigated a process to test for the presence of neuropathy. Nevertheless, in 1980 labelling regulations for therapeutic preparations of folic acid were published by the FDA and included the following statement “Folic acid in doses above 0.1 mg daily may obscure pernicious anaemia in that hematologic remission may occur while neurological manifestations remain progressive (US Food and Drug Administration 1980: 69043)²⁶.

iv) Interference with zinc absorption and metabolism

²⁶ Several scientists have since argued that this safety concern could be addressed by adding vitamin B₁₂ to any intervention involving folate fortification or folic acid supplementation (Herbert 1996; Oakley 1997).
The findings of several studies had indicated that folate may interfere with zinc absorption and metabolism (Mukherjee et al. 1984; Simmer et al. 1987). Other studies had not detected an adverse effect of folic acid on either zinc absorption or metabolism (Keating et al. 1987). These inconsistent findings may be explained by differences in study design and difficulties associated with accurately measuring zinc status in humans. Those investigations that had reported adverse effects on zinc status generally had used amounts of folate well above physiological levels and a comprehensive review of this topic concluded that "There is no convincing evidence that folate supplementation compromises zinc status in pregnancy" (Zimmerman and Shane 1993: 128).

v) Interference with the action of drugs
It was postulated that very high intakes of folate may interfere with the action of certain drugs, including anticonvulsants and folate antagonists (such as methotrexate), used to treat many conditions such as epilepsy and cancer (Butterworth and Tamura 1989; Zimmerman and Shane 1993). Conversely, anticonvulsant drugs had been shown to have a role in reducing serum, red cell and cerebrospinal levels of folate (Reynolds 1973). Nevertheless, the antagonism between folate and certain drugs may have been overstated as the conditions for which these drugs are prescribed are managed within a clinical setting and general practitioners would normally be expected to be able to advise on appropriate caution.

vi) Unknown longer term consequences
The long term consequences of exposing population groups, particularly children and the elderly, to prolonged and unprecedented novel levels of folate was unknown.

6.6 Ethical dilemmas in translating the epidemiological evidence into public health policy

The following five policy options were available, either singly or in combination, to policy-makers for the primary prevention of NTDs:

i) Maintain the status quo until more evidence and understanding emerges.
ii) Nutrition education to promote increased intakes of foods that are naturally good sources of folate.

iii) Nutrition education to promote the consumption of folic acid supplements by target individuals.

iv) Mandatory fortification of foods with folic acid.

v) Voluntary fortification of foods with folic acid.

Conceptually, the translation of the folate-NTD evidence into a public health policy response was relatively straightforward. It was apparent that NTDs most likely arose as a consequence of a defect in folate metabolism in genetically predisposed individuals. A pharmacological dose of folate was required to 'treat' this metabolic defect. The policy response to the folate-NTD evidence that was consistent with this evidence was to identify target individuals and then offer appropriate advice and treatment. For example, women who previously had had an NTD-affected embryo could be identified and encouraged to consume a 4.0 mg folic acid supplement on a daily basis during the periconceptional period. Other women who were at risk of conceiving an occurrent NTD case could have been encouraged to consume a nutrient supplement containing 400 μg folic acid (the amount used in many of the epidemiological studies) on a daily basis during the periconceptional period.

In practice the translation of the folate-NTD evidence into a public health policy response was less straightforward than an immediate conceptual assessment indicates. Although the identification and prevention of potential recurrent cases was relatively simple, they represented only approximately 5 per cent of all NTDs in Australia (Field 1978). Unfortunately, both the targeting and choice of a primary prevention strategy for reducing the risk of occurrent cases was problematic. It was not possible to identify susceptible individuals for occurrent cases nor was there a screening instrument to detect the genetic defect(s). Moreover, there were peculiar circumstances to consider in planning the policy response. The human embryonic central nervous system develops early in pregnancy and normally the closure of the neural tube occurs between the 23rd and the 28th day after conception (Sadler 1998). This is a period during which a woman may be unaware that she is pregnant. This circumstance was compounded by data from the US that approximately 50 per cent
of pregnancies were unplanned (Grimes 1986)\textsuperscript{27}. Therefore many women may not have realised the importance of increasing their folate consumption during the critical periconceptional period. Consequently all women of child-bearing age became the target group for increasing folate intake.

The difficulty in targeting the primary prevention strategy and the uncertainties associated with the folate-NTD evidence presented dilemmas to policy makers in selecting from among the different policy options when translating the epidemiological evidence into public health policy. The pros and cons that were known for the different policy options that were available at the time of the policymaking process are discussed in this section and summarised in Table 6.1.

i) Maintain the status quo until more evidence and understanding emerges

The policy option to maintain the status quo until more evidence was assembled to inform policy-making reflected the stance that on balance it would have been premature to act given the many uncertainties regarding the preventive action of folate and its potential impact on public health and safety. The policy response had two aspects. Firstly, it reflected an assessment that either the understanding of the public health issue was not sufficient to justify a policy response and/or the potential risks of an intervention outweighed the potential benefits. Secondly, it included a process of actively seeking more evidence to address the uncertainties.

The pros associated with this policy response were that it provided the opportunity to obtain more evidence to address uncertainties, e.g. to conduct in vitro studies and animal trials to collect data on dosage and to observe if prevalence continued to decline across the population. Also, if a policy response was deemed appropriate, it provided the opportunity to trial different policy interventions and to evaluate their respective effectiveness against public health criteria. The cons of this policy response were that it delayed the target individual's access to the potential benefits of an intervention. Also, relying on the emergence of further evidence was problematic as the strength of the existing evidence mitigates, on ethical grounds, against conducting any new human clinical trials.

\textsuperscript{27}It has since been reported that an estimated 40 per cent of pregnancies are unplanned in Australia (Marsack et al. 1995).
As outlined in Chapter 2, there are four ethical principles to provide guidance in policy-making: respect for autonomy; non-maleficence; beneficence; and justice. This policy option captured the dilemma for policy-making of assessing at what point is there a sufficient body of available evidence to act versus denying individuals access to the information. The ethical principle that was relevant to assessing the pros and cons associated with this policy option were that of justice in relation to protecting the rights of the human embryo.

ii) Nutrition education to promote increased intakes of foods that are naturally good sources of folate

The policy option of nutrition education reflected the assessment that the target individuals should be provided with information regarding the epidemiological evidence and education on how to make dietary changes to act upon this information. Conceptually, nutrition education to promote the consumption of a healthy balanced diet is intended to help the population achieve the recommendations of public health nutrition reference standards such as the dietary guidelines and the RDIs. Nutrition education is not intended to promote the consumption of pharmacological levels of a nutrient and therefore is not consistent with the nature of the public health issue.

The pros associated with this policy response are that the intervention could have been targeted to the relevant individuals and it would have helped to promote informed choice for these individuals. Also, nutrition education to promote increased intakes of foods that are naturally good sources of folate is consistent with the dietary guideline messages and could have contributed knowledge and skills to promote food selection for a diet that would have ensured individuals in the target group had the best foundation for overall nutritional health. A balanced diet would have helped ensure the consumption of adequate amounts of other nutrients such as vitamin B₁₂, which may act synergistically with folate to reduce the risk of NTDs.

The cons of this policy response were that the circumstances associated with the proportion of unplanned pregnancies and the closure of the neural tube before many women are aware they may be pregnant militate receptiveness to the policy intervention. Also, it had been claimed that nutrition education was
disproportionately effective for individuals from higher socio-economic backgrounds and its implementation to promote awareness of the folate-NTD relationship may have exacerbated disparities across society (Scott et al. 1994). This was particularly relevant to NTDs as a higher prevalence of NTDs had been reported among lower socio-economic status and literacy groups, traditionally those groups least compliant with the messages of nutrition education programs.

Although the required dose was uncertain most of the epidemiological studies had administered doses of 400 μg or more on a daily basis in addition to folate present in the diet. It would have been very difficult to consume an additional 400 μg folate/day by diet alone as this represented an approximate twofold increase from estimated consumption levels. Moreover, consuming extra serves of foods that are good sources of folate would have been relatively expensive and have required approximately 30 years of compliance. Naturally occurring folate is unstable and is readily oxidised with lengthy cooking and it is found with conjugates that reduce its bioavailability relative to the synthetic form, folic acid. Although three of the observational studies reported that dietary folate helps to prevent NTDs, these same studies did show that the risk of NTDs decreased as folate intakes increased when complemented with folic acid from nutrient supplements (Bower and Stanley 1989; Milunsky et al. 1989; Werler et al. 1993).

This policy option captured the dilemma for policy-making of assessing the potential risks and benefits of a policy intervention for target individuals. The ethical principles that were relevant to assessing the pros and cons associated with this policy option were non-maleficence, ie doing no harm, and beneficence, i.e. doing good, that must be balanced for the target individuals. Although target individuals who may be on anticonvulsant drugs, or have dietary practices that place them at risk of deficient vitamin B₁₂ intakes, can be advised to take particular care in planning their diets, the risks and benefits associated with other potential public health and
safety impacts are more complex to determine. This ethical dilemma was further complicated because the intended beneficiary of the policy intervention (human embryo) was not necessarily the same as the individual being exposed to possible risk from the extra dose of folate (woman of child-bearing age).

iii) Nutrition education to promote the consumption of folic acid supplements by target individuals.

The policy option of nutrition education to promote the consumption of folic acid supplements by women of child-bearing age reflected the assessment that target individuals should be provided with information regarding the epidemiological evidence and encouragement to take a 400 µg folic acid supplement on a daily basis. This policy response was the intervention consistent with the conceptual nature of the epidemiological evidence for the public health issue and most of the epidemiological studies were conducted using folic acid-containing supplements. Although the vehicle for delivering folate was different (supplements versus food), the issues associated with the implementation of this policy option are similar to the option of nutrition education to promote folate from foods and shared many of the same pros, cons and ethical dilemmas that needed to be taken into account in the policy-making process.

The pros associated with this policy option were that folic acid supplements could be delivered to target individuals while posing no risk to the remainder of the population. Also, the dose of folate could be precisely controlled with supplements. Unlike nutrition education to promote increased folate intake from foods that are naturally good sources of folate, the folic acid contained in supplements was relatively stable and bioavailable to effect folate status in target individuals. As with the nutrition education policy option, the cons of this policy response were the uncertainties regarding the target groups receptiveness to the policy intervention, it

28 For example, a pharmacological dose of folate is associated with multiple births and multiple births are associated with adverse health, social and economic outcomes, including worse health and development outcomes for the infant and maternal medical and obstetric complications. These adverse outcomes raise dilemmas in weighing up the risk-benefit ratio associated with folic acid supplementation to reduce the risk of NTDs. Lumley et al undertook a modelling exercise to assess the potential impact of consuming a pharmacological dose of folate on multiple births. The findings of this modelling exercise were that the projected number of prevented NTD-affected births was almost exactly offset by the projected number of increased perinatal and postneonatal deaths, birth defects and cases of cerebral palsy associated with multiple and consequent preterm births (Lumley et al. 2001).
may have had a disproportionate impact across the community, mass supplementation required an individual's compliance every day for 30 years and the cost of compliance may have been an excessive financial burden for many individuals.

In common with the nutrition education policy option, this option captured the ethical dilemma of assessing the potential risks and benefits of a policy for target individuals.

iv) Mandatory fortification of foods with folic acid

The policy option of mandatory fortification reflected an assessment that the food supply should be modified to provide a passive and continuous source of additional folic acid for target individuals.

The pros associated with this policy option were that it enabled folate to be delivered to the target group passively without the need for any conscious dietary change. This advantage mitigates the concerns associated with the peculiar circumstances of unplanned pregnancies. Moreover, folate fortification offered an intervention that was equitably available to all individuals at risk. Relative to the dietary change associated with the consumption of either additional foods that are naturally good sources of folate or folic acid supplements, folate fortified foods had a minimal additional cost for the consumer and would have impacted on dietary folate intake immediately. By increasing the folate exposure of the general population a secondary benefit of the folate fortification of food products may have been an increased folate nutrure of population groups at risk of marginal folate deficiency, eg the elderly. Also, there may have been other potential public health benefits associated with intakes of folate in pharmacological amounts.

The cons of this policy response were the non-specific nature of its delivery of folic acid and that it involved manipulating the characteristic nutrient profile of food products by adding novel levels of folic acid. The policy would result in an increased exposure to folic acid of everybody who consumed the fortified foods without necessarily securing their informed consent.
This policy option captured the dilemma for policy-making of balancing an individual’s interest with the collective interest. The ethical principles that were relevant to assessing the pros and cons associated with this policy option were respect for autonomy, non-maleficence and beneficence. Conventionally, public health policy interventions, such as food fortification, are implemented for the benefit of the population, or collective interest, and due consideration must be directed towards the rights of the individual. However, in this instance the policy option represented the exposing of the majority to the intervention for the potential benefit of the minority.

From the perspective of respecting autonomy, the folate fortification policy option was a form of ‘reverse paternalism’, i.e. this policy option was imposing upon the liberty of the population, generally without consent, with the justification being to provide certain individuals with more opportunities to increase their dietary folate intake. In balancing respect for the autonomy of the population with the individual’s interest policy-makers had to judge on what criteria should the policy be based to be proportionate with the public health issue. The proportionate response could in turn have been informed by comparing the policy option’s anticipated benefit to individuals and the collective (i.e. beneficence), and the potential to do no harm (i.e. non-maleficence).

On the one hand NTDs were a major cause of perinatal, infant and childhood mortality and morbidity in Australia. The emotional, social and economic costs of NTDs in terms of treatment, loss in productivity and pain and suffering were substantial for affected families and society as a whole. With approximately 500 NTD cases per year in Australia, of which an estimated 50-70 per cent of cases could be prevented, the potential was that additional dietary folate may have helped to prevent approximately 300 NTD cases per year. On the other hand, the non-specific nature of folate fortification of foods meant that the intervention would expose 19 million Australians to additional levels of folate and would manipulate the integrity of a common good, that is, the nutrient profile of food products. The consequence of the folate fortification policy option represented the corollary of Rose’s prevention
paradox. Mass prevention strategies that potentially have a major benefit for individuals often have inherent low-order risks. When these benefits and risks are viewed at the population level and over long time periods the harm may outweigh the benefits.

In assessing the impact of a mass preventive strategy on individual and collective interests there is no definitive way of balancing a benefit derived by one individual against harm suffered by another without making value-judgements (Kamm 1985). The challenges for policy-makers in interpreting and applying the principles of beneficence and non-maleficence are two-fold. Firstly, whereas the potential benefits to the target individual’s interest can be relatively easily identified and measured, the potential risks to the collective interest are less clear. For example, how do policy-makers account for the potential adverse effects resulting from increased exposure of all population groups to folate in the long term? How do policy-makers measure the impact on public health of modifying the integrity of a common good? Secondly, the ethical dilemma is complicated because the individuals who would benefit from folate fortification (human embryos) are not those who would be placed at risk, eg the elderly who suffer from vitamin B12 deficiency. For instance, how many cases of masking the symptoms of pernicious anaemia in the elderly are tolerable to prevent an NTD case? Alternatively, increased exposure to folate may confer secondary health benefits to those same population groups that otherwise were placed at potential risk, for example, the elderly may be placed at increased risk from the masking of the symptoms of pernicious anaemia but benefit from protection against certain chronic diseases.

v) Voluntary fortification of foods with folic acid

The policy option of voluntary fortification of foods with folic acid reflected a similar assessment of the required policy response to that for mandatory fortification and shared many of the pros, cons and ethical dilemmas that needed to be taken into account in the policy-making process.

The pros associated with this policy option were similar to those associated with mandatory fortification with the added benefit of providing greater consumer choice to select non-fortified food products and thereby greater flexibility for non-target
groups to avoid exposure. The cons associated with this policy option were similar to those associated with mandatory fortification with the added uncertainty that greater reliance for the policy's implementation is placed with food manufacturers.

In common with the mandatory fortification policy option, this policy option captured the ethical dilemma in policy-making of balancing the rights of the individual with the collective interest.
Table 6.1 Comparison of the pros and cons of the different policy options available at the time of the policy-making process

<table>
<thead>
<tr>
<th></th>
<th>Pros</th>
<th>Cons</th>
</tr>
</thead>
<tbody>
<tr>
<td>Maintain the status quo</td>
<td>Opportunity to obtain more evidence and assess effectiveness of policy options</td>
<td>Ethics of not acting on evidence Unethical to conduct more trials</td>
</tr>
<tr>
<td>Nutrition education</td>
<td>Limited efficacy demonstrated in some clinical trials Informed consent Can be targeted Other health benefits from a varied diet that includes additional intakes of fruit and vegetables Consistent with dietary guidelines</td>
<td>Effectiveness had not been tested Difficult to promote dietary change to target individuals Concerns about equitability Difficult to substantially increase dietary folic acid intake Concerns about cost and long term compliance Uncertainties with risk-benefit assessment</td>
</tr>
<tr>
<td>Supplementation</td>
<td>Efficacy proven in clinical trials Informed consent Can be targeted The dosage can be precisely delivered</td>
<td>As for nutrition education except dietary folic acid intake can be substantially increased</td>
</tr>
<tr>
<td>Fortification - mandatory</td>
<td>Does not require behaviour change Equitable and rapid response Other potential health benefits General increase in folic acid status, especially in the elderly.</td>
<td>Efficacy and effectiveness had not been tested Uncertainty regarding informed consent Difficult to deliver folic acid dose with specificity for target group and sensitivity to avoid excessive exposure for non-target groups Manipulating characteristic nutrient profile of foods with novel levels of folic acid Ethical dilemmas associated with balancing individual rights with the collective interest</td>
</tr>
<tr>
<td>Fortification - voluntary</td>
<td>As for mandatory fortification with greater consumer choice and flexibility for non-target groups to avoid exposure</td>
<td>As for mandatory fortification but with greater reliance for implementation resting with food manufacturers</td>
</tr>
</tbody>
</table>

6.7 The policy responses to the folate-NTD evidence internationally

Additional insights to guide Australian policy-makers at the time of the policy-making process were available from international developments relating to this public health issue. Policy recommendations had been issued in 10 other countries (Cornel and Erickson 1997). In the US, UK and Ireland, where relatively liberal provisions existed for the addition of nutrients to food products and the addition of
folic acid to food products on a voluntary basis has been permitted for many years, the recommendations were to obtain folate from a combination of folate-rich foods, folic acid supplements and folate fortified foods (Cornel and Erickson 1997).

During the period that the Australian policy-makers were reviewing the folate-NTD evidence, in the US the possible mandating of folate fortification of staple foods was being debated. On the 12 January 1993, the FDA Commissioner was quoted as saying, “As a scientific and policy matter, it is one of the more difficult [issues] I have confronted ... Before we fortify the food supply for 250 million Americans, we need to make sure we get it right.” (Williams 1994: 12). Commentators in the US were reporting that there was ‘substantial disagreement’ regarding folate fortification in general and a folate-NTD health claim in particular at the FDA Food Advisory Committee and Folic Acid Subcommittee (Nestle 1994). In a related policy development during this period, the FDA had recommended against permitting a folate-NTD health claim because of what it perceived to be the potential for risks to arise among certain population groups due to their exposure to possible excessive amounts of folate (US Food and Drug Administration 1993). One member of FDA’s Food Advisory Committee commented, “To allow a folic acid health claim on food labels is to open Pandora’s box ... [leading to an] ... all-out fortification race. ... [I have never been] ... so aware of the politics driving a decision” (Gussow 1994: 21).

In Canada, China, New Zealand, South Africa, Spain and The Netherlands the recommendations were to obtain folate from a combination of folate-rich foods and folic acid supplements (Cornel and Erickson 1997). Following their interpretation of dietary modelling data, the Canadian authorities concluded that it was “… not possible to fortify foods to achieve the goal of an intake of 400µg of folate by women of child-bearing potential without exposing other groups in the population to excessive intakes.” (Cheney and Lee 1993: 741). In Norway the recommendation was to obtain folate from folate-rich foods only (Cornel and Erickson 1997).29

29 In 2001 folate fortification of food products was being implemented as the public health policy of six countries, all English speaking, the US (Food and Drug Administration 1996) and Canada (Health Canada 1998) where it had been mandated and the UK, Ireland, Australia and New Zealand (Cornel and Erickson 1997) in a voluntary capacity, although mandatory fortification was being considered in the UK (Committee on Medical Aspects of Food and Nutrition Policy 2000). The Netherlands (Walle et al. 1999), Denmark (Rasmussen et al. 1998) and Norway (Tell et al. 1998) have not recommended folate fortification.
6.8 The policy outcome

Within the scope of Standard A9 certain staple foods are permitted to be fortified with folic acid on a voluntary basis at up to a claimable level of 50% of the RDI per reference quantity. This provision was included in Standard A9 in response to recommendations prepared by the Expert Panel that were subsequently endorsed at the 117th Session of Council on 1-2 June 1994\(^{30}\). The target group for the policy intervention were women of child-bearing age. The recommended daily mean folate consumption for this group was 600-700 µg, i.e. an additional 400 µg to the estimated current daily mean folate consumption for this group. The Executive summary, Recommendations and Background to the establishment, of the NHMRC Expert Panel on Folate Fortification is attached at Appendix 8. The Expert Panel’s primary policy recommendations were (National Health and Medical Research Council 1994: viii-ix):

1. ‘That the National Food Authority, in its revision of Standard A9 of the Australian Food Standards Code, permit the addition of folate in the following manner:
   
   i) Voluntary fortification to 50 per cent RDI per reference quantity of:
      flour; savoury biscuits; bread; breakfast cereals; pasta; rice\(^{31}\); and yeast extracts.
   
   ii) Nutritional equivalence of: beverages derived from legumes (such as soy beverages) and textured vegetable protein.

2. That voluntary fortification be reviewed three years after the date of gazettal to determine its effectiveness and whether there is a need for mandatory fortification to be introduced. The NHMRC will coordinate the monitoring to determine the effectiveness of voluntary fortification.

---

\(^{30}\) Among the other policy recommendations prepared at this meeting was a call on health professionals to pay greater attention to the effects of drugs on older people [D113-3/6/94, Telegraph Mirror ‘Baby food may get vitamin additive’]. The potential for folate to mask the clinical symptoms of pernicious anaemia was not discussed within the context of this agenda item.

\(^{31}\) Rice was not included in the revised Standard A9.
3. That a nutrition message such as:

*A diet rich in the vitamin folate is important for women in their child-bearing years. This food is a good source of folate.*

be permitted to be used on those foods fortified with at least 25 per cent RDI folate per reference quantity32.

The Standard A9 provisions in relation to the addition of folic acid to food products are outlined in Appendix 9.

6.9 What the case study captures for analysing public health policy

The policy-making process associated with the folate fortification policy provides a rare opportunity to analyse how and why scientific evidence is used in the making of public health policy in a food regulation setting. It is not just that the existence of the case study itself provides an opportunity to analyse policy-making, the peculiar nature of the circumstances associated with the case study adds to its richness and ability to gain theoretical understandings and to make analytic generalisations (Davis 1998). This richness is essential because the research findings in this thesis will be based on the evaluation of this single, holistic case, rather than multiple cases, and as such the case needs to provide a powerful illustration of the critical issues under investigation (Hamel et al. 1993). According to Yin, a single case study design can be a legitimate approach to gain theoretical understandings if it satisfies any one of three rationales: it represents the critical case associated with a theory; it is a revelatory case; or it is an extreme or unique case (Yin 1994). The policy-making process that resulted in the folate fortification policy captured peculiar characteristics consistent with both a revelatory case and a unique case that enable critical aspects of public health policy-making to be analysed and explained.

---

32 The Expert Panel commented "... a health claim per se may not be desirable in Australia because many people do not know what a neural tube is. Moreover, any message that is to be helpful to consumers must be simple." (National Health and Medical Research Council 1994: 30).
6.9.1 A revelatory case study

The policy-making process associated with the folate fortification policy is a revelatory case study for investigating public health policy-making because it responded to epidemiological evidence suggestive of a paradigm shift in the relationship between nutrition and health. The epidemiological evidence for the folate-NTD relationship indicated that folate may have a 'supraphysiological' role, i.e. a role beyond its conventional physiological roles, when consumed in amounts several times the RDI. This supraphysiological role is consistent with the burgeoning scientific area of interest related to potential gene-nutrient interactions. The policy is a primary prevention strategy predicated on delivering a pharmacological dose of folate to individuals afflicted with an abnormal genotype in order to treat a probable defect in a metabolic pathway(s).

The policy response to the folate-NTD evidence has been integral to a transition in the way that the relationship between food and health is perceived and addressed within the food regulatory system. Specifically, it has legitimised the concept of functional foods described in Chapter 2. Folate is positioned as a functional ingredient that most likely acts on the expression of the genome by rescuing specific genotypes. Its presence in a food denotes that food as being a commodity to help prevent a disease, as distinct from being a component of the total dietary balance. As such, folate fortification represents the linchpin between a conventional and contemporary approach to regulating public health policy issues such as food composition and food labelling\(^{33}\) in Australia. It provides a case study to analyse how and why this transition process has occurred.

6.9.2 A unique case study

The policy-making process associated with the folate fortification policy is a unique case study because it provides the investigator with an opportunity to analyse previously inaccessible phenomenon. The uncertainties and dilemmas associated with the epidemiological evidence of the relationship between folate and NTDs presented challenges to policy-makers in using the scientific evidence to make public

\(^{33}\) In August 1998 a pilot folate health claim trial was announced as the first officially sanctioned exemption to the general prohibition on health claims in Australia. This policy development was a direct consequence of the folate fortification policy and is discussed in Chapter 10.
health policy. The majority of NTD cases are the tragic outcome of a genetic defect in specific individuals. In accordance with the typology outlined in Chapter 4, the relationship between folate and NTDs is consistent with the medical model of public health. A targeted policy response was indicated. However, the policy response was a non-specific population-wide intervention. This intervention is consistent with the health promotion model of public health. The policy response provides an opportunity to analyse how and why a disjunction between theory and practice in the policy-making principles that were outlined in the typology in Chapter 4.

Food fortification policy raises unique ethical dilemmas as it acts as a public health intervention by exposing the population to an increased amount of the one or more nutrients that have been added to food products. The conventional rationale for food fortification had been to counter inherent nutrient deficiencies in the food supply and a significant prevalence of clinical symptoms of nutrient deficiencies across the population (Mertz 1994; Nestle 1994)\(^\text{34}\). These interventions have not tended to raise undue ethical concern because they are regarded as being for the benefit of the collective interest and represent a minimal imposition on individual autonomy as the intervention is restoring nutrient levels to those that would otherwise be considered 'normal'. The moral rationale for such an intervention is that the protection of the rights of a larger number of people sometimes requires the abrogation of the rights of a smaller number of people.

The uncertainties and dilemmas associated with the folate fortification policy challenged the conventional rationalisation of ethical considerations and the policy recommendations associated with this case study created a precedent for food fortification policy. At the time of the review of Standard A9 the Australian food supply contained sufficient folate to meet the RDI for all Australians (Australian Bureau of Statistics 1993). The folate fortification policy is adding folate to the food

\(^{34}\) In Australia, iodine fortification of iodised salt and thiamin fortification of bread making flour were mandated to reduce the risk of goitre and Wernicke-Korsakoff syndrome respectively before the folate fortification policy decision. Unlike folate fortification, the policy-making process for these two mandated interventions was based on an assessment that there was an inadequate amount of iodine and thiamin in the food supply and that there was clinical evidence of nutrient deficiency associated with these nutrients among the population.
supply to enable certain individuals to consume a pharmacological dose of folate while exposing the population as a whole to a lifetime of increased folate intake.

6.10 Conclusion

This chapter has described the issues associated with the making of the folate fortification policy in Australia. The epidemiological evidence that the consumption of an additional 400 μg/day folate during the periconceptional period can reduce the risk of NTDs and help prevent 50–70 per cent of cases is compelling. This thesis is concerned with investigating the policy-making process that was undertaken to assess the policy options available as primary prevention strategies for NTDs in response to the epidemiological evidence. In the absence of evaluative evidence assumptions must be made in extrapolating evidence derived from a clinical setting to inform public health policy interventions. Invariably people's core values will influence the policy-making process. As one nutritionist commented when advising his national food regulator on policy responses to the folate-NTD evidence, "With existing information ... [there is no clear scientific evidence for one particular intervention] ... At best one can obtain informed opinions (Beaton 1994: 8).

In Chapter 2, conceptual, scientific and ethical dilemmas were identified for food regulators when using scientific evidence to make public health policy. The revelatory and unique nature of this case study captures these challenges. The analysis of how and why one policy option prevailed will provide the opportunity to test theory of the use of evidence in the public health policy-making in a food regulation setting. To explain the policy-making process that resulted in the folate fortification policy a series of questions are asked of the case study, including:

1. How and why were the conceptual difficulties resolved?
2. How and why were the scientific uncertainties resolved?
3. How and why were the ethical dilemmas resolved?
4. What scientific evidence was used/ignored?
5. Who were the stakeholders? And what were their core values?
6. What arguments and actions did the stakeholders employ in promoting their core values?
7. What were the procedures, mechanisms and events associated with the policy-making process?

8. What was the influence of the political and institutional setting within which the policy-making process was conducted?

In the next three chapters the process that resulted in the folate fortification policy is deconstructed from three perspectives to gain insights into how and why scientific evidence was used in the making of the public health policy.
CHAPTER 7

An analysis of the case study at the decision-making process level of the food regulatory system

7.1 Introduction

The previous chapter described the case study that has been selected for analysis in this thesis. This description highlighted the epidemiological evidence for the folate-NTD relationship, the uncertainties associated with the epidemiological evidence, the dilemmas in translating the evidence into public health policy, the details of the policy outcome and the policy issues that the case study captures. The conceptual, scientific and ethical dilemmas identified in the review of the case study resulted in the posing of several questions regarding how and why evidence was used in making the folate fortification policy and provide a focus for analysing the policy-making process.

The complexity of the food regulatory system presents challenges for analysing how and why scientific evidence is used in making public health policy in this political setting. In Chapter 2, Easton’s model of a political system was adapted as a heuristic device for approaching the analysis of the policy-making process of the food regulatory system. Using this model the food regulatory system can be deconstructed into three levels: decision-making process; procedural; and political environment, and progressively analysed to gain deeper insights into the use of scientific evidence in the policy-making process.

In this chapter the case study is analysed from the perspective of the decision-making process level of the food regulatory system as the first of three analyses of the policy-making process that led to the folate fortification policy. The analysis of the case study at this level involves investigating the epidemiological evidence that was used and the factors involved in rationalising the scientific uncertainties and ethical dilemmas associated with the evidence and the planning of the policy's implementation. The data that were collected in this policy analysis are presented to
describe what happened from the perspective of the decision-making process level of
the food regulatory system. The data then are interrogated to identify themes that
emerge from the description to offer insights towards answering the posed questions.
Finally, the data and the themes are assessed for the contribution they make to
explaining the policy outcome and to reveal clues for potential further policy
analysis.

7.2 Description

In this section data are presented to describe what happened with the case study at
the decision-making process level of the food regulatory system.

7.2.1 The epidemiological evidence that was reviewed

The report of the Expert Panel indicates that the scientific evidence that was used in
the identification of the relationship between folate and NTDs was based on a
systematic review of relevant epidemiological studies (National Health and Medical
Research Council 1994). The Expert Panel concluded that, “Because of the number
of studies and major trials that have been conducted on this relationship, the negative
association between folate and NTDs can be regarded as well established” (National
Health and Medical Research Council 1994: 4). A summary of the types of studies
and trials conducted on folate and neural tube defects and the relative risks associated
with supplementary and dietary folate, as presented in the report of the Expert Panel,
is attached at Appendix 7. The Expert Panel estimated that 440 to 500 pregnancies
are affected by NTDs in Australia each year and that 50 to 66 per cent of these NTD
cases could be prevented nationally if the target group consumed sufficient folate
during the preconceptional period.

7.2.2 The rationalisation of the uncertainties associated with the epidemiological
evidence

In Chapter 6 a number of uncertainties associated with the epidemiological evidence
for the folate-NTD relationship were identified. Data providing insights into the
rationalisation for each of these uncertainties are presented below.
i) The uncertain biological mechanism
The lack of a biological mechanism to explain the folate-NTD relationship is not identified in the policy documentation. Instead, the Chairperson of the Expert Panel in acknowledging this uncertainty commented,

"We're not going to have complete understanding of nutrition and nutrient interactions for another hundred years so up until that time we're going to have to do something based on epidemiology instead of a complete understanding of the biochemical mechanisms." [13/9]

ii) The uncertain dose of folate required to prevent NTDs
The Expert Panel report specifies a target of an additional mean intake of 400 μg/day of folate for women of childbearing age. The determination of this target was based on the observation that in most of the case-control studies this was the supplement dosage that had been investigated additional to dietary intake and it was the common amount of folic acid available in nutrient supplements [D086-5/5/94, Expert Panel draft minutes 2\textsuperscript{nd} meeting].

iii) The uncertain role of other nutrients
The Expert Panel report notes the interest in the potential synergistic role of vitamin B\textsubscript{12} in reducing the risk of NTDs. The Expert Panel’s response to this uncertainty was to suggest that this matter required further research (National Health and Medical Research Council 1994).

iv) The uncertain prevalence trend of NTDs
The Expert Panel report does not identify as a dilemma the potential declining prevalence of NTDs irrespective of folate fortification. Instead the report presents data of the prevalence of NTD rates in selected countries as ecological evidence for the effectiveness of folate fortification (National Health and Medical Research Council 1994: 7). The report claims that there had been a decrease in NTD rates over the previous two decades in England, Wales and the US but not in Australia. The inference was that rates were lower in England and Wales and the US because folate fortification had been permitted in these countries. However, this interpretation of trends in NTD rates in Australia and other countries over the past two decades was
flawed. The report’s presentation of data on rates acknowledges that in contrast to the Australian data, the calculation of the US, English and Welsh rates did not routinely include the significant contribution of terminations. The report indicates that Scotland has a higher NTD rate (3.36/1000 births) than Australia (1.6-2.01/1000 births), but fails to mention that the Scottish population generally had access to the same folate fortified food products available in England and Wales. Moreover, folate fortified food products generally were not widely available in the US, England and Wales until the late 1980s, approximately 15 years after the trend in the reduction in NTD prevalence was first observed in these countries.

v) Potential safety concerns with consuming pharmacological doses of folate

The safety implications of increasing the dietary folate intake of the target group and the general population were assessed in two separate reviews of the scientific literature that were prepared for the Expert Panel. The first review assessed the potential safety implications of interactions between folate and zinc metabolism; folate and folic acid antagonist drugs; and folate and anticonvulsant drugs. This review was conducted by a senior Australian toxicologist and prepared as a background paper for the Expert Panel’s deliberations [D089-19/5/94, Expert Panel background papers for 3rd meeting]. The review concluded, “... the published literature and the experience of countries where food fortification has been practised for some years indicate that the incidence of significant adverse reactions is minimal.”

The second review focussed on assessing the potential safety implications associated with the relationship between folate and vitamin B₁₂ and the masking of the symptoms of pernicious anaemia. This review claimed that the safety concerns were over-stated and that the evidence for the potential concern that folic acid masks the symptoms of pernicious anaemia was founded on studies that were conducted nearly 50 years previously and using megadoses (5 mg or more) of folic acid. The review was included as an appendix in the Expert Panel’s report and concluded that these findings are of minimal practical significance as it is standard training for doctors to assess serum vitamin B₁₂ levels (National Health and Medical Research Council 1994).
According to the chairperson of the Expert Panel, he conducted his own literature review of the potential risks of increased dietary folate intake and emailed colleagues for their expert opinion. The Chairperson commented that some haematologists reported concerns, but these concerns were never based on actual cases [3/7]. Nevertheless, the Expert Panel did set a safe upper limit of intake of 1000 µg folate a day for all population groups in recognition of the FDA’s conclusions on this matter (Food and Drug Administration 1993).

The Expert Panel’s report comments that the published literature and the history of use without harm observed from the experiences of other countries where food fortification with folate has been implemented for some years indicates that folate fortification results in little or no adverse reaction. As one Expert Panel member recalled, “People were drawing on overseas experience and saying well they’ve had folate in the United States as a voluntary thing in breakfast cereals for ages what’s your problem? there’s no death in the streets.” [117/11]. The Expert Panel’s report concludes that folate is generally a safe nutrient and non-toxic to humans.

7.2.3 The rationalisation of the dilemmas associated with translating the epidemiological evidence into public health policy

According to the report of the Expert Panel, the following options for reducing the incidence of NTDs were considered (National Health and Medical Research Council 1994):

- Nutrition education to encourage women to consume foods rich in folate.
- Mass supplementation of women intending to become pregnant.
- Mandatory fortification.
- Voluntary fortification.

The draft minutes of the Expert Panel’s meetings (no final version of the minutes for each meeting was prepared), indicate that the consideration of the different policy options available to reduce the prevalence of NTDs was restricted to a sub-component of one agenda item on one day of the Expert Panel’s meetings [D082, D086-29/4/94 and 5/5/94, Expert Panel draft minutes 1st and 2nd meetings]. The Expert Panel’s report devotes less than one page to explaining the consideration of
the policy options. There is no evidence to indicate that the specific policy option of maintaining the status quo while waiting until more evidence became available from a trial or from overseas experience was contemplated by the Expert Panel. The researcher attended the third and final meeting of the Expert Panel in place of another member of the NFA staff. At this meeting the Chairperson explained to members of the Expert Panel that their purpose was to focus exclusively on determining the foods that should be fortified, the fortification levels and whether the fortification should be mandatory or voluntary [FN-19/5/94, Expert Panel 3rd meeting].

An outcome of focussing almost exclusively on folate fortification was that the Expert Panel did not undertake a risk-benefit assessment of each of the policy options. As one of the epidemiologists on the Expert Panel acknowledged,

“That was a bit of a guess a bit of a worry, it would have been nice to have known ... [the risks and benefits] ... I still don’t know whether we’re talking about preventing 3 cases of Spina Bifida or 33 or 303. ... we never actually did a proper modelling of the risks and benefits” [I9/3-6].

Instead a crude assessment of economic costs that would be averted if the estimated number of cases of preventable NTDs was achieved was undertaken. It was estimated that approximately $2.3 million dollars in total costs could be averted each year by increasing the folate intake of the population (National Health and Medical Research Council 1994). This estimate was conservative, as it did not include costs of special education, costs beyond 10 years of age or emotional and social costs. Conversely, the assessment made no attempt to calculate the costs associated with potential risks from folate fortification.

Rather than conducting a risk-benefit assessment of each policy option the decision-making process was informed by assumptions about the likely effectiveness of each of the policy options. The assumptions that the Expert Panel made for each of the policy options were:
i) Nutrition education
According to the report of the Expert Panel, nutrition education alone would be unlikely to reach those groups most in need and as such it concluded that, "... this strategy will not be effective on its own." (National Health and Medical Research Council 1994: 15). The evidence that was used in reaching this conclusion is not apparent from the Expert Panel's report. The draft minutes of the Expert Panel's second meeting reports that only three options for reducing the incidence of NTDs were discussed and these did not include nutrition education [D086-5/5/94, Expert Panel draft minutes 2nd meeting].

ii) Mass supplementation of women intending to become pregnant
The Expert Panel questioned the likely effectiveness of a folate supplementation program to reduce the risk of NTDs on the basis of the proportion of pregnancies that are unplanned. According to a member of the secretariat for the Expert Panel, mass supplementation and nutrition education policy options were considered, but, "It really came down to the critical time frame to take folate ... and the fact that so many women ... don't plan the pregnancy and don't know they're pregnant ... we kept coming back to that all the time." [I16/8]. Curiously, the report of the Expert Panel claimed support for this assessment that mass supplementation would be ineffective by citing a paper in which the author had explicitly concluded that folate supplementation was the preferred policy response to the folate-NTD evidence.35

iii) Mandatory fortification
According to the draft minutes of the Expert Panel's second meeting, mandatory folate fortification of food products was a problematic policy option due to the lack of overseas experience with this option, technical difficulties with analysis and potential resistance from the food industry [D086-5/5/94, Expert Panel draft minutes 2nd meeting]. The Chairperson of the Expert Panel explained that a recommendation for mandating folate fortification would not have been politically expedient, he commented,

35 Page 13 of the Expert Panel's report misrepresents the conclusions of Rush (Rush 1994)
“My preference all the way through was to make the fortification compulsory make it a stronger case, but to have argued that under that political climate probably wouldn’t have succeeded, or if it had succeeded would have had to have a couple more rounds at public consultation and might have taken another year or two.” [13/2].

A commonly cited reason for not recommending mandatory folate fortification was the criticism that the NHMRC had received from bread manufacturers in response to its decision to mandate thiamin fortification of bread making flour as an intervention to reduce the risk of Wernicke-Korsakoff syndrome in 1991 (see Chapter 6). As the food industry representative on the Expert Panel commented, food manufacturers “... were a little bit wary of flour-based products being used as a vehicle for whatever nutrient was flavour of the month” [110/2].

An internal DHSH briefing paper expanded upon the Expert Panel’s concern regarding potential resistance from the food industry with the comment, “Industry were very sensitive to issues related to the addition of vitamins and minerals to foods and the panel did not want to inflame the situation by recommending mandatory fortification” [D174-25/9/95, DHSH briefing paper for NHMRC Chairperson]. The briefing paper also cited concerns raised by consumer groups that fortification was a form of ‘medicalising’ the food supply. The conclusion presented in the briefing paper was that voluntary fortification offered a satisfactory compromise.

iv) Voluntary fortification

In recommending voluntary fortification as the preferred policy option the report of the Expert Panel states,

“In weighing up the many technical and economic issues that may result from a recommendation for fortification, the Expert Panel decided that voluntary fortification would be the most appropriate first step. This will allow those manufacturers who are ready to fortify to do so ... and permit other manufacturers to undertake the appropriate research for their products.” (National Health and Medical Research Council 1994: 28-29).
The Expert Panel members sought additional evidence for potential benefits of folate fortification, including the possible role of folate in preventing heart disease, anaemia and dementia and according to the Chairperson of the Expert Panel, "They just added icing to the cake." [I3/4]. The Expert Panel’s report notes the following advantages for voluntary folate fortification:

- "All women in the target population, regardless of economic or educational status, would have access to more dietary folate.
- Folate intakes would be increased without the need to change food selection practices or to remember to take a supplement.
- Folic acid would be provided in a continuous and passive manner.
- Folate deficiency in the elderly would be prevented and corrected.
- The nutritional status of other population subgroups, such as disadvantaged groups and Aboriginal and Torres Strait Island peoples, would be improved.
- The risk of colorectal adenoma in men and women may be lowered" (National Health and Medical Research Council 1994: 24).

Two surveys investigating knowledge about folate and nutrient supplement usage were conducted to provide data that would assist in assessing the accuracy of the Expert Panel statements that nutrition education and the promotion of mass supplementation for the target group were likely to be ineffective in reducing the risk of NTDs. The surveys were conducted in August 1995 and February 1996 to coincide with the time period when the folate fortification policy was announced.

Table 7.1 presents descriptive data from the combined surveys for knowledge about folate and folic acid-containing supplement behaviour for population sub-groups defined according to sex, age and State of residence characteristics. In 1995-96, almost half of Australian adults (44.6%) had not heard of folic acid or folate and only 10.8% knew that it helped to prevent birth defects. A much higher proportion of men, than women, had not heard of folate and for both men and women the proportion of adults who had not heard about folate was highest in the youngest and oldest age groups. The proportion that had heard of folate was highest (~67%) in Western Australia (WA) and the Australian Capital Territory (ACT). Victoria was the only State in which more than 50% of adults had not heard of folate. In sub-groups in
which a higher proportion of adults was aware of folate, the proportion that knew why folate was important for women of childbearing age was also higher. The proportion of adults aware of the relationship between folate and NTDs exceeded 20% only in women aged 25-44 years (23.6%) and in residents of WA.

The proportion of women who had taken a supplement containing folic acid (10.0%) was twice that for men (5.0%) and for both men and women this proportion increased with age, except for those aged 65 and over. The proportion that had taken a supplement containing folic acid was highest in Queensland and WA and significantly below the average for all States in Tasmania.
Table 7.1  Knowledge about folate and use of folic acid supplements in
Australian adults by age, sex and State of residence

<table>
<thead>
<tr>
<th>Sub-group</th>
<th>Number in sample</th>
<th>Population weighted prevalence&lt;sup&gt;(a)&lt;/sup&gt; (%)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Had not heard of folic acid/folate</td>
<td>Had heard of folic acid/folate:</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Helps to prevent birth defects</td>
</tr>
<tr>
<td>Sex</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>289</td>
<td>69.1*</td>
<td>2.6*</td>
</tr>
<tr>
<td>25-44</td>
<td>974</td>
<td>47.8</td>
<td>8.5*</td>
</tr>
<tr>
<td>45-64</td>
<td>687</td>
<td>56.0*</td>
<td>4.5*</td>
</tr>
<tr>
<td>65 and over</td>
<td>399</td>
<td>63.7*</td>
<td>2.8*</td>
</tr>
<tr>
<td>18 and over</td>
<td>2349</td>
<td>55.6*</td>
<td>5.7*</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24</td>
<td>290</td>
<td>38.8*</td>
<td>7.4*</td>
</tr>
<tr>
<td>25-44</td>
<td>1394</td>
<td>22.9*</td>
<td>23.6*</td>
</tr>
<tr>
<td>45-64</td>
<td>828</td>
<td>32.9*</td>
<td>14.0*</td>
</tr>
<tr>
<td>65 and over</td>
<td>561</td>
<td>59.4*</td>
<td>5.7*</td>
</tr>
<tr>
<td>18 and over</td>
<td>3073</td>
<td>33.8*</td>
<td>15.7*</td>
</tr>
<tr>
<td>State of residence</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New South Wales</td>
<td>971</td>
<td>45.2</td>
<td>10.8</td>
</tr>
<tr>
<td>Victoria</td>
<td>964</td>
<td>53.5*</td>
<td>6.7*</td>
</tr>
<tr>
<td>Queensland</td>
<td>721</td>
<td>39.1*</td>
<td>9.2</td>
</tr>
<tr>
<td>South Australia</td>
<td>681</td>
<td>39.3*</td>
<td>14.4*</td>
</tr>
<tr>
<td>Western Australia</td>
<td>666</td>
<td>33.3*</td>
<td>20.2*</td>
</tr>
<tr>
<td>Tasmania</td>
<td>502</td>
<td>47.2</td>
<td>8.7</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>375</td>
<td>38.0*</td>
<td>15.9*</td>
</tr>
<tr>
<td>Australian capital Territory</td>
<td>542</td>
<td>32.7*</td>
<td>19.3*</td>
</tr>
<tr>
<td>All adults</td>
<td>5422</td>
<td>44.6</td>
<td>10.8</td>
</tr>
</tbody>
</table>

* Prevalence statistically significantly different from that for all adults P < 0.05

(a) Weighting factors provided by the Australian Bureau of Statistics are used to adjust the sample data to provide population estimates which minimise the effects of non-response bias on the age-sex-area distribution of the sample relative to that of the total population.
Data on the median folic acid and vitamin B\textsubscript{12} intake of Australian adults who had consumed a folic acid and/or vitamin B\textsubscript{12}-containing supplement on the day before the survey are presented in Table 7.2 according to the type of supplement consumed. Of the 578 individuals who had taken either a folic acid or vitamin B\textsubscript{12}–containing supplement, only 48 had consumed a supplement that contained folic acid without B\textsubscript{12}. This represented less than 1 percent of the population and only 1.6% of the target group. By contrast, 6.7% of the population and 8.8% of the target group had consumed a supplement that contained both folic acid and vitamin B\textsubscript{12}. The median intake of folic acid from supplements without B\textsubscript{12} was 300 µg per day compared with 200 µg from folic acid supplements that also contained B\textsubscript{12}. Overall, the median intake for those who consumed a folic acid-containing supplement was 200 µg both in men and women, and ranged from 20 µg to 15,000 µg.

In all sex and age sub-groups the proportion that had consumed a supplement containing vitamin B\textsubscript{12} was higher than the proportion that had consumed a supplement containing folic acid. The proportion of women who had a consumed a folic acid and/or vitamin B\textsubscript{12} supplement was approximately twice that for men irrespective of whether the supplement contained folic acid, vitamin B\textsubscript{12} or both folic acid and B\textsubscript{12}. In those who consumed a folic acid and vitamin B\textsubscript{12}–containing supplement on the day before the survey the median intake of vitamin B\textsubscript{12} was 25 µg compared with only 6 µg in those who had taken a supplement that contained only vitamin B\textsubscript{12}. 
<table>
<thead>
<tr>
<th>Group</th>
<th>Age (years)</th>
<th>Folic acid without B&lt;sub&gt;12&lt;/sub&gt;</th>
<th>Folic acid and B&lt;sub&gt;12&lt;/sub&gt;</th>
<th>B&lt;sub&gt;12&lt;/sub&gt; without folic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>No.</td>
<td>Percent of group</td>
<td>Folic acid (µg)</td>
</tr>
<tr>
<td>Male</td>
<td>18-44</td>
<td>6</td>
<td>0.5</td>
<td>225</td>
</tr>
<tr>
<td></td>
<td>45 and over</td>
<td>2</td>
<td>0.2</td>
<td>325</td>
</tr>
<tr>
<td></td>
<td>18 and over</td>
<td>8</td>
<td>0.4</td>
<td>250</td>
</tr>
<tr>
<td>Female</td>
<td>18-44</td>
<td>27</td>
<td>1.6</td>
<td>300</td>
</tr>
<tr>
<td></td>
<td>45 and over</td>
<td>13</td>
<td>0.8</td>
<td>300</td>
</tr>
<tr>
<td></td>
<td>18 and over</td>
<td>40</td>
<td>1.2</td>
<td>300</td>
</tr>
<tr>
<td>All adults</td>
<td>18 and over</td>
<td>48</td>
<td>0.8</td>
<td>[60-15000]</td>
</tr>
</tbody>
</table>
Combined data from the August 1995 and the February 1996 survey on the proportion of Australian adults who took one or more nutrient supplements during the day before the survey and during the previous two weeks are presented in Table 7.3. Overall 23.8% of the adult population had taken at least one nutrient supplement on the day before the survey and 30.0% had taken at least one supplement during the two weeks before the survey. These data indicate that a significantly higher proportion of women than men took one or more supplements both on the day before the survey and during the two weeks before the survey. The percentage of men taking a nutrient supplement did not differ with age, whereas there were age-related differences in women. In young women, aged 18-24 years, the prevalence was lower and in older women, aged 45-64 years, it was significantly higher and different from the average.

Table 7.3  Percent prevalence and [95% confidence interval] for a nutrient supplement intake by sex and age

<table>
<thead>
<tr>
<th>Sex</th>
<th>Age</th>
<th>Number in group</th>
<th>Consumed a nutrient supplement yesterday</th>
<th>Consumed a nutrient supplement in the last two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>18-24 years</td>
<td>289</td>
<td>17.4 [13.0-21.8]</td>
<td>25.2 [20.2-30.2]</td>
</tr>
<tr>
<td></td>
<td>25-44 years</td>
<td>974</td>
<td>17.7 [15.3-20.1]</td>
<td>25.2 [22.5-27.9]</td>
</tr>
<tr>
<td></td>
<td>45-64 years</td>
<td>687</td>
<td>19.6 [16.6-22.6]</td>
<td>24.6 [21.4-27.8]</td>
</tr>
<tr>
<td></td>
<td>65 years and over</td>
<td>399</td>
<td>18.0 [14.2-21.8]</td>
<td>21.3 [17.3-25.3]</td>
</tr>
<tr>
<td>Males all ages</td>
<td>2349</td>
<td></td>
<td>18.2 [16.6-19.8]*</td>
<td>24.5 [22.9-26.1]*</td>
</tr>
<tr>
<td>Female</td>
<td>18-24 years</td>
<td>290</td>
<td>20.3 [15.7-24.9]</td>
<td>25.2 [20.2-30.2]</td>
</tr>
<tr>
<td></td>
<td>25-44 years</td>
<td>1394</td>
<td>28.3 [25.9-30.7]</td>
<td>37.2 [34.7-39.7]</td>
</tr>
<tr>
<td></td>
<td>45-64 years</td>
<td>828</td>
<td>34.9 [31.7-38.1]*</td>
<td>39.7 [36.4-43.0]*</td>
</tr>
<tr>
<td></td>
<td>65 years and over</td>
<td>561</td>
<td>29.9 [26.1-33.7]</td>
<td>32.0 [28.1-35.9]</td>
</tr>
<tr>
<td>Females all ages</td>
<td>3073</td>
<td></td>
<td>29.3 [27.3-31.3]*</td>
<td>35.3 [33.7-36.9]*</td>
</tr>
<tr>
<td>Total</td>
<td></td>
<td>5422</td>
<td>23.8 [22.7-24.9]</td>
<td>30.0 [28.8-31.2]</td>
</tr>
</tbody>
</table>

*Sub-groups for which the prevalence was statistically significantly different from the overall prevalence.
The analysis of the data collected from the nutrient supplement survey identified that at the time of the decision-making process, the average intake of folic acid from supplements was 10.8 μg in men, 28.3 μg in women and 29.7 μg in the target group. The low contribution of folic acid-containing supplements to average total intake of folate was primarily due to the low level of supplement use. The data indicate that only 10.4% of women aged 18-44 years consumed a folic acid-containing supplement on the day before the survey. This proportion is substantially lower than that recorded by a national survey in the US that found that 32.2% of the target group consumed folic acid-containing vitamin supplements (CDC 1998). The proportion taking a folic acid only supplement was much lower and comparable with ~2% in the 1995 NNS (Australian Bureau of Statistics 1997) and 2.7% from a survey conducted in Ireland during the same period (Sayers et al. 1997) for consumption of folic acid only supplements.

Relative to the RDI of 200 μg for adults and the additional 400 μg recommended by the NHMRC for women of child-bearing age the average intake of folic acid from supplements was small. The average intake of folic acid from supplements was also small when compared with intake from food. According to data collected in the 1995 NNS, the mean intake of folic acid from food was estimated to be 307 μg for men and 233 μg for women in 1995 (Australian Bureau of Statistics 1997). On average nutrient supplements contributed only approximately 3% and 11% towards the total folate intake for men and women respectively and only 11% to the total folate intake for women of child-bearing age.

The median contribution of folic acid-containing supplements to the folate intake of women who consumed them was 200 μg per day. This figure is consistent with the daily median folic acid intake of 200 μg for women reported in an earlier study of Australian adults (Baghurst 1989). At the time of the decision-making process, women whose diet provided 233 μg of folate (the average intake) and who consumed a supplement containing folic acid on a daily basis achieved an intake of around 400 μg per day (the RDI for pregnancy) and not the 600-700 μg proposed by the NHMRC as the mean target intake for women of childbearing age.
The data on knowledge of folate and use of folic acid-containing supplements among the target group provide equivocal evidence of the likely effectiveness of nutrition education and mass supplementation as policy options to increase the dietary folate intake to levels recommended by the Expert Panel. The data indicate that both knowledge of folate and folic acid-containing supplement usage were low at the time of the surveys and unlikely to have a significant impact on the folate intake of the target group. Alternatively, at this time there had been no national and few state education campaigns implemented to inform individuals about the relationship between folate and NTDs and the importance of consuming folic acid supplements.

The only substantial education campaign that had been implemented was a statewide health promotion project for the prevention of NTDs in WA from mid-1992 until March 1995 (Bower et al. 1996). It is relevant to consider therefore that the proportion of adults who had heard about folate and its relationship with NTDs was higher in WA than in any other State. This finding is supported by a longitudinal study that has reported a significant increase in knowledge and supplement intake after the 2.5 year WA promotion campaign (Bower et al. 1997). The data from the present survey indicate that the use of folic acid-containing supplements increased with increasing knowledge, for example, folic acid supplement use is also high in WA relative to most other states.

### 7.4.4 The planning of the folate fortification policy intervention

Once voluntary folate fortification was recommended by the Expert Panel as the policy option in response to the folate-NTD evidence a substantial amount of work was undertaken to plan how to implement the policy intervention. The challenge with the planning of the intervention was to determine what food vehicles should be fortified and at what level of fortification to deliver the recommended amount of folate to the target group while not over-exposing the target or other population subgroups. The Expert Panel estimated the likely impact of folate fortification on the mean and distribution of folate intakes by interpreting information made available from dietary modelling activities undertaken by the Nutrition Sections of the NFA and the DHSH.

Dietary modelling is a technique that draws on knowledge of existing dietary intake patterns and assumptions about anticipated intake patterns to prepare estimates, or
'virtual' measurements, of the impact of changes in the nutrient composition of food products on the future dietary intake of population groups (Rosenberg 1999). The quality of dietary modelling data for informing policy-making depends on the assumptions made about the design and interpretation of the procedure and assumptions about the databases that are used. The following section assesses the Expert Panel's assumptions associated with the use of dietary modelling data.

i) Analysis of assumptions regarding the design and interpretation of the dietary modelling procedure

The policy recommendations prepared by the Expert Panel were based on estimates of dietary folate intakes for the target and other population groups from two separate dietary modelling activities prepared by the Nutrition Sections of the NFA and the DHSH. The NFA was responsible for undertaking dietary modelling activities that simulated the impact on dietary folate intake from the fortification of combinations of staple food products at either 25% or 50% of the folate RDI per reference quantity. The preliminary findings from these activities by the NFA indicated that at a fortification level of 50% RDI of staple foods, women aged 25-34 years would be consuming a mean folate intake of 500 µg a day, with intakes of approximately 290 µg a day and 730 µg a day at the 10th and 90th percentiles respectively (National Health and Medical Research Council 1994). The Expert Panel concluded that, "At the levels of increased folate proposed there is no foreseeable risk to any population group." (National Health and Medical Research Council 1994: viii).

The Nutrition Section of the DHSH estimated the effect of fortification at either 25% or 50% of the RDI per reference quantity on the dietary folate intake of consumers who follow public health nutrition advice as represented by the 'core food groups'. This modelling indicated that if the recommended number of servings for each of the food groups was consumed most population sub-groups would not exceed the 1 mg upper level of safety for folate intake. These data were then interpreted by the Expert Panel as providing reassurance of the safety of the folate fortification intervention.

35 The 'Core food groups' was a theoretical modelling exercise undertaken by the NHMRC to translate the recommendations of the Australian RDIs and Dietary guidelines into advice about recommended amounts of food to meet at least 70 per cent RDIs and approximately half the dietary energy intake (Cashel and Jeffreson 1995).
Several queries arise in relation to the interpretation of the dietary modelling data and the assumption upon which they were based in the decision-making process. The NFA dietary modelling data that were submitted to the Expert Panel were qualified by NFA staff at the time as being preliminary. For example, the NFA was concerned that it had been provided with inadequate time to prepare the dietary modelling data that was submitted to the Expert Panel, arguing that the modelling was preliminary and more detailed dietary modelling information was to be forthcoming [D097-25/5/94, NFA response to draft minutes of 3rd Expert Panel meeting]. The subsequent and more refined modelling scenarios that were provided by the NFA to the Expert Panel were not included in the Expert Panel's report.

In a Commentary on the Expert Panel's recommendations, the NFA concluded that, "According to dietary modelling data prepared by the Authority and the DHSH, the implementation of the Council's recommendations present a potential public health and safety risk for certain population groups in Australia." [D126-June 1994, NFA Commentary on Expert Panel report, NFA24]. The NFA's concern was two-fold. Firstly, whereas the Expert Panel had based its conclusions on dietary modelling for the mean intake of population groups, it was argued that male 'high consumers' (individuals at the 90th percentile of energy intake), or those individuals who had an otherwise average diet but consumed one of the fortified foods at the 90th percentile of intake would consume more than 1 mg of folate per day. In the commentary it was acknowledged that the policy recommendations were voluntary and the modelling was assuming all staple foods would be fortified. Nevertheless, the commentary argued that the modelling was conservative, because:

- It did not account for the contribution of folic acid from nutrient supplements to total folate intake.
- The 24 hr recall food consumption data inherently underestimates food intake (Mertz 1992; Hegsted 1993).
- The folate content of Australian foods was based on a combination of US and UK food composition data. These composition data have been reported as underestimating folate content in the US (Bailey 1992) and in the UK (Phillips et al. 1982).
- The modelling could not anticipate any increase in consumption of fortified foods once they were promoted.
Secondly, the NFA commentary noted that the core food groups exercise was calculated to account for only approximately half the dietary energy intake, i.e. it allows for the inclusion of additional food in the diet. As the dietary modelling based on the core food groups calculated that several population groups approached that upper level of safety for folate, the NFA was concerned that when the additional food consumption was taken into account the upper safety level would be exceeded. Also, it was noted by the NFA that the core food groups do not allow for any serves of fruit and vegetable to be considered as juice, that is, it was assumed that these serves would not be fortified [D126-June 1994, NFA Commentary on Expert Panel report, NFA24].

ii) Analysis of assumptions associated with the use of databases

The dietary modelling procedure required data about existing folate composition of food products and folate intakes of the target group and other population sub-groups. These data were not available to the Expert Panel at the time of the policy-making process. The dietary modelling activities were based on dietary intake data derived predominantly from the 1983 National Dietary Survey of Adults (Cashel et al. 1986). The existence of the 1995 NNS and the nutrient supplement surveys mean that more complete data of total folate intake at the time of the decision-making process are now available and the accuracy of the dietary modelling activities can be assessed.

Using a similar dietary modelling procedure to that undertaken by the NFA, the National Food and Nutrition Monitoring Unit (NFNMU) has revised anticipated folate intakes resulting from food fortification by drawing on data from the 1995 NNS, but not including nutrient supplement data. The NFNMU's findings are that for the target group the pre-fortification mean folate intake is 229 µg and with universal 50% RDI folate fortification of staple foods the mean folate intake would be 479 µg. These data are comparable with the 244 and 500 µg respective findings estimated using the 1983 database (Abraham and Webb 2000).

The NNS did not quantify the contribution of nutrient supplements to dietary intake. Also, the Expert Panel report identified that supplements had not been included in the calculations. As indicated in Table 7.2, the data collected from the nutrient
supplement surveys highlight that at the time of the decision-making process, the average total intake of folate from food and supplements was well below the 1 mg level set by the Expert Panel as the upper level of safety for the intake of individuals. Seven participants (0.1%) had taken in excess of 1 mg of folic acid on the previous day but only one of these participants was aged 65 and over. The average intake of vitamin B₁₂ from supplements (2.6 μg for men and 4.5 μg for women) exceeded the RDI of 2 μg per day for both men and women. Moreover, nutrient supplements that contained folic acid also generally contributed at least the RDI for vitamin B₁₂ in all age and sex sub-groups, including the elderly who are particularly vulnerable to the masking of vitamin B₁₂ deficiency by folate supplements.

The quantitative data indicate that at the time of the decision-making process the assessment that there was a need to increase the folate intake of the target group was reasonable if the Expert Panel’s target of an additional 400 μg was to be met. Also, the dietary modelling procedure notwithstanding, the revised data indicate that it is unlikely that the 1 mg upper level of safety for folate intake would be exceeded for the target or other population sub-groups when more recent dietary intake data and the contribution of folate from nutrient supplements are taken into account.

7.5 Identification of themes

In this section the data describing what happened at the decision-making process level of the food regulatory system are interrogated to identify themes that offer insights for answering the questions posed at the conclusion of the review of the case study.

7.5.1 The perception of the scientific uncertainties and ethical dilemmas associated with the epidemiological evidence

The data consistently highlight that those individuals involved in the decision-making process regarded the epidemiological evidence as overwhelming and the selection of folate fortification as the policy response was a relatively simple and straightforward decision. As the Director of the NHMRC’s Public Health Committee (PHC) at the time observed,
“This is totally good news, mums and babies and spina bifida and I don’t recall any discussion saying, “well this is setting a bad precedent to fortify with folate”, because I think that the evidence put to us was that this was a totally harmless thing.” [115/8].

This observation was shared by one of the Expert Panel’s epidemiologists who commented that there, “... didn’t seem to be any down side ... there were substantial benefits and virtually no identifiable risks ... folate was a pretty simple question” [19/3-9].

The NHMRC News release to the media announcing its policy recommendations stated, “We have the opportunity to provide a simple response to a complex and tragic problem. It’s an opportunity we can’t afford to miss” [D108-2/6/94, NHMRC News release, ‘Folate should be in our food to protect babies against spina bifida’]. Similarly, the Director of the PHC at the time commented,

“... if there’s a non-toxic and non-dangerous thing where you can fortify the folate in foods and breakfast cereals ... people are not going to overdose on cornflakes. ... everybody agrees ... you had a particularly emotional outcome. It was really obvious something with a pretty serious condition which could in theory ... be almost totally prevented” [115/5].

The policy options of nutrition education and the promotion of folate supplements were assumed to be costly, inequitable and likely to take a long time to then have a questionable effectiveness. For example, the Director of the PHC made the further comment that,

“... if you’ve got a good news story, where you can take some action ... through legislation ... you don’t have to go down the health education track of every new generation of mothers you’ve got to persuade them to eat more greens. Life’s complicated enough as it is. So if you can do something safe and simple and its like having road signs or seatbelts that’s just engineered into life. People don’t have to worry about the folate, that’s taken care of. ... let’s move onto the harder things. This was a relatively easier thing to do.” [15/9].
Among Expert Panel members there was a general lack of acknowledgement that there were stakeholders opposed to folate fortification. The day after the NHMRC had accepted its Expert Panel’s recommendations the Chairperson of the Expert Panel conducted two radio interviews informing radio listeners of the NHMRC policy recommendations. In response to a question from the interviewer asking ‘Why was folate fortification a vexed issue?’ the Chairperson of the Expert Panel responded, “I didn’t realise it was such a vexed issue. Other countries have been doing it for some time.” [D110-3/6/94, transcript of Jeremy Cordeaux radio program]. Later that day in response to a similar question from another interviewer he responded,

“Other countries have added folate to their food supply for a number of years and have shown that this does reduce the incidence of defects ... I don’t think that there could be any groups that would be lobbying against folate.” [D112-3/6/94, transcript 2RN radio program].

There was a general sense among the Expert Panel members that folate fortification had been widely accepted internationally and that this option was no longer a novel approach. As one of the Expert Panel’s epidemiologists commented,

“... everywhere the recommendations were flowing freely ... Australia wasn’t out on a limb here and other places already had foods fortified so it wasn’t that we were taking an outlandish step ... safety issues had already been addressed elsewhere.” [15/5].

Conversely, the Chairperson of the NFA at the time commented that the Authority had believed that developments in the international arena were generally supportive of the NFA’s policy response opposing folate fortification. For example, she recalled, “The NFA was looking to Canada particularly in relation to folate because Canada had recently reviewed the issue and decided against fortification” [12/38].
7.5.2 The quality of the decision-making process

The data indicate that generally the uncertainties and dilemmas with which the public health issue was associated received cursory attention or were not acknowledged in the decision-making process. The perception of the former Chairperson of the NFA was that, “The risks either did not get mentioned, or were trivialised.” [12/5]. Indeed, so assured was the Expert Panel about its assessment process that its report included the statement, “Because the Panel concluded that the addition of folate to specific foods at the proposed levels poses no foreseeable risk to any population subgroup, it is unnecessary to monitor vitamin B₁₂ deficiency in the elderly.” (National Health and Medical Research Council 1994: 31). There is no evidence that the Expert Panel identified risks of potential harm beyond immediate safety impacts on individuals.

As a member of the Expert Panel’s secretariat observed,

“If you do the process properly and you go through adequate consultation then perhaps you take those issues [uncertainties and dilemmas] into account more, but because we were so pressured by time, and we didn’t consult, I just don’t think that was taken into account” [16/9].

This concern was reflected by the former Consumer representative on the NFA Board who believed that the decision-making process inappropriately confined itself to the technical aspects of the policy issue and overlooked the broader principles,

“There’s a problem for stakeholders in that the issues become so complex and so technical that it’s very difficult to get to the principles that are underlying it because you can get bogged down in the technicalities of the decision and the principles are not so readily accessible ... [folate fortification] ... does set a precedent for making decisions in a non-scientific way, in a way that is not consistent with generally accepted public health principles.” [18/5-9].

Despite the scientific uncertainties, the decision-making process erred on the side of intervening, rather than adopting a more cautious approach. Although supportive of the policy outcome, each of the two epidemiologists on the Expert Panel expressed reservations about the process by which the scientific evidence was reviewed and interpreted. As one of the epidemiologists commented,
"I felt in quite a difficult position really because I was the one supposedly with lots of the information and yet I didn't think we had enough time to digest that or argue with me, you know. I mean I could have said anything really and it seemed to have been accepted." [15/9].

The other epidemiologist expressed concern that too much reliance was placed on the Expert Panel members, rather than the secretariat, to prepare the background reading and to quantify the arguments. This epidemiologist commented,

"There was no attempt to summarise the literature for us. I certainly didn't have time ... I know I was one of the scientific experts, but I simply didn't have time. I knew enough to know that I wasn't in tiger country" [19/9].

Thus, even when the use of evidence was confined to technical risk analysis and planning procedures there were doubts about the quality of the process associated with collecting, analysing and applying the evidence.

7.6 Assessment

This chapter has presented the results of the analysis of the case study from the perspective of the decision-making process level of the food regulatory system to provide insights into the use of evidence in the policy-making process. The analysis was guided by a series of questions that were posed at the conclusion of the review of the case study. In this section I assess the data and the themes that emerged from the analysis for the contribution they make to explaining the policy outcome and to reveal clues for potential further policy analysis.

The data indicate that the decision-making process was informed by a relatively systematic review of a substantial amount of epidemiological evidence. Also, scientific experts prepared literature reviews of the major safety concerns that had been identified for excessive exposure of individuals to folate. Once the voluntary folate fortification policy option was selected, the Expert Panel focussed on
undertaking a risk analysis process to plan the technical details of the policy recommendations.

Generally, the Expert Panel viewed the decision-making process as simple and straightforward and did not acknowledge or address the scientific and ethical dilemmas with which it was associated. Essentially the decision-making process was conducted as a technical exercise to identify food vehicles and fortification levels that would enable the target group to consume a recommended dose of folate while not over-exposing the population as a whole to an excessive folate intake.

There were various oversights, errors and assumptions associated with the technical planning of the policy. Oversights included failing to conduct a thorough assessment of the different policy options and thereby failing to undertake a risk-benefit analysis and neglecting to consult with stakeholders. Errors related to the incorrect interpretation of ecological data and conclusions reported in the literature relating to this policy matter. Assumptions included the anticipated effectiveness of the different policy options, the ability of the selected food vehicles and level of fortification to achieve levels of dietary folate exposure consistent with efficacy and safety criteria, and the positive interpretation of policy recommendations of selected other countries.

The results of the analysis of the more comprehensive quantitative data that are now available, i.e. data from the nutrient supplement survey and the NNS, provide equivocal support for the Expert Panel’s assumptions about the effectiveness of different policy options. Also, the quantitative data indicate that the dietary modelling assumptions and estimates for setting targets and assessing potential safety concerns associated with the technical planning were not unreasonable in determining the need for the target group to increase its folate intake. These data do support the assumption that the upper level of safety would not be exceeded. Irrespective of these findings it is not clear why the Expert Panel could not wait until more information became available or why the NFA’s extra dietary modelling was not considered. It would appear that the Expert Panel was driven by an overwhelming need to be seen to be doing something and to secure an outcome, rather than necessarily undertaking a thorough decision-making process in reviewing all the policy options available.
It is possible that the explanation for the observations was that the decision-making process undertaken by the Expert Panel simply lacked rigour and the policy outcome may or may not have been the same if there had been greater rigour at this level of the food regulatory system. This explanation supports the assessment that, lack of rigour notwithstanding, it is analysis of the decision-making process alone that is sufficient to explain how and why scientific evidence was used in the policy-making process.

Alternatively, the explanation might be that the lack of rigour did not arise of its own accord and the observations reflect the existence of a more strategic pattern to the use of evidence in the policy-making process. This explanation would suggest that the decision-making process did not operate independently of influences associated with a broader policy-making process.

A deeper level of analysis is required to determine which of these explanations, on the balance of the available evidence, is the more plausible. The themes provide insights and clues into what happened in making the public health policy at the decision-making process level of analysis and raise several questions about potential influences upon this level of the food regulatory system, including:

i) Why was the Expert Panel and not the NFA responsible for undertaking the decision-making process for this food regulation policy matter?

ii) Why were the scientific and ethical dilemmas associated with the interpretation and application of the protection of public health and safety in the decision-making process generally neither acknowledged nor addressed?

iii) Why was the policy response to the folate-NTD relationship rationalised as a relatively simple technical exercise?

iv) Why did the process rely on incomplete evidence, errors and assumptions?

These questions will help guide the deeper analysis. The deeper level of analysis involves investigating the procedural level of the food regulatory system within which the decision-making process operates. The results from this level of analysis are presented in the next chapter.
CHAPTER 8

An analysis of the case study at the procedural level of the food regulatory system

8.1 Introduction

In the previous chapter the case study was analysed at the decision-making process level of the food regulatory system. The findings from this previous analysis provided many insights into the policy-making process that resulted in the folate fortification policy. A series of questions emerged to guide a deeper level of analysis of the case study. The purpose of the deeper level of analysis is to assess the relevance of these questions and to identify otherwise hidden explanatory factors to determine whether there is a more strategic pattern to explain how and why scientific evidence was used in the case study.

In accordance with Easton’s model of a political system, a deeper level of analysis into the food regulatory system requires an analysis at the procedural level of the system. The procedural level of the food regulatory system captures the requirements for processing applications and proposals to vary the food standards code. Analysis at this level can reveal insights into the arguments and actions of the stakeholders involved in the policy debate and the circumstances associated with the establishment of the Expert Panel.

In this chapter the case study is analysed from the perspective of the procedural level of the food regulatory system as the second of three analyses of the policy-making process that led to the folate fortification policy. The data that were collected from this policy analysis are presented to describe what happened with the case study at this level of the food regulatory system. The data then are interrogated to identify themes that emerge from the description to offer insights towards answering the posed questions. Finally, the data and the themes are assessed for the contribution they make to explaining the policy-making process that resulted in the folate fortification policy outcome and to reveal clues for potential further policy analysis.
8.2 Description

The first step in analysing the procedural level of the policy-making process is to identify the circumstances and stakeholders associated with placing the policy issue onto the political agenda in order to understand how the public health issue was framed.

Policy recommendations regarding folate and NTDs first appeared in Australia in June 1992 when the NHMRC published a statement on the relationship between dietary folic acid and NTDs following the recommendation of Council’s former Health Care Committee (HCC). The NHMRC Statement concluded with several recommendations that included:

- That genetic counselling and periconceptional folic acid supplementation should be offered to all women who have had a child with a NTD and who are planning another pregnancy.
- Dietary advice about folate rich foods should be offered to women who are planning a pregnancy or who are likely to become pregnant.

The Statement did not recommend fortification of food products with folate and as such did not engage directly with the food regulatory system.

Two epidemiologists from the Western Australian Research Institute on Child Health Ltd (WARICH) drafted the NHMRC policy position. It was these epidemiologists who in 1989 had published findings from a case-control study that had made a significant contribution to the pool of epidemiological evidence of the relationship between folate and NTDs (Bower and Stanley 1989).

Coincidentally, the NHMRC Statement was published during a period in which the NFA was considering the policy basis for the addition of vitamins and minerals to food products through its review of Standard A9. Standard A9 regulates the addition of vitamins and minerals to foods and the claims that can be made about the vitamin and mineral content of foods. As the report of the Expert Panel states, “At the same time that the NHMRC was considering the issue of folate and NTDs, the NFA commenced a review of Food Standard A9 – Vitamins and Minerals, which included
consideration of the vitamin, folate.” (National Health and Medical Research Council 1994: 1).

It is through its coinciding with the review of Standard A9 that the case study engaged with the review of fundamental public health policy issues associated with food composition and food labelling. In this section data are presented to describe the evolution of the policy response to the folate-NTD epidemiological evidence as it intertwined with the review of Standard A9 against the food regulatory system’s formal procedures for assessing applications and proposals (as outlined in Chapter 2).

8.2.1 Background to the review of Standard A9
Since the 1960s, the addition of vitamins and minerals to foods and claims that can be made about the vitamin and mineral content of foods have been regulated under Standard A9 of the Australian Food Standards Code. Initially, Standard A9 provided for several categories of food to be fortified with liberal and in some cases, unrestricted, amounts of up to seven vitamins and four minerals on a voluntary basis. Folate was not permitted to be added to foods. The addition both of iodine to iodised table salt to address iodine deficiency and thereby reduce the risk of goitre, and vitamins A and D to table margarines and spreads as substitute foods for butter, were mandated. Health claims on food products and in advertising were regulated under Standard A1(19) and were not permitted. Table 8.1 summarises the provisions of Standard A9 as they evolved from the 1960s to the present day. The Table highlights the effect of different versions of the Standard on the permitted addition of folate to food products and in relation to breakfast cereals to illustrate the practical implications of the Standard.

The scientific basis for the allocation of the particular vitamins and minerals to the food categories specified in Standard A9 was not readily apparent and by the late 1970s it was recognised that the standard was in need of significant reform. The process of reviewing Standard A9 was the responsibility of the former NHMRC food standards setting system and it sought to address inconsistencies and anomalies

37 NHMRC “Statement on the relationship between dietary folic acid and Neural Tube Defects such as spina bifida.” Approved by the 113th Session of the National Health and Medical Research Council, June 1992.
within the Standard. During this period there was a diversity of views among many stakeholders regarding the addition of nutrients to foods and the claims that could be made in relation to this addition. The issue remained under review for 12 years within the NHMRC food standards setting system without resolution. The review of Standard A9 was then taken over by the NFA. The review process was known as Proposal 24 – Vitamins and Minerals (Proposal 24).

When setting about its task to review Standard A9, the NFA considered it was important that a set of scientific principles be established on which the revision, and future revisions, could be based. The Authority adopted the Codex principles (Codex Alimentarius Commission 1987) as the original basis of the revision. The Codex principles and the conditions they specify for the addition of vitamins and minerals to foods are outlined in Chapter 2 of this thesis. A copy of the Codex principles is attached at Appendix 1.

In its revision of Standard A9, the NFA adopted a policy position “…predicated on conserving the inherent nutritional integrity of the food supply, through the protection of the characteristic nutrient profile of individual foods or groups of foods” [D065-27/10/93, NFA Minute to the Minister]. The NFA employed the Codex principles to capture in practical terms the concept of protecting the ‘nutritional integrity’ of food. The NFA believed that the Codex principles were consistent with the Authority’s primary statutory objective of protecting public health and safety in the setting of food standards. The NFA commented,

“Safety would be assured by setting the maximum addition of nutrients at levels comparable with those found naturally in the food prior to processing ...
Public health would be protected through the beneficial effect of safe nutrient intake on health and by minimising the risk of inappropriate fortification.”
[D131-20/7/94, Reconsideration report, p2].

8.2.2 Full assessment

In early 1992, the Authority agreed to omit to invite public submission on Proposal 24, and having regard to the prior deliberations of the NHMRC, undertook a full

---

38 On 1 January 1991, the NHMRC mandated thiamin fortification of bread-making flour at 0.64 mg/100 g flour as an intervention to reduce the risk of Wernicke-Korsakoff syndrome.
assessment of this proposal, accepted the draft revised Standard and proceeded to an inquiry. On 4 March 1992, the NFA, after the full assessment, gazetted a draft revised Standard A9 requesting written submissions on the draft by 4 September 1992. One effect of the revision was to decrease the range and quantity of vitamins and minerals permitted to be added to most individual food categories. To control the level of addition of permitted vitamins and minerals, the concept of a maximum claim was introduced. Where the reference quantity of a food contained at least 10% but less than 25% of the RDI of a vitamin or mineral, a claim could include a statement to the effect that the food is a source of that vitamin or mineral. Where the reference quantity of a food contained at least 25% of the RDI of a vitamin or mineral, a claim could include a statement to the effect that the food is a good source of that vitamin or mineral. The provisions of the revised Standard A9 are summarised in Table 8.1.

Forty submissions were received in response to the NFA's invitation for comment on the draft revised standard [D028-May, 1993, NFA 16 Preliminary Inquiry Report]. There was general agreement on the need to revise Standard A9 and to establish scientific principles. However, there was a difference of opinion regarding how these principles should be interpreted and applied. The NFA's policy position was supported by the Dietitians Association of Australia (DAA), the ACA and several senior nutritionists but was opposed by the Australian Breakfast Cereal Industry Association (ABCIA), Roche Products Pty Ltd, the PHC, the Council of the Nutrition Society and several senior nutritionists.

The arguments among those stakeholders opposing the draft revised standard were three-fold. Firstly, that significant segments of the population do not have nutritionally adequate diets. For example, the ABCIA cited advice that was provided to it by the Commonwealth Scientific and Industrial Research Organisation (CSIRO) to claim that there were nutrient deficiencies in Australia. The CSIRO had based its claims on interpretations of the proportion of the Australian population not meeting the RDIs for specific nutrients as interpreted from dietary intake data from the 1983 National Dietary Survey of adults (Cashel et al. 1986). Secondly, that there were potential health benefits to be gained from increasing the population's intake of antioxidant vitamins. Therefore for both of these arguments food fortification was regarded as necessary for public health and safety. Thirdly, the ABCIA argued that
export markets could be threatened because the proposed Standard A9 would require
dual production runs and this would increase manufacturing costs. In a detailed
submission the ABCIA requested that a reference quantity of a breakfast cereal be
permitted to be fortified to a level of 50 per cent of the RDI for 12 vitamins and
minerals [D0019-September 1992, ABCIA submission to draft Standard A9].

The specific issue of folate fortification as an intervention to reduce the risk of NTDs
was raised within the review of Standard A9 on the 4 September 1992 in a
submission to the NFA from the epidemiologists at the WARICH. The WARICH
submission sought for the NFA to recommend the fortification of a staple food, such
as bread or breakfast cereals, with folic acid at 50% RDI for non-pregnant women in
a serve [D015-4/9/92, WARICH submission to draft Standard A9].

During the comment period for the draft revised Standard A9, a professor of human
nutrition orchestrated a series of advocacy activities to lobby the NFA to change its
policy approach to food fortification. For example, the professor coordinated an
alliance of 13 senior nutritionists to sign submissions to the NFA stating their
opposition to the Codex principles as the basis to food fortification policy. The
submissions were presented in the form of identical copies of a one page statement
that began “We, the undersigned do not agree with the draft food standard A9 on
Vitamins and Minerals, released by the National Food Authority on March 4, 1992 as
applied to breakfast cereals.” [D013-3/9/92, letter from professor to Pincus]. The
signatories advocated for a Standard that would permit the addition of six vitamins,
including folate, and four minerals to breakfast cereals at 50 % of the RDI per
standard serving. Additional comment was made calling for the addition of beta-
carotene to food products as an intervention to reduce the risk of some types of
cancers or for the prevention of lung cancer in smokers in particular39. The covering
letters for the submissions were signed by the professor who commented that, “There
is widespread disagreement among nutritionists and dietitians across Australia with
the proposed standard and I would ask you to take these signatures as representative
of a much larger similar opinion.” [D013, D016-3/9/92 and 10/9/92, letter from
professor to Pincus].

39 Paradoxically, within two years clinical trials investigating the relationship between beta-carotene
and cancer were stopped prematurely as beta-carotene was reported to be associated with an increased
risk of lung cancer in smokers (Albanes et al. 1995)
8.2.3 Inquiry

Following consideration of the public comment, the NFA prepared modifications to the draft revised standard but decided that the Codex principles on which the draft revision was based should be retained. The recommendations were incorporated into a preliminary amended draft standard and a Preliminary Inquiry Report was circulated to State and Territory regulatory authorities and to those organisations and individuals who had provided submissions on the revision of Standard A9.

In response to the three general arguments that had been submitted by stakeholders opposing the draft revised standard, the NFA prepared the following comments. In relation to the evidence for the existence of nutritional deficiencies in the Australian population, the NFA expressed concern that the data from the 1983 National Dietary Survey were being misinterpreted by the ABCIA and certain scientists [D044-June 1993, Appendix 2 to Attachment 1, NFA 17]. The NFA commented that whereas dietary intake data can provide an indication of those nutrients for which the probability of nutrient inadequacy in the population is greatest, they alone cannot provide evidence of inadequate nutritional status. The NFA also commented that, as RDIs apply to the nutritional needs of population groups, they exceed the actual nutrient requirements of practically all healthy persons and are not synonymous with requirements [D027-5/2/93, 'The Food Standard', NFA].

The NFA stated that there was insufficient evidence to substantiate the potential health benefits to be gained from fortifying food products with antioxidant vitamins. In a direct retort to concerns about the potential for the revised Standard to have an adverse influence on trade, the Authority commented,

"Some industry sectors have pleaded their case on the basis that the Authority’s proposal would upset their marketing plans and in so doing hinder trade and commerce ... particularly in the breakfast cereal market. The Authority’s primary objective is public health and safety, before the commercial interests of particular marketers and industry generally. ... there is no reason for the nutritional needs of other countries to dictate the composition of food consumed by Australians." [D054-2/7/93, NFA 'Questions & Answers on Vitamins and Minerals'].
Following the submission from the WARICH, the NFA conducted a literature review of the scientific evidence to support folate fortification of foods to prevent NTDs [Preliminary Inquiry Report]. In response to the review, the NFA concluded that folate fortification was not consistent with the Codex principles as there was no inherent folate deficiency in the food supply and there was no evidence that large sections of the population were exhibiting folate deficiency. The NFA also noted that there were scientific uncertainties to consider and as such it would be premature to recommend folate fortification. Instead, the Authority recommended that a complementary nutrition education and targeted supplementation program was the preferred policy response to the epidemiological evidence. This policy option was regarded as likely to provide women of child-bearing age with greater understanding regarding their total diet and broader health outcomes, including possible NTD implications, and greater flexibility to satisfy their folate requirements without the risk that fortification may pose to other segments of the population.

Twenty submissions were received by the NFA in response to the Preliminary Inquiry Report with an equal number supporting as opposing the draft Standard. In general, consumer and health organisations, and state health departments supported the NFA’s interpretation of the Codex principles and food manufacturers and several nutritionists opposed the draft standard. Several stakeholders chose to address the issue of folate fortification within this broader political debate. The Chairperson of the Expert Panel recalled, “... it became a kind of semi-political thing, you had several fairly strong players, who shall remain nameless, urging the government to do something” [I3/3]. The NFA’s Principal Nutritionist at the time recalled that the policy-making process became “... coloured by personalities and peoples agendas. It’s very hard to get to the true scientific facts.” [I4/17].

In June 1993 the NHMRC endorsed a Revised Statement on the relationship between dietary folic acid and NTDs. The revised NHMRC Statement was prepared in response to the publication of further epidemiological evidence of the relationship between folate and NTDs and recommendations produced by the US Department of

---

40 NHMRC ‘Revised Statement on the relationship between dietary folic acid and Neural Tube Defects such as spina bifida.’ Approved at the 115th Session of the National Health and Medical Research Council, June 1993.
Health and Human Services (Department of Health and Human Services 1992) and the Expert Group to the UK Department of Health (Department of Health 1992). In addition to the recommendations previously made in the 1992 Statement, the Revised Statement recommended, "... fortification of staple foods such as bread and cereals with folic acid, as is recommended in the USA and Britain, should be introduced in Australia." The statement did not specify the food products that should be fortified, the degree of fortification or whether the fortification should be voluntary or mandatory, nor was a target intake recommended. As with the NHMRC's 1992 version, it was clinical epidemiologists at the WARICH who were responsible for drafting this policy Statement.

In its submission to the NFA addressing the folate-NTD evidence, the Health Department of Western Australia stated that it was "virtually impossible" to achieve a 100% recognition of the issue by the target group and so nutrition education was not a realistic policy option. Moreover, they stated, "... it is desirable for foods to be fortified with folate and therefore provide part of a balanced diet rather than to have to resort to recommend the intake of folate supplements in capsule form in order for individuals to reach the necessary folate intake." [D032-2/6/93, submission from WA to Preliminary Inquiry Report]. The following month the Western Australian Minister for Health wrote to the Commonwealth health minister recommending that the review of Standard A9 be amended to require the fortification of breakfast cereals with folic acid at 25% RDI per reference quantity [D053-2/7/93, letter from Foss to Richardson].

A professor of paediatrics41 was consistently identified by key informants and in documentary sources as a powerful and passionate stakeholder advocating in support of folate fortification as the preferred policy response to the folate-NTD evidence. Through her association with the WARICH she had conducted internationally recognised epidemiological research into the relationship between folate and NTDs. Also, her association with the WARICH had involved collaboration on folate promotion campaigns with the Health Department of Western Australia and this department acknowledged that this had provided the stimulus for its submission to the NFA [D032-2/6/93, submission from WA to Preliminary Inquiry Report]. It had

41 This stakeholder was one of the four of the 26 invited key informants who declined to be interviewed for this study.
been this professor in collaboration with one of her colleagues at the WARICH who had been responsible for preparing the 1992 and 1993 NHMRC Statements on the relationship between folate and NTDs and in making the original submission that placed the matter onto the Standard A9 agenda.

The professor's involvement in the preparation of the 1993 NHMRC Revised Statement was critical to the shaping of the policy-making process that ultimately led to the folate fortification policy as it placed the NFA policy position at odds with that recommended by the country's leading health and medical research agency. According to the NFA's Principal Nutritionist at the time it was the professor's ability to exert influence within the NHMRC system that was an important factor in the folate fortification recommendation being approved by Council. The informant commented that the professor of paediatrics is "... a very powerful lady. ... she is well respected and listened to because of her personality and presence and also her medical knowledge through the NHMRC system, through the health department system, and maybe even at the minister's office." [I4/16-17].

On 21 July 1993, a letter signed by an alliance of five senior nutrition academics was sent to the Commonwealth Minister for Health requesting that he "reject" the revised Standard A9 proposed by the NFA as it was regarded as being "... unnecessarily restrictive compared to existing Australian guidelines." [D057-21/7/93, letters from professors to Richardson]. The letter continued,

"The idealist, "middle class" solution proposed by the NFA is that all necessary nutrients should be obtained from a balanced, varied diet. ... [conversely] ... A standard which allowed fortification of cereal products to 50% RDI would allow health authorities to negotiate with food manufacturers to develop and introduce appropriate new products in these areas."

Additional comments were made in relation to the evidence for folate to reduce the risk of NTDs and for beta-carotene to reduce the risk of certain cancers. The nutritionists also expressed concern that the proposed standard was more restrictive than the equivalent standard for Australia's trading partners and this would adversely affect food manufacturers who would have to produce separate products for the domestic and export markets.
The professor of human nutrition\(^{42}\) who had recruited 13 of his colleagues to sign identical copies of a statement requesting an expansion of permissions for breakfast cereal fortification, continued to be a powerful advocate for nutrient fortification of food products in general, and folate fortification in particular, throughout the review process for Standard A9. In addition to his submissions to the NFA and being a member of the alliance of five senior nutritionists who wrote to the health minister, this professor identified that he had contributed to several other submissions that had opposed the NFA's policy principles [D025-4/11/92, transcript of Public Hearing of Inquiry into Standard A9, p19]. Also, he made several appearances in professional forums advocating for increased flexibility for food manufacturers to fortify their products with nutrients, including folate.

The ACA was a strong advocate for the Codex principles as the public health basis for the addition of nutrients to foods throughout the NFA's review of Standard A9. In relation to the policy response to the folate-NTD relationship, the ACA disputed that the evidence was appropriate to justify a population-wide intervention and recommended a targeted strategy based on folate supplements and nutrition education as the policy response [D035-7/6/93, ACA submission in response to Preliminary Inquiry Report]. Also, the New South Wales Health Department commented that it supported the NFA's position and believed it was premature to introduce folate fortification [D036-8/6/93, New South Wales Health submission in response to Preliminary Inquiry Report].

During the inquiry period, four other stakeholders made submissions to the NFA in relation to the policy response to the folate-NTD evidence. Their comments were confined to addressing specific technical matters associated with folate fortification as distinct from stating explicit public health policy arguments. These stakeholders were a nutritionist, the DAA, the Australian Institute of Health and Welfare and the South Australian division of the Australian Government Analytical Laboratories.

Minor modifications were made to the preliminary amended draft standard. The modifications included permission for folate addition to food products based on the

\(^{42}\)This stakeholder was one of the four of the 26 invited key informants who declined to be interviewed for this study.
Codex principle of restoration that permitted manufacturers to restore folate to their food products to levels that existed before processing. Manufacturers were not required to add the folate to the specified levels, but if they were to choose to add vitamins and minerals to foods, they were limited to the amount that can be claimed by maximum claims per reference quantity specified in the standard. The NFA proposed that the maximum claim for folate per reference quantity at a restoration level was 15 per cent of the RDI for adults, an intake equivalent to 30 μg of folate. These provisions are summarised in Table 8.1.

8.2.4 Recommendations to the National Food Standards Council
In March 1994 the NFA submitted the draft revised Standard A9, including its policy recommendations in response to the evidence of a relationship between folate and NTDs, to the NFSC for approval. The NFSC considered the NFA’s recommended draft revised Standard A9 and after a 4-4 vote from the Ministers for Health of the eight States and Territories the Commonwealth Minister for Health cast the deciding vote against his own agency’s recommendations. The NFSC decided to refer the recommended draft Standard back to the Authority for reconsideration within a 3-month period, taking into account [D069, 28/3/94, NFA Information paper, Outcomes of the NFSC Meeting]:

i) That fortification of foods with vitamins and minerals should be permitted where there is no risk to public health or safety.

ii) That the issue of fortifying foods with folate should be considered by the National Health and Medical Research Council.

The decision by the NFSC was definitive in shaping the policy-making process in response to the folate-NTD evidence. The NFSC had adopted the no-harm principle to interpret the protection of public health and safety, that is, the burden of proof was placed on the regulator to demonstrate risk rather than on the stakeholder(s) seeking change needing to demonstrate a scientific need or efficacy before being permitted to add nutrients to food products (the precautionary principle). The no-harm principle presumes an intervention is safe until proven otherwise.

Not only did the NFSC not accept the NFA policy recommendation in response to the epidemiological evidence of the folate-NTD relationship, it also intervened to
shift the responsibility for preparing a revised policy recommendation from the NFA to the NHMRC.

8.2.5 The establishment of the NHMRC Expert Panel on Folate Fortification

In accordance with the NFSC’s advice, on the 5 April 1994 the Scientific Director of the NFA sent a letter to the Chairperson of the NHMRC, requesting that the NHMRC send a report and policy recommendations on the folate-NTD issue to the NFA by the 10 June 1994. The letter concluded with the statement, “I look forward to receiving your recommendations with regard to fortification of foods with folic acid.” [D073-5/4/93, letter from Burch to Smallwood]. The NHMRC was required to appoint an Expert Panel to review the scientific evidence and policy options and then prepare policy recommendations to be submitted to the NHMRC for ratification and approval and then the NHMRC was to report back to the NFA with these recommendations all within a 10 week period.

The Nutrition Section of the DHSH was invited by the NHMRC to provide the secretariat for the Expert Panel and to select the experts and draft the terms of reference for the Expert Panel. The draft terms of reference were discussed with Expert Panel members and adopted at the first of the Expert Panel’s three meetings [D082-29/4/94, Expert Panel draft minutes 1st meeting]. The terms of reference are included in the Background to the Expert Panel’s report that is attached at Appendix 8. They indicate that the Expert Panel had the mandate, in principle, to consider all policy options in response to the folate-NTD evidence. The NFA’s role in the process was confined to providing dietary modelling data for a range of folate fortification scenarios to the Expert Panel.

The terms of reference notwithstanding, the name of the Expert Panel was ‘The NHMRC Expert Panel on Folate Fortification’ (my emphasis). The perception of the majority of the Expert Panel members that were interviewed was that a consideration of all of the policy options was not the intended function of the Expert Panel. As one Expert Panel member observed, “... that’s what it was, a committee to establish folate fortification. ... it wasn’t a committee to examine the public health practice of reducing NTDs.” [114/7-8]. When another Expert Panel member was asked whether the Expert Panel considered policy options other than fortification, her perception was, “I don’t know whether in fact they were allowed to.” [117/6].
Although the perception of most Expert Panel members was that the function of the Expert Panel was to provide the technical input into preparing a folate fortification intervention, most believed that this was the appropriate policy response. For example, according to the Chairperson of the Expert Panel, the review was an,

"... exciting possibility of actually doing something of benefit to public health rapidly and therefore the whole question was how can we get folate into the food supply as soon as possible. And for that reason we were strongly advised by the minister's advisers that we had to go for voluntary fortification" [13/2].

Another Expert Panel member, a Senior Nutritionist in the DHSS at the time, stated,

"There was health education and supplements being given to pregnant women. Yes, they were on the agenda, but they were in the too hard basket, they would take years. They [DHSS] wanted to achieve something within their three-year term with food fortification." [114/10].

The Expert Panel met three times in April-May 1994. Data from many sources of the decision-making process consistently indicate its rushed nature. According to the Chairperson of the Expert Panel, "... the whole brief as far as NHMRC was concerned was to come up with a solution very rapidly" [13/2]. As another Expert Panel member commented, "... it all had to happen yesterday!" [15/11]. This comment was echoed by a member of the Expert Panel’s secretariat who recalled that the process was "... pretty dreadful ... it was just a panic. ... the timeframes were so constrained, we flew by the seat of our pants a lot of the time." [116/15]. This member of the Expert Panel’s secretariat noted that the rushed timeline meant that,

"We didn’t do any consultation ... and that was a major, major problem with the process ... we should have been able to get the public into the process ... it would have given the committee an indication of the spectrum of views ... how in touch were we with consumer issues? – Not very." [116/8].
Several informants associated with the Expert Panel, presented an alternative assessment of the influence of the timeline within which the Expert Panel was required to operate. Their view was that nutrition was regarded as a particularly controversial and ponderous discipline in which nutritionists couldn’t agree with each other. For example, the Chairperson of the PHC at the time recalled his experience of being involved with a nutrition committee that was debating the revision of the dietary guidelines. He commented that it was, “Unbelievable, they nit picked about this bloody stuff ... it was people’s pet hobby horses. Various professors of nutrition disagreeing with each other.” [15/4].

Against this background the timeline for the policy-making process was regarded by several Expert Panel members not so much as a burden but as an opportunity to achieve a result. One Expert Panel member recalled,

“... we felt nutrition had a reputation both within government and within industry as being a very cumbersome institution. Nutrition in particular, had a reputation for not ever coming up with anything in a very short time and we wanted to show that it could be done. ...[getting the result in the time] ... was probably unheard of in any NHMRC panel” [114/8].

The comments of these informants suggest that to them it was the policy process as much as the policy outcome that was the priority.

On 24 May 1994, the Bread Manufacturers Industrial Association of Australia wrote to the NFA and to all Commonwealth, State and Territory Ministers for Health opposing the possible folate fortification of bread “... to address a possible medical problem within a selected sector of our population.” They posed the rhetorical question, “... is the humble loaf of bread to become the vehicle for mass medication of the consumer?” [D095-24/5/94, Bread Manufacturers response to NHMRC]. At the same time, the Bread Research Institute of Australia Inc, an independent scientific and technical research organisation wrote to the NFA expressing concerns that folate fortification had not been adequately substantiated as a policy option and other policy options should be considered. The Institute concluded, “If the issue is
not one of ‘public’ health, then mass medication is not justified” [D096-3/6/94, Bread Research Institute response to NHMRC].

At the 117th Session of Council on the 1-2 June 1994, the NHMRC accepted its Expert Panel's recommendations and on the 3 June 1994 the NHMRC wrote to the Chairperson of the NFA informing her of the Council’s decision.

8.2.6 Draft Reconsideration report
As a consequence of the NFSC advice, when reconsidering draft Standard A9, the NFA modified its interpretation of the principles used as the scientific basis for its policy to permit more liberal nutrient addition to food products. The preparation of the first draft of the reconsideration report coincided with the removal of the sentence, “The standard is based upon a public health philosophy that vitamin and mineral intakes should, so far as possible, be obtained from foods which are natural sources of those vitamins and minerals.” (the draft indicated the changes made as a result of the reconsideration) [D117-12/6/94, NFA draft Reconsideration report]. The text describing the Codex principles was removed from this draft and all subsequent versions of Standard A9. In practical terms the minimum criterion for determining whether a vitamin or mineral could be added to basic foods was reduced from 10% RDI to 5% RDI of the nutrient in the unprocessed marker food. Food categories which historically had been fortified with a vitamin or mineral by a significant proportion of manufacturers, predominantly breakfast cereals, could continue to be fortified with those nutrients at moderate levels.

The NFA's interpretation of the protection of public health and safety related to food fortification shifted from the precautionary principle to assessing the safety of 'high' intakes (defined as 2 – 5 times RDI levels) of nutrients proposed for addition. The review was conducted by staff of the NFA and an independent nutritionist who was commissioned to undertake a literature review to assess the scientific evidence of the safety of six key nutrients proposed for likely addition; vitamin A, vitamin C, vitamin E, calcium, zinc, and iron [D118-12/6/94, NFA draft Reconsideration report]. It was concluded “… in general the nutrients proposed for addition were, on the basis of current knowledge, safe at high intakes”.

210
The Authority sought to retain a set of policy guidelines that were based on the Codex principles as far as was practicable. Nevertheless, in its reports the NFA qualified its recommendations with reference to having been instructed to undertake the work and prepare the recommendations in response to advice from the NFSC. For example, the Commentary on further amendments to the draft Standard noted "As a result of the direction from NFSC, the principles which previously formed the basis for permissions to add vitamins and minerals to foods have been modified." [D117-12/6/94, NFA draft Reconsideration report].

The NFA's role in assessing the folate-NTD evidence was confined to responding to the Expert Panel's recommendations and to arguing safety and technological details rather than policy principles. The NFA substantially accepted the recommendations for the voluntary folate fortification of cereal-based foods, fruit and vegetable juices and meat and yeast extracts be permitted, to 50% of the RDI per reference quantity. In a thinly veiled criticism of the decision-making process associated with the Expert Panel's recommendations, the NFA observed, "The Authority recognises that the NHMRC was required to provide advice in a very short space of time, and that this constrained the work which could be done." [D117-12/6/94, NFA draft Reconsideration report].

On 12 June 1994 the NFA released a draft revised Reconsideration report for public comment. The draft Reconsideration report had been prepared following the request of the NFSC to reconsider the draft Standard to permit the wider fortification of foods with vitamins and minerals where there is no risk to public health and safety. The NFA offered heavily qualified acceptance of the NHMRC folate fortification recommendations, as illustrated by the comment, "The Authority has reservations regarding the fortification of basic foods with folate as a large scale public health intervention to prevent NTDs. The subject is a matter of continuing scientific debate." [D117-12/6/94, NFA draft Reconsideration report]. The draft report containing the revised draft standard was sent out for public comment for two weeks. The provisions in the reconsidered draft Standard are outlined in Table 8.1.
8.2.7 Reconsideration report

Thirty one submissions were received by the NFA in response to the draft reconsideration report. In general, industry bodies supported the draft standard, or advised that the proposed fortification levels were not high enough, and consumers and some health professionals preferred the Authority's previous recommendations. During this period several stakeholders emerged to lobby in support of a policy response to the folate-NTD evidence of targeted nutrient supplements and nutrition education and opposing folate fortification of food products.

In its submission to the NFA, the Commonwealth Ministry of Health in New Zealand commented that it supported the Codex principles as the basis for the addition of nutrients to foods and opposed the fortification of food with folate [D131-20/7/94, Reconsideration report]. On 8 July 1994 the ACA wrote to the Commonwealth Minister for Health stating,

"The introduction of widespread folate fortification ... amounts to a public health experiment on Australian citizens without their consent while there remains serious doubts about the beneficial effects and there are known adverse effects for subgroups in the population." [D128-8/7/94, letter from ACA to Commonwealth Minister for Health].

Several senior nutrition academics based in Melbourne formed an alliance that sought to support the NFA's policy approach for the addition of nutrients to foods. The alliance made a submission to the NFA advocating that the policy response to the folate-NTD evidence be deferred for further consideration. They described folate fortification as an "experiment" and commented that, "It is striking that if the product were anything but food the issue would be – what type of warning should be on the label? (their emphasis)" [D127-1/7/94, Submission from Melbourne alliance to NFA].

At the meeting of the NFA Board in June 1994, the NFA Members acknowledged there were concerns raised by some stakeholders, particularly in relation to the recommendation to fortify staple foods with folate. However, they stated that their 'hands were tied' and that they had been instructed by the Commonwealth Minister
for Health to accept the NHMRC recommendations [FN10–12/6/94 Comments of Board Members at NFA 24].

On 20 July 1994, the NFA, at the request of the NFSC, referred the reconsidered draft Standard A9, including the folate fortification recommendations, to the NFSC Out of Session. Ironically, after the NHMRC had rushed the process to report back to the NFA with its recommendations by the 10 June 1994 deadline, there were appeals by several State Ministers for Health against the folate fortification decision (see Chapter 9). These appeals delayed the Out of Session process and it was another 12 months before the revised Standard was gazetted.

8.2.8 The launch of Standard A9
A media conference on ‘An amendment to the Food Standards Code Standard A9 – Vitamins & Minerals’ by the Hon. Dr Andrew Thcophanous M.P Parliamentary Secretary to the Minister for Human Services and Health at Parliament House Canberra was held on 8 June 1995 to launch revised Standard A9. Paradoxically, the two invited speakers at the launch who joined the Parliamentary Secretary in commenting on the benefits of the revised Standard A9 had been among the most vigorous opponents of the NFA’s original policy position. The speakers were a representative from the ABCIA and the professor of human nutrition who had orchestrated several advocacy activities opposing the NFA’s earlier policy principles.

In the Parliamentary Secretary’s speech the Standard was presented as a form of public health intervention being described as “... an opportunity for governments and industry in particular to work together to address broad community health and nutritional concerns.” [D163-8/6/95, Speech by Parliamentary Secretary at launch of Standard A9]. The speech continued by stating that,

“This new Standard puts in place a regime which is intended to have a positive impact on all Australians dietary intake of vitamins and minerals. The most important aim is to effectively reach target groups. This includes people facing economic hardship and hose (sic) living in remote communities where fresh fruit and vegetables are rare.”
In contrast to the official statements at the media launch, the ACA issued its own media release attacking the policy outcome and stating,

"The National Food Authority today launches their blueprint for vitamin and mineral addition to foods, which, rather than protecting the public health of Australians, panders to the marketing whims of the food industry. Heavy industry lobbying has resulted in the Council of Health Ministers overturning the original National Food Authority decision" [D164-8/6/95, ACA Media release, ‘Health Ministers sell out consumers’].

8.2.9 The gazettal of Standard A9

With the gazettal of revised Standard A9 on 14 June 1995 the Australian Food Standards Code was amended to accommodate the folate fortification policy recommendations and for the first time in Australia food products could legally be fortified with folate. Relative to the original NFA recommendations to the NFSC a broader range of nutrients is now permitted to be added to cereal products, and the levels of fortification was increased from restoration levels to moderate levels of fortification. The final Standard A9 provisions are similar to the original ABCIA submission of September 1992. A summary of the change in the policy principles during the review of Standard A9 is presented in Table 8.1. The practical implications of the change in policy principles is illustrated by the progressive expansion in the permitted range and amount of vitamins and minerals that can be added to breakfast cereals and the food products to which folate can be added.
<table>
<thead>
<tr>
<th>Event</th>
<th>Food fortification and labelling policy</th>
<th>Vitamins and Minerals that may be added to a reference quantity of breakfast cereal (as purchased) and maximum amount (proportion RDI)</th>
<th>Maximum folate claim per reference quantity of foods (proportion RDI)</th>
</tr>
</thead>
</table>
| 1960s-1980 | Policy principles for adding nutrients to food: Logic not apparent
Claims that can be made about added nutrients: Proportion of daily allowance: >1/6 - <1/2 daily allowance
Good source: ≥ ½ daily allowance
Health claim not permitted | Reference quantity = 60g
Thiamin – no limit
Riboflavin – no limit
Niacin – no limit
Vitamin A – 100%
Vitamin C – no limit
Vitamin D – 100%
Iron – 3 times
Calcium – 3 times
Iodine – 3 times
Phosphorous – 3 times | Not permitted |
| 1980s NHMRC review | Under review | As above | As above |
| 4/3/92 Full Assessment (draft revised Standard A9) | Policy principles for adding nutrients to food: Codex principles
Claims that can be made about added nutrients: Source: ≥ 10% RDI
Good source: ≥ 25% RDI
Health claim not permitted | Reference quantity = 30g
Thiamin – 0.6mg#
Niacin – 2.0mg#
Iron – 5.0mg# | Food aid biscuits<sup>43</sup> – 200μg#
Extracts<sup>43</sup> – 100μg#
Formula dietary food<sup>43</sup> – 100μg# |
| 1993 Inquiry | Policy principles for adding nutrients to food: The number of nutrients permitted to be added to foods on a restoration basis is increased (magnesium and folate addition to cereals).
Claims that can be made about added nutrients: Source: ≥ 10% RDI
Good source: ≥ 25% RDI
Health claim not permitted | Reference quantity = 30g
Thiamin – 0.55mg (50%#)
Riboflavin – 0.4mg (25%#)
Niacin – 2.5mg (25%#)
Vitamin B-6 – 0.2mg (10%#)
Folate – 30μg (15%#)
Iron – 3.5mg (25%#)
Magnesium – 50mg (15%#) | Savoury biscuits<sup>56</sup> – 30μg (15%#) Food aid biscuits – 200μg (100%#)
Bread<sup>47</sup> – 60μg (30%#) Breakfast cereals (as purchased)<sup>43</sup> – 30μg (15%#)
Flour<sup>49</sup> – 60μg (30%#)
Pasta<sup>50</sup> – 60μg (30%#)
Extracts – 100μg (50%#)
Formula dietary food – 100μg (50%#)
Fruit drinks<sup>51,52</sup>
Fruit juice<sup>53</sup> – 60μg (30%#)
Tomato juice<sup>54</sup> – 40μg (20%#)
Vegetable juices<sup>55</sup> – 30μg (15%#)
Soy beverages<sup>56</sup> – 12μg (6%#)
Textured vegetable protein (reconstituted)<sup>57</sup> – 10μg (5%#) |

<sup>43</sup> Biscuits formulated to contain not less than 200 g/kg protein (g/Nkg x 0.25) nor less than 200g/kg fat. Reference quantity is 40g.

<sup>44</sup> Extracts of meat, vegetables or yeast (modified or not) and substances containing not less than 80% of extract of meat, vegetables or yeast (modified or not). Reference quantity is 3g.

<sup>45</sup> Reference quantity is amount recommended to replace one meal.

<sup>46</sup> Biscuits containing not more than 200g/kg fat and not more than 15g/kg sugar. Reference quantity is 30g.

<sup>47</sup> Bread, brown bread, wholemeal bread, rye bread. Reference quantity is 100g.

<sup>48</sup> A reference quantity is 20g.

<sup>49</sup> Flour, wholemeal, rye flour, rye meal, oatmeal, maize meal, rice flour, mistorea thereof. Reference quantity is 65g.

<sup>50</sup> Reference quantity is that amount that is equivalent to 1% of dry cells.

<sup>51</sup> Fruit drinks containing at least 250mL/L of the juice, purée or concentrate of the fruit after which it is named, fruit drink concentrate which, after dilution as directed on the label, contains at least 250mL/L of the juice, purée or concentrate of the fruit after which it is named. Reference quantity is 200mL.

215
Table 8.1  The evolution of Standard A9 and the policy response to the folate – NTD evidence (cont’d)

<table>
<thead>
<tr>
<th>Event</th>
<th>Food fortification and labelling policy</th>
<th>Vitamins and Minerals that may be added to a reference quantity of breakfast cereal (as purchased) and maximum amount (proportion RDI)</th>
<th>Maximum folate claim per reference quantity of foods (proportion RDI)</th>
</tr>
</thead>
</table>
| 1994  | Policy principles for adding nutrients to food: Vitamins and minerals may be added if present at 5% RDI in food before processing. Foods which historically have been fortified with a vitamin or mineral may continue to be fortified with those nutrients. Folate fortification of staple foods at 50% RDI per reference quantity. Claims that can be made about added nutrients: Source: ≥ 10% RDI. Good source: ≥ 25% RDI. Health claim not permitted. | Reference quantity = 'a normal serving'  
Thiamin - 50%  
Riboflavin - 25%  
Niacin - 25%  
Vitamin A - 25% (as carotene)  
Vitamin C - 25%  
Vitamin E - 25%  
Vitamin B6 - 25%  
Folate - 50%  
Iron - 25%  
Calcium - 25%  
Magnesium - 25%  
Zinc - 15% | Savoury biscuits - 100μg (50%)#  
Food aid biscuits - 200μg (100%)#  
Bread - 100μg (50%)#  
Breakfast cereals (as purchased) - 100μg (50%)#  
Flour - 100μg (50%)#  
Pasta - 100μg (50%)#  
Extracts - 100μg (50%)#  
Formula dietary food - 100μg (50%)#  
Fruit drinks*  
Fruit juice - 100μg (50%)#  
Tomato juice - 100μg (50%)#  
Vegetable juices - 100μg (50%)#  
Soy beverages - 12μg55*  
Textured vegetable protein (reconstituted) - 10μg55* |

# = Fortification level  
* = Restoration level

32 The maximum permitted level of folate that can be added to a reference quantity of fruit drinks is calculated based on the proportion of the drink that is derived from fruit juice.

33 Fruit juice, reconstituted fruit juice, concentrated fruit juice after dilution as directed in the label. A reference quantity is 200mL.

34 Tomato juice, concentrate tomato juice after dilution as directed in the label. A reference quantity is 200mL.

35 A reference quantity is 200mL.

36 Soy beverages containing not less than 30g/kg protein. A reference quantity is 200mL.

37 A reference quantity is 100g.

38 No claim permitted.

39 No claim permitted.
8.3 Identification of themes

In this section the data describing what happened at the procedural level of the food regulatory system are interrogated to identify themes that offer insights towards answering the questions posed in the assessment of the analysis of the case study at the decision-making process level.

8.3.1 The stakeholder arguments in response to the epidemiological evidence of the folate-NTD relationship

There were several different arguments and strategic actions in response to the folate-NTD evidence among stakeholders. According to a Senior Nutritionist at the NFA at the time, predominantly it was,

"... the medical fraternity who were not only writing things, they were appearing and making statements in the press ... [the NFA was] ... able to get a subset of the nutrition professors and senior academics around the place who were prepared to support the Authority's approach but there were clearly others who weren't. So it was divided and of course in politics if you have a divided front then you are exploited." [II7/15].

The Principal Nutritionist in the DHSH at the time concurred with her NFA colleague. In reflecting on the arguments and strategic actions by stakeholders in response to the folate-NTD evidence she surmised, "Within academia there was a split as there always is in nutrition. ... it all comes back to the philosophical approach that one has to the food supply" [II4/3]. It is this concept of the 'philosophical approach' to the food supply, which is fundamental to understanding the different arguments and strategic actions of the different stakeholders involved at the procedural level of the policy-making process that resulted in the folate fortification policy.

The philosophical approach of the NFA was that without a set of principles to guide policy the policy-making process would lack a public health context and instead react on a case by case basis, albeit to offer a potential benefit to individuals in the immediate timeframe, but to the potential erosion of the integrity of the food supply.
and to the potential longer term detriment of the population. The former NFA consumer representative’s assessment of those opposing the NFA policy was that,

“...There was definitely an emotional factor in there. We have to do something, if there’s something that we can do that might reduce birth defects then we should do it. So that became a very strong emotional appeal. We had on the other hand, "... it doesn’t do any harm, so why not?" kind of argument. So put together those become powerfully persuasive. And somewhere in there the whole public health principle, the whole FAO, WHO and Codex principles got lost.” [18/7].

In speculating on the motivation of certain epidemiologists who were promoting folate fortification, a Senior Nutritionist at the NFA at the time recalled,

“... some of them had been involved in treating spina bifida people ... it was its elegance and simplicity which really captured the imagination of people. It was something that could be easily done, something that people could passively consume and look at the saved lives.” [117/15].

The corollary of this perception was that in pursuing the Codex principles as the basis to its policy response the NFA was, according to the Authority’s chairperson at the time, “... made to feel like we were killing babies” [12/30]. A representative of the ACA attributed the emotional nature of NTDs as being decisive in shaping the lobbying environment. She commented that the ACA was aware that there were academics who were opposed to folate fortification, but they were not that visible,

“... to come out and fight the establishment on something like folate could have been quite confronting to some of those academics. They may have wanted to, but did they really want to be labelled as ‘mad academic’ who wanted all the babies to die?” [121/22].
8.3.2 Membership of the Expert Panel

The membership profile of the Expert Panel was to be an important factor in shaping the policy-making process and ultimately the policy recommendations. As the Principal Nutritionist in the DHSH who coordinated the selection process for the members of the Expert Panel acknowledged, “Quite frankly, one could have chosen a panel which could have said no [to folate fortification]. … I could have drummed up a panel with an expert in this and an expert in that.” [14/8]. Instead, she described the Expert Panel as having been established using the “normal approach” of looking for experts who were available and approaching organisations to recommend people and that this process had resulted in a “very good” Panel [14/8]. The nine members of the Expert Panel and their related area of expertise are listed in the Background to the Expert Panel’s report that is attached at Appendix 8.

Opinion on the selection process for, and the profile of, the Expert Panel membership was divided among informants interviewed for this study and generally reflected whether the informant had or had not been an Expert Panel member. One of the Expert Panel’s epidemiologists commented, the Panel comprised a balance of “… true believers versus sceptics” [19/4]. In a criticism of the earlier NFA involvement in the preparation of policy recommendations, the Food Industry Representative on the Expert Panel commented, “The idea of the Expert Panel seems to be a much better process than having individual bureaucrats … with a particular ideology, or philosophy, that appeared to be driving it.” [110/5].

Other informants expressed reservations about the membership profile of the Expert Panel arguing that it was dominated by clinical practitioners to the detriment of experts from a public health background. For example, the Principal Nutritionist of the NFA at the time, commented “People making a public health recommendation have a responsibility to the whole community. Not just to the 500 or so neural tube babies that are born each year … it gets bigger than a particular clinical condition no matter how emotional it is.” [14/25].

The selection of experts for policy committees is an inherently subjective process. One method for assessing the integrity of the selection process is to compare the
profile of Expert Panel members with the profile of stakeholders advocating a particular policy position. The stakeholders who engaged with the procedures of the food regulatory system either to support or oppose folate fortification are listed in table 8.2.

Table 8.2 Stakeholders who made comment on folate fortification

<table>
<thead>
<tr>
<th>Stakeholders opposing folate fortification</th>
<th>Stakeholders supporting folate fortification</th>
</tr>
</thead>
<tbody>
<tr>
<td>The NFA</td>
<td>The NHMRC</td>
</tr>
<tr>
<td>The ACA</td>
<td>A professor of paediatrics</td>
</tr>
<tr>
<td>The New South Wales Health Department and the Ministry of Health in New Zealand</td>
<td>The Health Department of Western Australia</td>
</tr>
<tr>
<td>A Melbourne-based alliance of senior nutrition academics</td>
<td>An alliance of senior nutrition academcis</td>
</tr>
<tr>
<td>Stakeholders associated with the bread manufacturing industry</td>
<td>A professor of human nutrition</td>
</tr>
</tbody>
</table>

On the one hand the composition of the Expert Panel appears reasonable. The Chairperson had a history of chairing NHMRC nutrition committees, the Expert in Folate Fortification had prepared the report on folate for the 1991 review of the RDIs and the Expert in Folate Research was an internationally recognised epidemiological expert in folate-NTDs. In relation to the remaining members, a member of the Expert Panel’s secretariat commented, “... they were all pretty straightforward.” [I16/6]. She noted that care was taken to ensure that the Expert Panel was balanced with a food industry and a consumer representative. Moreover, she highlighted the relative conservatism of the policy recommendations, in commenting that the Expert Panel “… could have said mandatory [fortification], it could have said we have to have a health claim, it could have really gone the whole hog. They certainly tossed those issues around and they pulled themselves back.” [I16/7].

On the other hand, the Chairperson\textsuperscript{60}, the Expert in Folate Fortification\textsuperscript{61}, and the Expert in Folate Research\textsuperscript{62}, all had expressed a strong pro-fortification policy

\textsuperscript{60} A member of the alliance of senior nutritionists who had written to the Commonwealth Minister for Health requesting he reject the NFA’s policy approach to food fortification.

\textsuperscript{61} The professor of human nutrition who had been a key player advocating for food fortification in general and folate fortification in particular.
position and had actively lobbied in support of this position, before the Expert Panel was established. Moreover, no stakeholders who had previously opposed folate fortification were selected to be Expert Panel members. According to one of these stakeholders, a professor of nutrition, "... the NHMRC committee reflected one of the camps and not the other ... the outcome of this NHMRC publication was predetermined by the choice of the people who went on it." [120/3-6].

Also, myself, the NFA's officer responsible for preparing the NFA's policy recommendations in response to the folate-NTD evidence, was not invited to be an Expert Panel member. Instead, an NFA Senior Nutritionist who had no prior involvement with the matter was invited to be an Expert Panel member in her capacity as an expert in food regulation but not as an NFA representative62. The Consumer Representative on the Expert Panel, was not known to the ACA, and had no prior involvement in public health nutrition, food regulation, or folate-NTD epidemiology. This consumer representative was not invited to join the Expert Panel until the final meeting. During this final meeting, the Consumer Representative appeared intimidated by certain Expert Panel members and made no contribution to the discussion beyond saying "yes" when the Chairperson called for a show of support for the policy recommendations [FN08-19/5/94, 3rd Expert Panel meeting]. As an epidemiologist on the Expert Panel recalled the person representing consumers was "... a bit overwhelmed ... I don't think there was time for her" [15/13].

8.3.3 Alliance between nutrition professors and food manufacturers

Whereas certain food manufacturers lobbied extensively in relation to the review of Standard A9, only one sector of the food industry, stakeholders associated with bread manufacture, became directly involved in the case study and that involvement was to oppose the folate fortification policy option. Predominantly, it was scientists who were involved in the policy debate in response to the folate-NTD evidence.

The perception within the NFA and among various stakeholders was that there were certain professors of nutrition and certain nutrition agencies that formed alliances

---

62 The colleague at the WARICH of the professor of paediatrics who had advocated for folate fortification.
63 Subsequently, this individual invited me to deputise in her place at the Expert Panel's third meeting.
with breakfast cereal manufacturers during the review of Standard A9 to oppose the NFA policy recommendations and lobby for wider food fortification permissions. The Principal Nutritionist at the NFA at the time commented,

"I was really unaware of any professional input [in support of food fortification] that didn't come from some association with industry. That association could have been funding for research, it could have been funding for positions in a department" [I4/15].

In its Preliminary Inquiry Report into the review of Standard A9, the NFA specifically identified the CSIRO and several professors of nutrition as supporting the conclusions of the ABCIA in its advocacy for wider food fortification permissions [D044-June 1993, Appendix 2 to Attachment 1, NFA 17]. The evidence that certain professors of nutrition and the CSIRO were actively supporting breakfast cereal manufacturers includes:

i) Letters signed by these stakeholders and sent to the NFA and the Commonwealth Minister for Health between late 1992 and mid-1993 requesting that breakfast cereal specifically be permitted to be fortified with 10 nutrients at 50% RDI per reference quantity [D057-21/7/93, letters from professors to Richardson]64.

ii) Newspaper articles that appeared in late 1992 in which these stakeholders were quoted raising concerns for the nutritional health of Australians if breakfast cereals were not permitted to maintain their nutrient fortification profiles [D020-5/9/92, Weekend Australian, 'Battle looms over the breakfast table']

iii) At the NFA Public Hearing in November 1992, the professor of human nutrition claimed that the NFA's policy approach, based on the Codex principles, would adversely affect the nutritional health of the Australian population because of its impact on the nutritional profile of breakfast cereals [D025-4/11/92, transcript of Public Hearing of Inquiry into Standard A9, p20].

iv) At the NFA Public Hearing in November 1992 and in their submission in response to the draft revised Standard A9, the ABCIA quoted extensively from data provided to it by the CSIRO to claim that the nutritional health of Australians would be put at risk if permissions to fortify breakfast cereals with

---

64 During this period, the ABCIA request for fortification permissions specified 12 nutrients at 50% RDI per reference quantity.
a range of nutrients were not extended [D025-4/11/92, transcript of Public Hearing of Inquiry into Standard A9, p50].

v) On the 23 November 1993 a press release was distributed to radio stations across Australia quoting CSIRO research that children have taste preferences for sweet foods such as breakfast cereals and parents ‘shouldn’t worry’ about this phenomenon from a nutrition perspective. The press release was distributed by a public relations (PR) agency as part of a marketing campaign for the MBCM. The radio announcer posed the rhetorical question to his audience, ‘Is CSIRO being paid by [the MBCM] or by [PR agency] for their research or to use their high profile scientist to promote the breakfast cereal, and if so, perhaps CSIRO and/or [PR agency] and [the MBCM] ought to be a bit more up-front about that’ [D066-23/11/93, transcript of 2CN program]

A different view of the alliance between nutrition professors and food manufacturers was presented in the submission in response to the Preliminary Inquiry Report from Goodman Fielder Limited, Australia’s largest food manufacturer. In its submission this food manufacturer expressed concern that the NFA had dismissed the arguments of “Some of Australia’s leading nutritionists and scientists ... rather emotively” [D033-2/6/93, Goodman Fielder submission Preliminary Inquiry Report]. The submission then stated,

“There appears to exist within the Authority a belief that the credibility of these scientific researchers is questionable because they receive some funding from the food industry. It should be pointed out that much of the important research in the area of human nutrition, in which Australia is amongst the leaders, would not be carried out but for the support of Australia’s largest manufacturing industry.”

It was two of the professors of nutrition who were actively opposing the NFA policy principles for the review of Standard A9 in the media and at professional forums who were then selected to be members of the Expert Panel. The former Principal Nutritionist at the NFA observed, “It’s interesting to see how many on that Expert Panel have got grants from industry.” [I4/20]. Another informant expressed doubts
about the due diligence of certain Expert Panel members and posed the view that “There were one or two breakfast cereal manufacturers who probably had undue influence on some of the members of the committee.” [120/7]. Two other informants identified one particular Expert Panel member as having been directly influenced by the MBCM [12/20; 14/20]. One of these informants, the former Principal Nutritionist at the NFA, recalled how this Expert Panel member had explained to her that if they did not support the MBCM they were “… going to lose half their staff …[who were] … funded by one of the major industry players” [14/20].

Conversely, there is no evidence that either the epidemiologists at the WARICH or the NHMRC in general, both of whom had directed their actions exclusively to the folate-NTD debate, had formed an alliance with any food manufacturers.

8.3.4 Intertwining of the review of Standard A9 and the policy response to the folate-NTD relationship

Although it was a coincidence that the review of the folate – NTD evidence arose at the same time as the review of Standard A9 and was therefore addressed within the review of food fortification, the two reviews were intertwined, with each shaping the policy-making process of the other. As the Principal Nutritionist within the DHSH at the time, and member of the Expert Panel commented,

“The Minister basically was clearly getting advice from two sources … first of all there was a very strong group of people who were working with NTDs … [who] … were able to lobby because it is a very emotive issue. Secondly … came food fortification, which had a completely different set of lobbyists, but the two were intertwined – you couldn’t separate the two. The food lobbyists were using … [folate fortification] … as an excellent example of a reason to fortify the Australian food supply. And the lobbying was very intense, very intense.” [114/2-3].

This informant explained that discussions regarding how to reduce the risk of NTDs had been proceeding informally within the DHSH for some time. She stated,
"... what the whole fortification issue [review of Standard A9] did was focus it on folate fortification. ... Now that’s what we [DHSH] couldn’t control, so we had to run with it and we had already generated all this interest and had prepared people for some sort of action to be taken, but what happened was that we were forced into folate fortification. The panel was given an impossibly short time to come up with the answers." [I14/6].

The NFSC instructions imposed a rigid timeline on the Expert Panel deliberations and were interpreted by many of the Expert Panel members as predetermined the policy outcome. As one Expert Panel member commented,

“You could infer from ... the fact that they are only given three months in which to do this and the fact that it came from a food standards committee recommendation, that food fortification was clearly going to be the main focus of their work. And they didn’t really have the opportunity to investigate other interventions." [I17/13].

According to this Expert Panel member,

“Ideally what should have happened with folate is it became a public health issue that should have been taken up outside all of this other guff. ... and looked at objectively ... But of course that doesn’t usually happen like that there’s usually some sort of trigger and in this case it was the A9 review.” [I17/26]

Other stakeholders highlighted the reciprocal influence of the policy response to the folate-NTD evidence within the broader policy review of food fortification. As the former Chairperson of the NFA commented,

“... my impression was that folate came to the fore near the end. It really was a trying to salvage it [review of Standard A9] through folate from an industry
perspective and also it was a good emotional one because if you questioned them it was as if you were being horrible in relation to women and neural tube defects, it was emotional in relation to damaged babies – "how could you question or object?" Even if you were just trying to maintain your consistent scientific approach it was harder once they picked on folate." [12/3]

8.4 Assessment

In this section I assess the data, and the themes that emerged from their analysis, for the contribution they make to answer the questions from the previous analysis to identify whether there is a causal link between these two perspectives in explaining the policy outcome. This perspective's contribution to explaining the policy-making process is then assessed to identify the existence of potential logic gaps in the data and to reveal clues to pose questions for a deeper policy analysis.

The analysis of the case study at the procedural level of the food regulatory system is predicated on the peculiar circumstance that the case study coincided with the NFA’s review of Standard A9. Through its association with the review of Standard A9 the policy-making process that led to the folate fortification policy engaged broader public health policy issues related to food composition and food labelling.

The data presented in this chapter indicate that there was a diversity of stakeholders who engaged with the procedural arrangements of the food regulatory system in response to the folate-NTD evidence. The NFSC decision had a profound influence on the policy-making process in response to the folate-NTD evidence and determining which stakeholder's preferences prevailed. The primary influence of the NFSC decision was that the statutory objective of protecting public health and safety in the setting of food standards was interpreted in terms of the no-harm principle rather than the precautionary principle. The concept of protecting the nutritional integrity of foods cannot readily be substantiated in terms of the no-harm principle and therefore has no legitimacy according to the NFSC's interpretation of the policy objective. As such, the Codex principles were redundant. Instead, it was technical risk analysis procedures that can measure indicators in accordance with the no-harm
principle that were legitimised. Effectively, the application of the NFSC decision was that fortification was the only policy option that would be considered.

A secondary influence of the NFSC decision was the shifting of responsibility for the preparation of policy recommendations in response to the folate-NTD evidence from the NFA to the NHMRC and the imposition of a rigid timeline in which to prepare these policy recommendations. The NFSC exerted no direct influence over the selection of the Expert Panel members, deferring responsibility for this task to the nutrition section of the DHSH. The Expert Panel members had the capacity to exert their authority regarding the interpretation of the epidemiological evidence and the necessary timeline for preparing high quality policy recommendations. That the Expert Panel members chose to accept the conditions imposed by the NFSC and their policy recommendations readily augmented those decided by the NFSC further suggests that the diversity of expert opinion towards policy responses to the folate-NTD evidence was not reflected in the membership profile of the Expert Panel.

The data also provide evidence of a coalition between breakfast cereal manufacturers and professors of nutrition who were also members of the Expert Panel. The existence of this coalition raises doubts about the integrity of the Expert Panel in preparing its policy recommendations in terms of the potential for certain members to attempt to influence the decision-making process to serve commercial interests. However, this perception is not borne out by data that indicate a lack of direct food industry interest in this particular issue and that the Expert Panel did not recommend a health claim as a component of its recommendations. The influence of the coalition on the policy outcome was more likely to have been indirect. The influence can be traced through its contribution to the review of Standard A9 and the sequence of events that then led to the NFSC decision to establish the Expert Panel and, in turn, to the professor's selection onto the Expert Panel.

The findings from the present analysis can be assessed for their ability to explain the questions posed in the previous chapter and thereby determine if a causal link can be established between these two analyses regarding the use of evidence in the policy-making process. The NFSC intervention explains why it was the Expert Panel and
not the NFA that was empowered to undertake the decision-making process for this food regulation policy matter. The NFSC intervention also provides an explanation for many of the oversights, errors and assumptions, including the limited dietary modelling and the lack of assessment of alternative policy options, observed in the decision-making process. Although the policy narrative makes no reference to the NFSC imposing a rigid timeline and effectively dictating folate fortification as the only viable policy option, many Expert Panel members identified these impositions as placing a heavy burden on their deliberations. The influence of these impositions on the policy-making process manifested itself in two particular ways. Firstly, it precluded any opportunity for the Expert Panel to consult with stakeholders, or the public. Secondly, it restricted the amount and level of debate within the Expert Panel.

Irrespective of the external constraints placed on the Expert Panel’s operation, the members of the Expert Panel had the ability to raise safety and ethical concerns about the policy response to the folate-NTD evidence. The membership profile of the Expert Panel provides an explanation as to why the decision-making process generally did not acknowledge or address the scientific and ethical dilemmas associated with the epidemiological evidence and why the policy response was rationalised as a relatively simple technical exercise. Specifically, stakeholders whose policy preference was folate fortification dominated the composition of the Expert Panel. None of those stakeholders whose policy preference was targeted folic acid supplements and nutrition education and who raised the scientific and ethical dilemmas during the review of Standard A9 were invited to be members of the Expert Panel.

These observations provide plausible answers to the questions posed in the previous analysis. Thereby they support the explanation that the use of evidence in the case study was not confined to the decision-making process level of the food regulatory system but was linked with the procedural level.

It is possible that the explanation for the observations at this level of analysis was circumstance. For example, the NFSC intervention may reflect the logical outcome of the diversity of stakeholders engaging with the procedures of the food regulatory
system and the Expert Panel’s membership profile may have arisen by chance. This explanation supports the assessment that the use of evidence in the policy-making process was confined to the interaction between the decision-making process level and the arguments of stakeholders at the procedural level of the food regulatory system.

Alternatively, the explanation might be that it is not so much the arguments of stakeholders and chance alone that were responsible for the NFSC intervention and Expert Panel membership profile respectively. Rather these observations may reflect the existence of a more strategic pattern to the use of evidence in the policy-making process. This explanation would suggest that the decision-making process and procedural level did not operate independently of influences associated with a broader policy-making process.

A deeper level of analysis is required to determine which of these explanations, on the balance of the available evidence, is the more plausible. The themes provide insights and clues into what happened in making the public health policy at the procedural level of analysis and raise several questions about potential influences upon this level of the food regulatory system, including:

i) Why did the NFSC reject the NFA policy recommendations?

ii) Why did the NFSC interpret the protection of public health and safety in terms of the no-harm principle and not the precautionary principle?

iii) Why was responsibility for the policy-making process in response to the folate-NTD evidence shifted from the NFA to the NHMRC?

iv) Why did the membership profile of the Expert Panel not reflect the diversity of expert opinion towards policy responses to the folate-NTD evidence?

v) Why were the Expert Panel’s deliberations subjected to a rushed timeline?

These questions will help guide the deeper analysis. The deeper level of analysis involves investigating the political environment level of the food regulatory system within which the procedural level operates. The results from this level of analysis are presented in the next chapter.
CHAPTER 9

An analysis of the case study at the political environment level of the food regulatory system

9.1 Introduction

In the previous chapter the case study was analysed from the perspective of the procedural level of the food regulatory system. The findings from that analysis, and the earlier analysis from the decision-making process level, provided many insights into the policy-making process that resulted in the folate fortification policy. A series of questions were posed to guide a deeper level of analysis of the case study. The purpose of the deeper level of analysis is to assess the relevance of the posed questions and to identify otherwise hidden explanatory factors to determine whether there is a more strategic pattern to explain how and why scientific evidence was used in the case study.

In accordance with Easton's model of a political system, a deeper level of analysis into the food regulatory system requires an analysis of the political environment within which it operates. Analysing the case study from the political environment perspective of the food regulatory system can assist in explaining its emergence in political terms, mapping the political field and delineating the forces and dynamics shaping the policy-making process.

In this chapter the case study is analysed from the perspective of the political environment level of the food regulatory system as the third of three analyses of the policy-making process that led to the folate fortification policy. The data that were collected in this policy analysis are presented to describe what happened in the making of the folate fortification policy at this level of the food regulatory system. The data then are interrogated to identify themes that emerge from the description to offer insights towards answering the posed questions. Finally, the data and the themes are assessed for the contribution they make to explaining the policy-making process that resulted in the folate fortification policy outcome.
9.2 Description

In this section data are presented to describe what was happening at the political environment level of the food regulatory system at the time of the case study. The first step in analysing the political environment level of the policy-making process is to identify the political context within which the case study was framed.

As described in the analysis presented in the previous chapter, the review of the policy response to the folate-NTD evidence coincided with the review of Standard A9. In turn, the review of Standard A9 was immersed within a political environment dominated by a microeconomic reform agenda initiated by the Australian government in the mid-late 1980s and characterised by change in the administrative procedures for the food regulatory system. On 19 August 1991 the NFA was established to manage food regulation in Australia. The first task of the NFA was to complete all unfinished business inherited as a backlog of applications and proposals from the former NHMRC food standards setting system including the revision of Standard A9. A two-year time limit was imposed to complete the backlog. The proposal to review Standard A9 was continued in force by the Authority by virtue of Section 71 of the NFA Act 1991.

It is through its coinciding with the review of Standard A9, which was itself immersed in the reform of the structural and administrative arrangements of the food regulatory system, including the establishment of the NFA, that the case study engaged with the political environment level of the food regulatory system.

9.2.1 Mapping the political field – the tension between nutrition agencies within government

The replacement of the former NHMRC food standards setting system with the NFA ushered in a significant change in the locus of responsibility for public health nutrition policy in Australia. Under the institutional arrangements for the former NHMRC food standards setting system, it had been the Nutrition Section of the DSH who had been responsible for providing the secretariat for committee meetings and advising on the selection of committee, and sub-committee, members.
The advent of the NFA resulted in a change both in the institutional arrangements for setting food standards and the personnel who were responsible for administering these arrangements. Also, the changes created uncertainty between the Nutrition Sections of the NFA and the DHSH regarding the locus of responsibility for public health nutrition policy roles such as nutrition education and monitoring and surveillance. Ultimately, these uncertainties led to questions being raised in the Australian parliament about role delineation between the Nutrition Sections of the NFA and the DHSH [D093-24/5/94, Report of the Senate Estimates Committee C, p111].

The changes in institutional arrangements contributed to a level of tension and mistrust between the nutrition sections of the NFA and the DHSH and extended to tensions between individuals within these sections. For example, the Principal Nutritionist of the NFA at the time commented, “Who was in the Nutrition section of the Department? ... I’ll tell you, the name was [XX], who never had any public health experience in her life. ... Who came from purely a clinical background.” [14/19]. The Chairperson of the NFA at the time recalled that she had been concerned that individuals from within the DHSH had been attempting to influence decisions by directly advising the Commonwealth Minister for Health and subverting the statutory process [12/28]. When interviewed about this issue, a Senior Nutritionist from the DHSH at the time denied that there had been a process of actively lobbying the Commonwealth Minister for Health about Standard A9. Instead, she said, “I certainly remember within our section it [review of Standard A9] being discussed quite vigorously. And I’m sure our submission was probably critical, or offered constructive criticism, on the approach NFA was taking.” [116/11].

A secondary influence of the change in the institutional arrangements was a degree of disaffection among several nutrition professors who previously had been routinely appointed to provide advice on food standards’ deliberations as members of the FHC. The researcher attended the 22-23 June 1992 meeting of the FHC as the representative of the Australian Federation of Consumer Organisations. At this meeting the preparation of NHMRC’s response to the review of Standard A9 was scheduled as an agenda item. There were many comments from several professors of
nutrition in attendance expressing their frustration at being positioned to respond to the procedural arrangements of the relatively new food regulatory system [FN01-22/6/92, professors comments at FHC]. Under the new administrative procedures the status of the NHMRC, and the nutrition professors, was the same as that of all other stakeholders making submissions into the food regulatory system. In November 1992 at the NFA’s Public Hearing into the review of Standard A9, a professor of human nutrition who had orchestrated several advocacy activities opposing the NFA’s policy proposals for the revision of Standard A9, claimed that,

"... the system for obtaining a consensus of expert nutritional advice for the Authority seems to have not been working here. ... Until very recently any matters of food standards which could affect the public health nutrition were discussed thoroughly at the Nutrition Committee of the NH&MRC ... I urge you to go back to some such system." [D025-4/11/92, transcript of Public Hearing of Inquiry into Standard A9, p23].

In a later submission to the NFA this professor advocated that in responding to the folate-NTD evidence, “The NH&MRC will have to lead on this important issue.” [D031-31/5/93, submission from professor in response to Preliminary Inquiry report].

9.2.2 Mapping the political field – the broader policy context to the review of Standard A9

The primary purpose of the review of Standard A9 was to establish a scientific framework for protecting public health and safety when adding nutrients to food products. The NFA adopted the Codex principles to provide the scientific framework, as attached at Appendix 1. Because the Codex principles are broadly framed, some interpretation was required to apply them in practice. The NFA based restoration levels for food categories on the micronutrient profile of a ‘marker’ food. A marker food was a theoretical construct for each food category and its micronutrient profile was representative of the range of ingredients among foods in that food category. Only those nutrients that were present in the resulting restoration profile of each food category in significant amounts (at least 10% RDI/reference quantity) were permitted to be added.
The NFA’s interpretation of the Codex principles had a direct bearing upon both the legality of many nutrient fortified food products that existed in the marketplace and the product development plans of certain food manufacturers. A consequence of the NFA’s review of Standard A9 was that the food Authority became engaged in a broader policy debate regarding stakeholders interests associated with the competing roles of food as either a commercial commodity or as a public health resource. In the NFA’s rationale to its food fortification policy it explicitly linked the interpretation of the public health and safety policy objective to a preference for ‘basic’ foods over ‘highly fortified foods’. According to the NFA,

"... public health and safety issues can arise if consumers rely on highly fortified foods as a source of particular nutrients, in preference to basic foods in which these nutrients occur naturally, and so put at risk the nutrient adequacy of their diets. ... A Diet where recommended intakes of vitamins and minerals are obtained from a wide variety of basic foods is likely to contain all other dietary essentials necessary for health, including those which have not been identified or for which recommended dietary intakes (RDIs) have not been developed." [D131-20/7/94, Reconsideration report, p1]

The NFA was suspicious that the food manufacturers’ interest in the review of Standard A9 was motivated by marketing objectives, and in particular a desire to reform food labelling policy in relation to the use of health claims, rather than concerns for public health and safety. The Chairperson of the NFA at the time commented that she felt that the review of Standard A9,

"... was a ‘stalking horse’ for the next big fight which was going to be full health claims. So it was a combination of medicalising the food if you will, getting the stuff into the food, so that the later claims could be made about the health benefits of that food." [I2/4].

This assessment of the review of Standard A9 was shared by the NFA’s Consumer Representative at the time who commented,
"... the strong lobby from the food industry ... were fighting very hard on these fortification issues with a view to being able to pressure the Food Authority into being allowed to make health claims. The first step ... was to ensure that the regulations on fortification were not too strong so that it allowed them to move to the next stage of making health claims for their foods. So, it was fairly clearly a consumers versus food industry type issue" [I8/5].

An adversarial debate over the purpose of the review of Standard A9 emerged between stakeholders with these competing interests. One particular food manufacturer, the MBCM, emerged to mount a concerted and aggressive challenge to the NFA’s proposed review of Standard A9. The MBCM had many products that were fortified with various combinations of nutrients that would be affected if the NFA’s interpretation of the Codex principles were to provide the scientific basis for revised Standard A9. Moreover, in October 1984 this company launched a promotional campaign in the US claiming that the consumption of one of its bran-containing cereals would help reduce the risk of bowel cancer (Freimuth et al. 1988). This promotional campaign directly challenged the FDA’s long-standing policy prohibiting the use of health claims on food products and was a significant factor leading to the amendment of the prohibition on health claims in the US.

The MBCM initiated its own advocacy campaign to challenge the NFA’s review of Standard A9 as well as establishing and then managing the ABCIA as an alliance with several other breakfast cereal manufacturers to lobby for breakfast cereal manufacturers’ interests. The food Authority’s Principal Nutritionist at the time commented that, “They’d [the MBCM] been trying for years to get a whole range of fortification into their breakfast cereals ... so when the NFA was set up and we had started to revise the vitamin [Standard] here was their chance.” [I4/16]. According to the Scientific and Marketing Director at the MBCM at the time of the interview (November 1999), the company’s position during the review of Standard A9 was to seek “… internationalisation and harmonisation with those regulations, particularly fortification, to allow not just export but to facilitate new product trials rather than having to reformulate specifically for Australia.” [I6/7-8]. He commented,
"Obviously [the MBCM] lobbied pretty hard along with the breakfast cereal companies generally about A9. ... I don’t think people [at MBCM’s headquarters] really cared too much about the public health reasoning of ANZFA. They just saw the commercial outcomes and that’s really all they were interested in. ... fortification is a key part of what MBCM wants to do and does internationally. I suppose in terms of the products themselves just it was pushing to bring Australia in line with the US.” [I6/9-13].

Speaking in his capacity as a representative of the ABCIA at the Public Hearing into the review of Standard A9, the Managing Director of the MBCM in Australia commented, “It is critical to our company that a cornflake in Australia is equivalent to that in the United States or UK or Canada because that is our benchmark and it continues to have us strive to perfecting our product.” [D025-411/92, transcript of Public Hearing of Inquiry into Standard A9, p70].

The Chairperson of the NFA at the time of the review of Standard A9 regarded the MBCM’s interest in the review of Standard A9 as being more strategically motivated. She commented,

"The review of A9 was a ‘must-win’ for the local Managing Director of [MBCM]. He was under instruction from headquarters in [XX], to have Standard A9 liberalised for two reasons: to bring the regulations more in line with America; and to prevent Australia being used by Canada as an example to resist change being imposed by [MBCM] to their regulations. Canada’s policy on food fortification was similar to that in Australia and [MBCM] was trying to bring Canada’s regulations into line with those in the US.” [I2/35-36].

The review of Standard A9 and its association with competing stakeholder interests extended the policy context to engage with the fundamental issue of the respective roles of the State and the marketplace in managing the development of the food supply. For example, at the time of the review of Standard A9, the NFA expressed concern that the existing standard was fostering an environment in which nutrient fortification of the food supply was being determined by competitive marketing practices and the pressure for product differentiation, rather than being based on public health principles. The NFA commented,
"It must be recognised that Australia is exposed to marketing pressure by large multinational companies that base their formulations and marketing strategies on North American and European regulatory and market conditions. These may not be the best influence on Australian dietary patterns" [D065-27/10/93, NFA Minute to the Minister].

Conversely, certain food manufacturers were arguing that consumers were interested in ‘healthy’ food choices to fit in with their diet and lifestyle and it was not the regulator’s role to judge what was and was not appropriate for consumers, or to prevent the market from servicing this demand. Servicing this demand required industry to have increased flexibility to pursue research and innovation in food product development. As the Food Industry Representative on the Expert Panel commented,

"...it's nobody saying that you should do this, or you're in a position to do this, there are opportunities out there for people to take and then they decide whether they are appropriate for their company, their products, their marketing plan, or whatever." [II0/11].

9.2.3 Microeconomic reform agenda
The NFA was established in August 1991 as a direct result of the microeconomic reform agenda of the Australian government that had begun in the mid-late 1980s and was being implemented across all government departments. The competing roles of food as either a public health resource or commercial commodity presented unique challenges in interpreting and applying the microeconomic reform agenda to the work of the new food Authority. Whereas section 10 of the NFA Act 1991 listed the protection of public health and safety as the priority objective in the setting of food standards, the promotion of trade and commerce in the food industry was also listed as an objective, albeit at a lower order of priority.

According to a representative of the ACA, the review of Standard A9,
"... was an extremely difficult debate because we felt we were trying to argue science and the other side was trying to argue kind of a populist, like we don't want to hurt all these people and it's going to cost Australian jobs. All that sort of stuff that gets politicians really twitchy." [I21/5-6].

She continued by saying that in that political environment Ministers for Health have

"... to work out whether they are trying to protect people's health or whether they're more worried about the health of the industry." [I21/19].

Other commentators share this concern. According to one food regulation expert in academia,

"The emphasis on public health is dropping down the priority list in that whole of government approach to food related decision making ... food was seen to be a major commodity group and needed to be in the commodity related portfolios as opposed to the being protected as a health related issue. ... the Food Authority, or the health minister's, capacity to make independent decisions about food regulations is being consistently undermined." [I1/16-17].

Nevertheless, key decision-makers within government perceived no conflict in regard to the NFA's statutory objectives. For example, the Parliamentary Secretary with responsibility for the NFA at the time commented,

"I treated it [food regulation] as a discrete area of responsibility. Sure it came within the health portfolio, but it had all these other dimensions. From the beginning I think the Prime Minister was quite impressed that I treated it as an area which had these other dimensions. Therefore it is an interdepartmental area." [I19/9].
The Consumer Representative on the NFA Board during the review of Standard A9 observed that,

"The food industry lobbied very heavily at the highest political level for their position so that we [NFA] were constantly aware we had to defend ourselves against anything that would be seen as interfering with the free market and anything that wasn't good for big business. At times it was quite difficult ... to defend public health principles and the public interest against the forces of the free market and a deregulatory environment." [18/4-5].

Conversely, the Scientific and Marketing Director at the MBCM at the time of the interview observed that among food manufacturers there was,

"... enormous frustration at the slowness and what would have been seen as undue conservatism really, and a very ideological approach from [NFA Principal Nutritionist] ... the view was that it [NFA] was combative rather than supportive of the food industry." [16/11].

It is apparent that the Commonwealth Minister for Health and his State counterparts as well as Commonwealth Ministers in other Departments were being intensively lobbied during the review of Standard A9 by the MBCM directly and indirectly through the ABCIA [D050-25/6/93, NFA Minute to the Minister]. The available evidence suggests that the ABCIA was successful in influencing Ministers for Health in several states to raise concerns about the NFA’s recommendations and to initiate the dispute procedures of the NFSC. For example, on 7 July 1993 the Minister for Health in Western Australia wrote to the Commonwealth Minister for Health requesting that at the next NFSC meeting it be recommended that the NFA, "... be requested to recognise the long established market of breakfast cereals containing vitamins" [D053-2/7/93, letter from Foss to Richardson]. Curiously this Minister for Health acknowledged in the letter, "Whilst the health benefit may be small there seems little reason to eliminate established [breakfast cereal] products from the Australian market."
The effect of the Ministers for Health raising dispute procedures within the NFSC was to delay the ministerial Council’s consideration of the draft revised Standard until March 1994, i.e. beyond the original two year period intended to clear the backlog. In the interim period between the July 1993 and March 1994 meetings of the NFSC the intensive lobbying from stakeholders continued.

There was a clear contrast in access to the Commonwealth Minister for Health among stakeholders during the review of Standard A9. An article in the Sun Herald newspaper on 19 September 1993 commented that the Commonwealth Minister for Health was “siding” with food processors against the NFA’s proposed revised Standard A9 and that the Ministers for Primary Industries and for Industry were known to be angry about the Authority’s recommendations [D061-19/9/93, Sun Herald, ‘Cereal giants snap at tougher rules’]. According to the former Chairperson of the NFA, over the three months leading up to the NFSC meeting the Commonwealth Minister for Health continually cancelled scheduled meetings with NFA staff. She recalled that the Minister did not make himself available for a briefing from the NFA until the morning of the NFSC meeting when the NFA staff, “… saw him in the foyer of the hotel for about three minutes.” [12/13].

Conversely, the MBCM appears to have had relatively strong access to the Commonwealth Minister for Health during the period leading up the NFSC meeting. For example, the message in a facsimile sent during the 1993 Christmas period from the Managing Director of the MBCM to the Commonwealth Minister for Health read,

"Just a note to express my appreciation for your efforts on the vitamins and minerals issue this year. ... I am cheered by the message passed to me yesterday that you will have the vitamins and minerals issue fixed early in the New Year as soon as you get the Health Ministers together. Is there anything more we can do in the meantime?... thanks for your help and encouragement over recent months" [D067-21/12/93, Facsimile from Cook to Richardson].
Coincidentally, as reported in a newspaper article at the time, the Commonwealth Minister for Health was starting a fitness regime to become more of a role model for his portfolio. His personal trainer was Dr Telford from the Australian Institute of Sport who also happened to be a consultant to the MBCM and involved in the promotion of one of their ‘sports cereal’ products [D064-14/10/93, Canberra Times, ‘Richardson lightens up for the sake of his form’].

The NFSC decision to base the interpretation of the protection of public health and safety on the no-harm principle in relation to the review of Standard A9 suggests that Ministers for Health saw no contradiction between economic policy and public health objectives in a food regulation setting. The Consumer Representative on the NFA Board at the time commented in relation to the NFSC decision that,

"While there were many areas where you could succumb more readily to the free market culture or deregulatory environment, the basic food supply of a population shouldn't be one of those areas where you rolled over too easily ... I felt that responsibility very heavily that it really was up to the Food Authority to prove their case. The weight of evidence, the weight of argument was shifted to the Food Authority, when in fact I felt the responsibility should have been the food industries to demonstrate why it was okay in public health terms to deregulate." [I8/5].

In the interim period that Standard A9 was being reconsidered following the NFSC decision, the position of the NFA was continually criticised from within government for being opposed to food industry interests. The Authority was advised by the NFSC to consult with stakeholders including representatives of breakfast cereal manufacturers to discuss the revised draft Standard A9 before the document was finalised and distributed for public comment [D101-18/5/94, Attachment 4, NFA OOS meeting, ‘Consultative meeting with industry representatives to discuss the revised draft Standard A9’]. The regulator had to negotiate with the commercial interests with whom it had been contesting the policy-making process. According to a legal expert in academia, "At that time it was a situation where public health policy was being written by industry" [I7/10].
Throughout the period of the review of Standard A9, the NFA was required to interpret and apply its policy objectives under significant pressure in relation to the time it had to conduct its review and the level of support it received from its own minister and the wider political environment. For example, the Commonwealth Government's Office for Regulation Review issued a report in November 1993 citing the NFA's review of Standard A9 on "questionable nutritional grounds" as one example to illustrate its criticism of government regulation of business as being "overly stringent, prescriptive, and costly to comply with and enforce" [D063-29/11/93, The Age 'Regulation of business is still growing: report'].

According to a legal expert working in academia,

"[The NFA] was under siege, it was under-resourced. It really was under siege. It's dealing with one of the most political areas. Food is just so complicated. ... Parliaments have to realise that. That they've got to resource them well, put good people in there and back them up. Support them, not let them be the ones that everyone is gunning for." [17/7].

During the reconsideration period for the review of Standard A9 the role of the NFA and its nutrition staff was continually subjected to intense scrutiny. On one occasion stakeholders opposed to NFA's policy principles in relation to Standard A9 attempted to undermine the role of the Nutrition Section of the Authority by arranging for targeted questions of accountability to be raised in a Senate Estimates hearing of the Australian Parliament [D094-24/5/94, Questions taken on notice, Senate Estimates Committee C]. Among the questions taken on notice were:

Q1: How many nutritionists does the NFA employ and what proportion of its total staff are engaged primarily on nutrition issues?

Q2: Does the Authority accept that nutrition education is properly the role of the public health agencies of the Commonwealth and State Health departments and that its role should simply be to ensure that nutrition information on food products is accurate and adequate for consumers to make informed choices?

---

65 The questions were raised by Senator Bob Woods, who was later to become the Parliamentary Secretary responsible for the Food Authority.
Also, certain State governments in Australia were becoming directly involved in lobbying for the liberalising of Standard A9 and the overturning of the prohibition of health claims on food labels. For example, the Premier of Victoria at the time, Jeff Kennett, a Premier with a reputation for industrial and economic reform, announced “There is no reason why Victorian and Australian industries can’t excel in this area as long as we don’t get stuffed around by the bureaucracy of Canberra, who simply don’t understand what functional foods are all about.” [D125-22/6/94, Daily Commercial News, ‘Kennett slams Canberra on food’].

Throughout the reconsideration period the pressure directed towards the NFA continued and it remained isolated from political support. On 14 December 1994 the Chairperson of the Authority announced her resignation [D148-14/12/94, NFA Media release ‘NFA Chairperson announces resignation’]. Three days later the Canberra Times published an article questioning whether the MBCM was able to exert undue influence upon the Parliamentary Secretary and the NFSC and raised questions about the independence of the regulator. In analysing the circumstances associated with the Chairperson’s departure the article reported the allegation that “Ms Pincus felt obliged to go after being pressured by the Parliamentary Secretary in charge of food matters, [XX], who had in turn been pressured by the manufacturers led by [MBCM].” The article added, “Both [Parliamentary Secretary] and [MBCM] deny any role in her departure.” [D152-17/12/94, Canberra Times ‘No tears for Pincus’].

However, not all Australian governments were opposed to the NFA’s interpretation of the protection of public health and safety objective in relation to the review of Standard A9. Following the NFSC decision, the Queensland Minister for Health wrote to the Chairperson of the NFA saying that he could not endorse the reconsidered draft Standard. Among the Queensland Minister’s concerns were the safety and efficacy implications of the folate fortification recommendations within the Standard [D138-23/9/94, letter from Hayward to Pincus]. This invoked the debate procedures of the NFSC that required the Queensland Minister for Health’s comments in disagreement with the recommendation to be circulated to all members of Council together with the Authority’s response.
One effect of the Queensland Minister's intervention was to spur further lobbying by stakeholders towards the Ministers for Health. For example, during this dispute period the ACA lobbied the ACT Minister for Health regarding the folate fortification recommendations in the reconsidered Standard. In response to the ACA lobbying, the ACT Minister for Health then wrote to the NFA Chairperson informing her that he also intended invoking procedures to discuss the folate fortification recommendations at a meeting of the NFSC [D145-8/12/94, letter from Connolly to Pincus]. The Minister recalled,

"... it [folate fortification] was certainly presented as a minor technical point, is folate safe? Yes. Therefore, should there be any prohibition on it entering the food, entering mass market foods? No. ... the standard format for these Out of Session approvals as they go up to the Ministers was: industry views; and community views, and both were filled in as uncontroversial ... and that was not the case. ... that's where Ministers on these matters are generally going to be captives of their departments." [118/8].

The Minister's primary concern was his perception that there had been a lack of due process observed during the policy-making process and less with the details of the folate fortification recommendations. He commented, "I don't think I ever committed myself politically to any strong view for or against folate fortification ... I acknowledged that it's an issue that needs to be debated and took the view if there are experts saying one thing and experts saying another then at least we ought to hear what they've got to say. ... and is there an alternative?" [118/3].

The outcome of the Queensland and ACT Ministers for Health interventions was that reconsidered draft Standard A9 was placed on the agenda for the April 1995 NFSC meeting. However, the agenda item did not arise. On the 21 February 1995 the Premier of Queensland announced that the Minister for Health was to be replaced by the then Minister for Business, Industry and Regional Development. The Premier commented that the new Minister would be well suited to the role because among his achievements "He has worked tirelessly on building our manufacturing base, especially in new, innovative, value-added industries and those seeking to exploit
niche markets in Asia.” [D160-21/2/95, Premier of Queensland Media release ‘New ministers for transport, education and health]. Also during this interim period an election was held in the ACT and the government changed. The new ACT Minister for Health joined with her new Queensland colleague to retract their portfolios’s previous requests to invoke a dispute hearing of the NFSC.

9.2.4 Globalisation

The potential economic returns to be gained from increasing food exports and the concept of participating in the global marketplace was a powerful motivating factor in the policy arguments of stakeholders seeking to liberalise Standard A9. According to the former chairperson of the NFA,

“Now this gets into a whole other issue of whether you had to do it for the whole of Australia just so you could sell it to Asia. ... But the boys in Canberra always crossed their legs and pulled their forelocks whenever exports were mentioned. ... [MBCM] had a factory in Botany and they got to [Commonwealth Minister] who’s electorate it was and ... got to [Commonwealth Minister for Health] and they were able to disparage the Authority ...[calling them] ... terrible crazy’s, food police ... they were threatening to take the factory off shore” [I2/13].

The former NFA Chairperson’s comments are corroborated by additional comments from the Parliamentary Secretary for the NFA at the time,

“I didn’t see the harm of putting vitamins into cornflakes ... I didn’t see that we should be dictating to people whether they should be having additional vitamins or minerals. ...[MBCM] were saying "if this is going to happen we are going to have a problem" ... There was a danger that [MBCM] would leave Australia. ... you don’t allow yourself to be blackmailed by international companies, but on the other hand why would you want [MBCM] to get out of Australia merely because they want to put vitamins in [MBCM]? If It’s dangerous to health, that’s different.” [I19/4-5].
The Parliamentary Secretary continued,

"I was conscious of the fact that the Prime Minister was concerned that we shouldn’t be in a situation where we ended up adversely affecting our food industry. ... I knew what the department of industry thought, what the department of primary industry or agriculture thought ... and the department of trade. ... they were most concerned with any situation which would, a) lead to [MBCM] leaving Australia, or b) prevent [MBCM] from exporting." [119/S-6].

At the Public Hearing into the review of Standard A9 several submissions and presentations argued that the NFA was ‘out of step’ with international legislation or regulation, concerning the addition of vitamins and minerals to foods. It was argued that by being out of step with international practice the NFA was risking the export potential of Australian food products. The Authority’s assessment of this argument was that regulatory agencies overseas had adopted a variety of approaches to this issue. The NFA referred to Canada, New Zealand and some European countries as examples of countries where fortification of the food supply was not permitted unless there was a clear public health need. By contrast, the NFA acknowledged that a more liberal approach to fortification has been adopted in some other European countries and in the United States. [D047-June 1993, Inquiry report, Appendix 5, pp79-83]. Also at the Public Hearing, representatives of the ABCIA criticised the NFA’s proposed revised Standard A9 on the grounds that there was no evidence of harm among those populations that had been consuming breakfast cereals for the 30 years that these products had been fortified in Australia and internationally [D025-4/11/92, transcript of Public Hearing of Inquiry into Standard A9, p50].

Food manufacturers also lobbied outside of the food regulatory system and at the highest political level to bring pressure to bear upon the NFA in relation to food fortification and health claims under the guise of the need to exploit the concept of functional foods. For example, on the 10 June 1993, the Associate Secretary of the Department of The Prime Minister and Cabinet wrote to the NFA chairperson advising her of the outcome of the Council of Australian Government’s recent
second meeting at which functional foods had been discussed as an agenda item by State Premiers and Senior Commonwealth Ministers. The letter stated,

"The council agreed that Governments should facilitate efforts by the Australian food industry to capitalise on growth in export markets. ... To this end the Council agreed that the current restrictions specified in the Australian Food Standards Code, which inhibit the development of functional foods, need to be reviewed as a matter of priority." [D037-10/6/93, letter from Williams to Pincus].

After the NFA did not accept the ABCIA's arguments regarding the potential for food fortification to promote health and prevent chronic diseases in Australia in response to the draft revised Standard A9, the ABCIA placed greater emphasis in its advocacy campaign on arguments associated with globalisation and trade. For example, the ABCIA submission at the Inquiry stage of the review stated,

"The potential in export markets for high quality, nutritious, value-added products has become more evident, especially in the Asian region. ... the capability of fortifying for the domestic market is critical to the successful exporting of breakfast cereals to the Asian markets. The reason is that, if the domestic product cannot be fortified, then the cost of producing fortified products for export markets alone (their emphasis) escalates. ... If Australia cannot supply fortified breakfast cereals to these markets, other countries will satisfy the need and the much needed export opportunities for Australia will be lost." [D034-2/6/93, ABCIA submission in response to Preliminary Inquiry Report, p3].

In the Statement of reasons accompanying the Inquiry Report, the NFA directly challenged the arguments presented in the ABCIA submission when stating,

"The draft amendments to the Standard clarify that it is not industry's role to be making public health decisions about what nutrients should be added to
foods, and so to the food supply, whether these decisions are made on the basis of perceived nutritional deficiencies or for marketing reasons. This should clearly be seen and accepted as the responsibility of the National Food Authority in collaboration with health authorities." [D046-June1993, Inquiry Report, Attachment 6, Statement of reasons, p182].

On the 1 July 1993 a disagreement among members of the ABCIA was announced. The Director of Production of the Sanitarium Health Food Company wrote to the Director of Consumer and Corporate Affairs at the MBCM in his capacity as the Secretary of the ABCIA to advise him that Sanitarium objected to the ABCIA's submission to the Preliminary Inquiry Report and requested their name be withdrawn from the Association. The company commented that they believed "... the ABCIA concept is being used as an ambit to support specific proprietary aims and marketing strategies" [D052-1/7/93, letter from Sanitarium to ABCIA/MBCM]. In a letter to the Commonwealth Minister for Health and the NFA, Sanitarium stated that they could not justify the arguments being used by the ABCIA and elaborated upon their objections stating that "We do not support the use of breakfast cereals as "carriers" of an unjustified range of vitamins and minerals ... The use of breakfast cereals in an unjustified, quasi-therapeutic role could readily lead to unnecessary and misleading promotional statements" [D058-26/7/93, letter from Sanitarium to Richardson, NFA]. The response from the Director of Consumer and Corporate Affairs at the MBCM in his capacity as the Secretary of the ABCIA was to defend the ABCIA's submission to the NFA. The defence was based on the need to promote trade in export markets and to note that Sanitarium had a "different perspective" to the remaining members of the ABCIA because of its focus on the domestic market. [D055-9/7/93, letter from ABCIA/MBCM to Sanitarium].

On 5 August 1993 the Commonwealth Minister for Primary Industries and Energy wrote to the Chairperson of NFA asking that the issue of regulation and its impact on export performance be taken into account in the setting of food standards. The Minister commented that he had "... had submissions from industry representatives, particularly in relation to the recent Draft Revised Standard A-9, Vitamins & Minerals (his underline), questioning the apparent conflict between regulations and
Government policy encouraging export growth. ... While encouraging industry to become more outward looking and export oriented on one hand, it is important that the Government is not seen to be sending conflicting signals to industry.” [D060-5/8/93, letter from Crean to Pincus].

The Agri-Food Council and its accompanying Agri-Food Strategy were established by the Commonwealth government in 1993 to provide a focus for policies to enhance the international competitiveness of the Australian agri-food industries. The ultimate objective of the Strategy is to improve the international competitiveness of Australian agri-food industries. The Strategy’s philosophy is “... a focus on facilitating market-driven growth, removing impediments and minimising regulation, with the onus of proof lying with those advocating intervention.” [D062-September 1993, ACIL report ‘Food for Thought’, p1]. The Agri-Food Council is an intersectoral committee jointly chaired by the Commonwealth Ministers responsible for the Departments of Industry, Technology and Regional Development and for Primary Industries and Energy and with representation from major food manufacturers including the Chief Executive Officer of the MBCM.

The Regulatory Regimes Working Group of the Agri-Food Council commissioned ACIL Economics & Policy Pty Ltd to prepare a report reviewing the regulatory regime administered by the NFA. The report contained assertions that the NFA was “... unnecessarily protective of consumers, and to be trying to use food regulations as a tool to influence nutrition policy and diets. The latter is ... causing significant costs in suppressing consumer choice, and innovation, diversity and growth opportunities in the food industries.” [D062-September 1993, ACIL report ‘Food for Thought’, p1]. The role of nutrition was defined in terms of ‘promoting’ public health outcomes. As the objective in setting food standards is to ‘protect’ public health and safety, it was argued that there was no role for nutrition in food regulation. The ACIL report concluded that the meaning of the statutory objective to protect public health and safety, “...should be confined to health and safety in the strict meaning so as to exclude nutrition” [D062-September 1993, ACIL report ‘Food for Thought’, p24].
The interpretation of the role of nutrition in food regulation became a touchstone of how the public health and safety policy objective was to be interpreted. The role of nutrition was considered acceptable in the context of the ACIL report when it was defined in terms of serving a technical function, e.g. contributing to dietary modelling activities. Alternatively, the role of nutrition was deemed inappropriate by the ACIL report when it was used to reflect policy principles. The ACIL report was adopted at the 15/10/93 meeting of the Agri-Food Council and publicly released by the Grocery Manufacturers Association on 9/12/93 [D068-9/2/94, Wright letter to Commonwealth Minister for Health].

9.3 Identification of themes

In this section the data describing what was happening at the political environment level of the food regulatory system during the case study are interrogated to identify themes that offer insights towards answering the questions posed in the assessment of the analysis of the case study at the procedural level.

9.3.1 Lack of openness and transparency

The experience associated with the review of Standard A9 illustrates that after a matter has progressed through those procedures of the food regulatory system that are managed by the food Authority, policy decisions can be made that don’t necessarily reflect the Authority’s recommendations for varying food standards. Instead, Ministers for Health can intervene at the final stage of the policy-making process to accept, amend or reject policy recommendations. This process is consistent with the requirements prescribed in the NFA Act 1991. Yet, the circumstances associated with the review of Standard A9 illustrate deficiencies with the intent of the NFA Act 1991 in relation to protecting the openness and transparency of the process. Whereas, the activities of the food Authority are subject to public consultation and all decision-making processes are placed on a public record, subject to confidentiality criteria, the deliberations of the Ministerial Council are outside the objectives of the NFA Act 1991 and as such are not put on the public record. This lack of openness and transparency at the Ministerial Council stage of the policy-making process has the potential to diminish the transparency and undermine
the integrity of the food regulatory system. According to a legal expert working in academia,

"... it's absolutely outrageous they [NFSC] can make decisions and not be responsible to any constituency. Each of them goes back to their own constituency, but that's too diffuse really. And they do not have to give any reason, rationale, so there's nothing there ... we really don't know what went on. There's just no requirement at all for it to be exposed, which parliament was it exposed in?" [I7/6].

The Chairperson of the NFA provided a first hand insight into the actual management of the voting process undertaken by the Ministers for Health at the NFSC meeting. Her recollection was that the issue was resolved by the NFSC Chairperson taking the unusual step of not permitting any discussion on the matter with the NFA staff that were present. Instead he asked the Ministers around the table to simply vote yes or no to the NFA's recommendations,

"... it was all pre-programmed and we were at excrescence, we were at surplus to requirements. So, all that work and all that time... By just going around the table one of the health ministers that we'd previously been told was voting in support of our position saw other state ministers of his political persuasion and ... we lost one vote along the way. ... Remember every bureaucracy was on our side, so it wasn't like we were on a frolic of our own. ... but the ministers and the ministers' offices had been lobbied and many of them said that they'd never been lobbied so heavily." [I2/14].

She continued,

"By the time they got all round the table it was 4-all and [Commonwealth Minister for Health] hadn't voted and he said well it's 4-all, I'm sorry that has to happen because that means that I have to vote and I don't like to vote against my own team. ... but I vote against. And he said that "my reason is that I get up every morning and I go into the bathroom and I open up the bathroom
cupboard and I take a handful of vitamin pills every morning". ... It was so outrageous, it meant he didn’t have an idea of what we were talking about because we weren’t talking about taking vitamin pills. He said, “I take vitamin pills every morning and it hasn’t done me any harm.”” [12/15].

The former NFA Chairperson mused that despite the best intentions in leading up to the NFSC step the process can be subverted at this final stage,

“... to say I will vote against them because I take vitamin pills every morning and it’s never hurt me when we had hundreds of pages of sophisticated analysis of a range of vitamins in the contexts of food and integrity of the food supply ... it was just shocking.” [12/15-16].

In one final insight into the process she noted,

“That was the day he [Commonwealth Minister for Health] retired, resigned, that’s another accident of politics, that we got caught up in that process ... this was his last gift. And then he went off into the sunset to continue popping pills.” [12/49-50].

9.3.2 Differential access to the food regulatory system among stakeholders
There are many constraints facing stakeholders in accessing the food regulatory system. The data from this analysis indicate that there was differential access to the food regulatory system among stakeholders. The differential access was particularly manifest due to the disparity in time and financial resources among stakeholders and the affect this had on their capacity to undertake broader advocacy activities. According to an ACA representative,

“... the industry were extremely effective in putting bodies into minister’s faces. We were in a situation where we were lobbying ministers from a distance ... none of that is ever as effective as someone in your face, in your office, buying you a drink and generally being chummy.” [121/8].
The former Chairperson at the NFA reflected upon the issue of access from the perspective of the different level of sophistication among stakeholders in engaging with the food regulatory system, when she commented,

"... we're all into participative stakeholder public policy-making, but whatever you've got to worry about the mechanism that produces this sort of result because the other so called countervailing interests like say the consumers, or the public health nutritionists, or whatever, they never had either the money to go to the meetings, or the power, or else they were just very nice people and they didn't argue. If they had power they didn't know how to exercise it. So, even in a consensus environment they kept being done over." [12/28].

9.3.3 Hierarchy of government policies

The observations of the review of Standard A9 raise questions about the priority accorded food regulation policy decisions relative to the broad range of policy issues for which Ministers for Health are responsible. For example, the NFSC meetings were conducted as a component of the Ministers for Health broader meetings. According to the former ACT Minister for Health who had been involved as an NFSC member during the policy-making process in response to the folate-NTD evidence,

"... the [Health Minister's meeting] agendas were long, there were lots of detailed issues, but ... the real issues were always Medicare dollars ... the big bucket of Commonwealth dollars that was on the table. So, the reality was that ... there wasn't a great deal of time for the National Food Authority debates and discussion – it tended to be at the end of those meetings" [118/2].

Similarly, on a day-to-day basis food regulatory matters often are deferred to a minister for health's staff. The former ACT Minister for Health commented that the main responsibility of his principal private secretary was to,

"... divide the masses of submissions that went through the Minister's office into the routine and the difficult and contentious ones. and this [folate fortification] was definitely in the routine pile, and would have been signed off one evening with 30 or 40 other routine matters" [118/5].
Within the context of the hierarchy of government policy issues, the former Chairperson of the NFA raised an additional question about the autonomy of the food regulator when negotiating with stakeholders within this political environment. She reflected on the outcome of the NFSC decision as being,

"... a sad day ... in regulatory history in terms of how the decision was taken. The irony is when it was sent back to us [NFA] with instructions ... there was more negotiating with [MBCM] ... how far does one do it in negotiation with the regulatee? But at the end of the day, yes we went further than we'd initially intended to go, but we dragged [MBCM] back a long way from what they wanted. And maybe that was what they were just doing, ambit claims." [12/50-51].

9.3.4 Obscuring, disparaging and trivialising policy alternatives

The data indicate that the political environment of the food regulatory system during the period of the case study was characterised by adversarial confrontations between certain stakeholders. All stakeholders appear to have been guilty to some degree of using various strategies that sought to obscure, disparage and/or trivialise opponent’s policy arguments.

Whereas those stakeholders seeking wider permissions for food fortification were claiming benefits would accrue in terms of trade, increased choice for the consumer and research and development, the NFA was asserting that such a policy position was motivated by marketing objectives to the detriment of public health. Conversely, certain food manufacturers and nutritionists were alleging that through its policy principles the NFA was paternalistic and the terms ‘social engineering’ and ‘nanny state’ were frequently invoked to describe the actions of the NFA by those stakeholders opposing its policy principles. The Consumer Representative on the NFA Board during this period commented that people at the NFA “... were made to feel they were being luddites, or purists, or too idealistic, or whatever the derogatory term” [I8/3-4].
The review of Standard A9 was set against a campaign that sought to cast the NFA in disparaging terms and to trivialise its policy principles. Certain stakeholders opposing the NFA’s policy principles undertook the campaign. For example, among media articles at the time, the NFA was accused of being, “secretive and inflexible and is at risk of being captured by consumerist philosophies” [D049-25/6/93, Business Review Weekly ‘Food fight erupts over rule changes’]. In another article, breakfast cereal was described as being at the centre of a major ethical and nutritional row between “manufacturers and the food police, otherwise known as the National Food Authority” [D088-17/5/94, Sydney Morning Herald, ‘Breakfast battle over what comes naturally’]. After the NFSC decision, the newsletter of the Grocery Manufacturers’ Association reported that the NFA “suffered a telling defeat” at the NFSC, “The recommendation ignored the advice of most Australian food scientists and academic nutritionists and would have required the costly reformulation of breakfast cereals. ... It will hopefully be noted by the NFA that they must rely much more heavily on scientifically defensible health and safety evidence and less on diet or nutrition ideals in the future.” [D072-22/4/94, Grocery Manufacturers’ Association newsletter, p1].

9.3.5 The fickleness of the political environment
The analysis of the political environment for the case study illustrates that the policy-making process was subject to unanticipated circumstances. For example, in recalling the vagaries of the political process, the representative of the ACA recalled that, despite the Association’s efforts,

“God must have been on the industry side because ... we thought that we had enough votes in the Ministerial Council for the revised standard, to bring it down. ... within a week, or two weeks, there was a change of government in Queensland, the ACT and Tasmania. There was three governments, three changes that were enough to bring new ministers in who were very quickly seized upon by the industry. And then that decision went through very quickly” [I21/8-9].

255
9.4 Assessment

In this section I assess the data and the themes that emerged from their analysis for the contribution they make to answering the questions from the previous analysis to identify the nature and scope of the causal link between these two perspectives in explaining the policy outcome.

As identified in the previous chapter, the folate fortification policy did not emerge in isolation from broader political agendas. Instead the policy-making process coincided with the NFA's review of Standard A9. In turn, the review of Standard A9 coincided with the Authority's establishment as part of the political reform of the food regulatory system in Australia. Therefore, it is through its association with the review of Standard A9 that the folate fortification policy was engaged with the political environment within which the food regulatory system operates.

This level of analysis of the case study was characterised by a political debate about the control of the policy environment within which the composition and labelling of foods was decided. The review of Standard A9 was among the first major food regulation policy issues with which the NFA had to contend. The NFA chose the review of Standard A9 to outline its interpretation of the protection of public health and safety in food regulation. At a broader political level, the NFA believed the review of Standard A9 provided an opportunity to demonstrate its authority and leadership in determining the nature and scope of policy in relation to food regulation and public health. Essentially, the review represented a test of power between public and private sector interests in determining where the locus of control rested in influencing the fundamental public health nutrition antecedents of both the nutrient composition of the food supply and how it was to be promoted to the population. The review of Standard A9 captured ideological questions about the purpose of food regulation and the respective roles and responsibilities of the regulator and the regulatee in managing the development of the food supply.

An examination of the themes that emerged from this level of analysis reveals that the political environment affected the policy-making process by influencing the
structure and operation of the food regulatory system. There was an explicit and hidden process to influence the food regulatory system and ultimately determine the outcome of the policy response to the folate-NTD evidence. The explicit influence was that the neoliberal and globalisation reforms conspired to impose meaning on the NFSC’s interpretation of the policy objectives. The hidden influences were that the regulatory procedures lacked openness and transparency and were not equally accessible to all stakeholders. A non-level playing field was created for the political setting so that the interests of certain stakeholders were privileged while those of others were obscured or were trivialised.

Data that emerge from the analysis of the case study from this perspective contribute unique insights into the policy-making process and reveal answers to questions raised in the analyses of the case study at the decision-making process and procedural levels of the food regulatory system. The political environment’s imposition of meaning on the interpretation of the protection of public health and safety offers a plausible explanation as to why the NFSC requested the NFA amend its policy recommendations, why it interpreted the policy objective in terms of no-harm and why it shifted responsibility for the case study from the NFA to the NHMRC. An explanation for the rushed nature of the policy-making process for the review of Standard A9 is provided by the identification that by coinciding with the establishment of the NFA it was subject to the two year timeline to clear the backlog from the previous NHMRC system.

An explanation for the observed lack of diversity in expert opinion on the Expert Panel can also be provided by the data at this level of analysis. The responsibility for the selection of members for the Expert Panel resided with the Nutrition Section of the DHSH. In keeping with the NFSC decision, the Nutrition Section of the DHSH appears to have chosen exclusively those experts whose policy preference was consistent with the NFSC advice. Also, the data indicate that the Nutrition Section of the DHSH did not share the NFA’s commitment to the Codex principles as a basis for interpreting and applying the protection of public health and safety and its own views coincided with those of the selected experts. An alternative explanation is that the timeline burden imposed on the Nutrition Section of the DHSH by the NFSC
meant that pragmatism prevailed as there was a need to get results in a short period of time. Thus, there was a need to rely on those experts who were familiar with the NHMRC processes. The Nutrition Section of the DHSH was allocated just 2 months to submit the Expert Panel's recommendations. In this time, the Expert Panel had to be established, conduct meetings and prepare its recommendations. This alternative explanation suggests that the selection of the Expert Panel was not necessarily a result of bias. However, it does suggest a more systemic problem within the NHMRC system in that the existing profile of experts predominantly shared one view of how public health and safety was to be interpreted and applied to the policy-making process. By answering questions posed in the previous analyses links between the levels of analysis are demonstrated.

This chapter has presented the results of the analysis of the case study from the third of the three levels of the food regulatory system. The analysis at each level has identified data and themes that provide insights and clues into what happened in making the folate fortification policy. The iterations between the analyses have identified links between the levels of analysis. In the next chapter the individual assessments that emerged from the analysis of each of the three perspectives are synthesised to provide one coherent assessment of what happened. The assessment is then interpreted against the literature review to build theory of how and why evidence was used in the policy-making process.
CHAPTER 10

Discussion

10.1 Introduction

In the preceding three chapters the findings from the analysis of the case study were presented. The policy analysis used Easton's model of a political system (Easton 1965) to unravel the web of connections associated with the policy-making process that resulted in the folate fortification policy. The data that have been collected for the various events, processes and stakeholder actions associated with the case study offer many insights into otherwise hidden aspects regarding how and why scientific evidence is used in making public health policy in a food regulation setting.

Whereas Easton's model (Easton 1965) has provided the heuristic device to organise the deconstruction of the food regulatory system, it cannot explain the connections between the elements. It is the nature and scope of the links within the political model of the food regulatory system that is the phenomena with which this thesis is concerned.

In the present chapter the data obtained from the analysis of each of the three levels of the food regulatory system are analysed to reconstruct a coherent assessment of what happened in the making of the folate fortification policy. The aim is to gain understanding of how and why scientific evidence was used in the case study. The themes that emerged from each level of analysis are interpreted against the theoretical framework outlined in Chapter 3 to test which theory, if any, provides the best fit with the empirical data. The validity of the theoretical understandings is investigated by comparing predicted outcomes to those observed in relation to the policy's: implementation and impact; exploitation to amend health claims policy; and influence on the relationship between the regulator and coalition members. The generalisability of the theoretical understandings to the food regulatory system is discussed. Then the implications of the combination of the theoretical understandings and the policy outcome are discussed. Finally, the research is discussed in terms of the strengths and limitations of the findings.
10.2 Assessment of the policy analyses

In this section the data obtained from each of the three levels of analysis are reconstructed into one coherent assessment of what happened regarding the use of evidence in the making of the folate fortification policy.

When analysed at ‘face value’ the report of the Expert Panel indicates that the folate fortification policy was the outcome of a systematic review of strong epidemiological evidence and a dietary modelling approach to planning the technical details of the policy. Also, the Expert Panel members presented the policy-making process as having been a relatively simple and straightforward rational-linear process. The combination of the strong epidemiological evidence, the tragic nature of the health issue being addressed and the ready availability of a ‘solution’ were attributes that made the policy ‘saleable’ and ‘newsworthy’ and therefore an attractive political issue (Rochefort and Cobb 1993; Bridgman and Davis 2000).

The strength of the epidemiological evidence, the tragic nature of NTDs and the ready availability of a technological solution notwithstanding, policy-makers were required to address several conceptual, scientific and ethical dilemmas when responding to the evidence for the folate-NTD relationship. Generally, during the decision-making process and in the Expert Panel’s report there was a failure to acknowledge the existence of these dilemmas, let alone the means by which they were resolved. This situation illustrates Tesh’s notion of ‘hidden arguments’ in the policy-making process described in the introduction to this thesis (Tesh 1988). These circumstances highlight that the folate fortification policy should not be accepted naively on face value. It is experiences of the type portrayed by the case study that led Hancock to caution against imbuing policy with “… an undeserved and unrealistic coherence” in order to seek closure from a written statement of policy as the ‘last word’ (Hancock 1999: 22).

The policy analysis approach of deconstruction enabled the policy-making process to be unravelled and otherwise hidden factors to be revealed. Clues and logic gaps
emerged at each level of analysis and these were used to pose questions of the process by continually asking 'why?' These questions guided progressively deeper levels of analysis. At any one level the observations associated with the policy-making process may have been circumstantial. However, the process of iteration between the data at each level of analysis accounted for the questions associated with isolated observations. This iteration process demonstrates that there were explanatory links between the levels to strengthen plausibility that there was a strategic pattern to the policy-making process within the food regulatory system. As the data were interrogated against the progressively deeper levels of analysis it became increasingly unlikely that observations were haphazard occurrences. Despite the policy-making process often appearing to be haphazard, this overlooks the notion that policy-making is by its very nature for a reason (Gardner 1998). It is only when viewed in total that a pattern emerges and a coherent assessment of what happened can be constructed.

The explanation for the resolution of the scientific and ethical dilemmas associated with the folate-NTD evidence arises from the situation that the case study coincided with the review of Standard A9. At the procedural level of the food regulatory system the policy debate focussed on the interpretation of the statutory objective, to protect public health and safety. The debate expanded to encompass the arguments of stakeholders pursuing wider permissions for food fortification. A reciprocal relationship ensued. Specifically, the folate-NTD evidence was used by certain stakeholders to support their arguments for wider food fortification permissions. In turn, the resolution of the broader debate by the NFSC in favour of wider food fortification permissions meant that voluntary folate fortification of staple foods was permitted irrespective of the epidemiological evidence for a folate-NTD relationship. Ostensibly, the Expert Panel was established to legitimise and provide the technical details for a predetermined policy position imposed by the NFSC.

The explanation for the resolution of the policy debate regarding the interpretation of the public health and safety policy objective arises from the situation that the review of Standard A9 itself coincided with political reforms of the food regulatory system. At this level the policy debate was focussed ideologically on arguments about the
respective roles of the public and private sectors in managing the development of the food supply. A reciprocal relationship also ensued at this level. Specifically, the wider permissions for food fortification were used by certain stakeholders to support their arguments for potential economic benefits that would accrue from placing greater control of the management of the food supply with the private sector. In turn, the resolution of the broader debate in favour of greater control with the private sector meant that the no-harm principle was invoked to replace the precautionary principle in interpreting the public health and safety objective. The burden of proof was placed onto the State to justify why wider permissions for food fortification should not be allowed, rather than onto those seeking to manipulate the composition of the food supply demonstrating a public health need for a policy change.

The coherent assessment that emerges from reconstructing the individual analyses is that the folate fortification policy outcome was the product of a series of interrelated processes that involved the three levels of the food regulatory system. Easton’s conceptualisation of the biological nature of the political system is relevant here (Easton 1965). The decision-making process in response to the folate-NTD evidence was not undertaken in isolation but displayed ‘organic’ characteristics. It was intertwined with procedures involved with the review of Standard A9 that were intertwined within a political environment characterised by microeconomic reform. The interactions between the levels of the food regulatory system had a reciprocal effect on each other. This served to strategically manipulate the use of evidence in the policy-making process so that the folate fortification policy option prevailed.

10.3 Interpretation of the results from the analyses

Whereas the analysis in the previous section provided a coherent assessment of what happened with evidence based practice for the case study, it does not explain how and why scientific evidence actually was used in the policy-making process. This section presents an interpretation of the results from each of the policy analyses of the case study against the theoretical framework presented in Chapter 3. This interpretation is used to test which theory, if any, provides the best fit with the
empirical data from the case study and thereby meets Easton’s plea for gaining understanding of the interrelationship between elements within his political system model.

The insights that emerged from the progressively deeper analyses reveal that the folate fortification policy was the outcome of a complex political process involving a web of interactions. These insights militate against the rational-linear nature of the policy process implied by the Expert Panel and presented in the policy narrative. Moreover, the Expert Panel’s failure to undertake a risk-benefit assessment to consider all policy options negates any suggestion that the decision-making process was rational and deductive.

Among the theories within the theoretic framework presented in Chapter 3, the garbage can theory, Kingdon’s policy streams model and Hall’s health policy model all offer explanations for aspects of the evidence based practice observed for the case study. For example, they conceptualise the importance of the ‘striking a balance’ phenomena that occurred between the epidemiological evidence, the political will and promoting folate fortified food products as a social strategy. Also, the various research utilisation theories offer explanations for the NFSC selecting a policy option that resonated with the political environment of the time. Yet, these theories are not able to account for the complex and strategic pattern of evidence based practice that was observed for the case study. The research utilisation theories generally assume that researchers and policy-makers are homogenous communities and politics effects evidence based practice by impacting on the communication channels between these two communities. The case study data dispute this relatively simple explanation. The data highlight the need for a more sophisticated assessment of the mechanism that explains how and why scientific evidence was used in the case study.

A relevant starting point for a more sophisticated assessment of evidence based practice for the case study is to note that all stakeholders had access to the same epidemiological evidence for the folate-NTD relationship. Nonetheless, different stakeholders expressed a preference for different food regulation policy options to effect a public health outcome. In expressing their preference all stakeholders
claimed to be upholding the protection of public health and safety. This situation raises some fundamental questions. How could all stakeholders claim this legitimacy given their policy recommendations differ? Why did the folate fortification policy option prevail over all other policy options?

The stakeholder’s different interpretations of using food regulation as a policy instrument both to effect and to protect public health illustrate that these policy objectives are socially constructed. There were competing stakeholder values associated with public health constructs and this emphasises that the use of evidence in the case study was inherently political. As Mulkay comments,

“All areas of scientific research are characterized by situations in which the established technical cultures permit the formulation of several reasonable alternatives, none of which can be shown conclusively to be more correct than another. It is in making choices between such alternatives, whether at the level of broad definition of the problem or at the level of detailed analysis, that scientists’ political commitments and the pressures of the political context come into play most clearly.” (Mulkay 1979: 117-118).

In the review of the theories of evidence based practice presented in Chapter 3, the theoretical explanations provided by Milio and Leeuw offer relevant insights into the case study by illustrating how group theory can explain the way that stakeholders interact with the policy-making process to influence what constitutes evidence. The critical aspect determining what constitutes evidence is captured in the framework developed by Lomas that describes the values that influence a policy decision as emerging from a complex interaction of interests, ideologies and beliefs (Lomas 1997). The different policy preferences of stakeholders in response to the folate-NTD epidemiological evidence aligned with either the medical or the health promotion model of public health as outlined in the typology in Chapter 4. As such, these policy preferences reflected distinct core values and can be categorised into either of two groups.

i) Stakeholders supporting targeted folic acid supplementation with nutrition education
The core values of stakeholders who supported this policy option reflected an interpretation of the protection of public health and safety consistent with the health promotion model of public health. In accordance with this model, food was regarded as a public health resource and food fortification recommended as a policy intervention only in response to evidence of a population wide nutrient deficiency. It was not to compensate for metabolic defects in at risk individuals. The protection of public health and safety was interpreted in holistic terms of protecting the nutritional integrity of food as an ecological resource for the health of the population.

ii) Stakeholders supporting folate fortification

The core values of those stakeholders who supported a policy option of folate fortification reflected an interpretation of the protection of public health and safety consistent with the medical model of public health. In accordance with this model, food was regarded as a commodity the composition of which could be manipulated to reduce the risk of disease in at risk individuals. The protection of public health and safety was interpreted in terms of a risk analysis approach. This involved a technical planning exercise of selecting appropriate food vehicles and the level of folate fortification to balance efficacy and safety criteria.

Sabatier and Jenkins-Smith’s ACF provides a particularly relevant and powerful theoretical framework for interpreting the data and synthesising an explanation of the interrelationship between facts and values in the making of the folate fortification policy (Sabatier and Jenkins-Smith 1993). The ACF explains policy as the product of competition between advocacy coalitions. Advocacy coalitions seek to manipulate the political setting to achieve their core values. Scientific evidence is used by the advocacy coalitions depending on how it aligns with their core values. Thus, to understand how and why evidence is used in the public health policy-making process there is a need to understand how and why competing core values are resolved.

Because of the value-laden nature of evidence based practice, core values are a better basis for identifying and predicting coalitions than groups who might share similar job descriptions. For example, during the case study nutritionists within government and academia had different opinions about the use of evidence. Sims refers to this as
the phenomena of ‘duelling scientists’ (Sims 1998). Conversely, there was a confluence in the interests of certain food manufacturers with those scientists with a positivist-reductionist approach to the way that the complementary objectives of using food regulation as a policy instrument to effect public health outcomes while protecting public health and safety are interpreted and applied. Together the food manufacturers and the scientists formed a dominant, albeit predominantly unintentional, coalition.

During the review of Standard A9, food manufacturers were generally disinterested in the specific case study. Their interest was the broader food fortification political agenda and ultimately being able to market their modified food products with health claims. Similarly, the clinical epidemiologists and the Expert Panel in general, focussed on the issue of NTDs, and were largely oblivious to the potential wider ramifications of the folate fortification policy. As such they were ‘tactical’ but not ‘strategic’ in their policy activities. Whereas a strategic approach to public health policy-making is located within a broad set of policy goals and takes into account the wider policy environment, a tactical approach contains the policy response within the immediate field of the policy problem (Stretton and Orchard 1994; Walt 1994). This tactical approach to policy-making is consistent with Tansey’s analysis that “Politics is about power, benefits and ultimately implementing policies to secure particular interests. ... Often, policies relate to immediate problems with little thought for the overall aims and goals of society.” (Tansey and Worsley 1995: 213). Moreover, by not recommending mandatory folate fortification, the Expert Panel inadvertently handed the strategic control of the policy’s implementation to the discretion of food manufacturers.

That the case study coincided with the review of Standard A9 resulted in these two distinct groups of stakeholders unintentionally complementing each other’s political agendas and activities. In contrast, certain professors of nutrition were intentionally associated with this coalition. These academics shared the food manufacturers’ interests and the clinical epidemiologists’ values. Hence, they acted as the conduit within the coalition between these two otherwise disparate groups of stakeholders.
By iterating between the levels of analysis of the case study, a pattern emerges to elucidate the mechanism by which the core values within this dominant coalition were privileged over other coalitions, comprising the NFA, consumer and broader public health stakeholders. Specifically, the findings of the case study reflect external (system) events and internal policy subsystem factors of the ACF.

The findings that reflect the external events of the ACF include those related to the existence of a policy hierarchy within the political environment, the governance of the food regulatory system and the ideological influence of neoliberalism. These findings are discussed below.

The case study demonstrated that a policy hierarchy exists in Australia. With all else being equal, the food regulatory system objectives were subservient to economic objectives. The Parliamentary Secretary’s rationalisation of the importance of securing the MBCM’s continued operation in Australia and the involvement of the Prime Minister illustrate that the case study was confronted with the dichotomy of ‘high’ politics versus ‘low’ politics (Walt 1994). The Ministers for Health on the Ministerial Council were required to weigh up trade objectives with public health objectives in making food regulation policy. The food regulatory system was not an autonomous statutory process, but one embedded within the broader political economy. Effectively, the food Authority’s role was confined to being a manager of process and technical matters responding to a higher order political level who assumed responsibility for interpreting public health policy objectives.

In the microeconomic reform climate characterised by deregulation, the governance of the food regulatory system was affected so that the capacity of the food Authority was diminished. Members of the dominant coalition were effective in operating outside of the formal procedures of the food regulatory system in order to achieve their policy objectives. These members went ‘over the head’ of the food regulator by liaising with individuals and agencies more senior within the DHSH as well as with other government departments. So successful were these members of the coalition in these activities that they were able to generate opposition to the NFA policy principles from across government, including the Authority’s own Parliamentary
Secretary and Minister for Health. The NFA was isolated within government. These findings are consistent with Sims’ observation that, “Members of a coalition usually concentrate their efforts on agencies and officials that are relatively sympathetic to their point of view while seeking to minimize the authority of unsympathetic governmental units.” (Sims 1998: 42).

The case study illustrates that food as a commercial commodity appeared to outrank food as a public health resource in the government departmental hierarchy, is not unique to Australia. In a case study of food and nutrition policy in the UK, Mills highlights the critical explanatory role of the relative strength of one government department (Agriculture) compared with another (Health) in determining the policy outcome. Mills argues that we should not expect the decision-making process to consider individual policies in isolation. Instead, he suggests that policies are made within a wider ‘policy community’ in which the implications of different policies relative to others is assessed. In this analysis policy associated with food production appear to outrank policy associated with public health (Mills 1993). According to Mills food policy communities are to be defined “... in a way which emphasizes not only their bargaining function, but also their ability to exclude actors and opinions through the resources they control. This allows the continuation of the policy community.” (Mills 1993: 116).

Complementing the aspect of governance that diminished the capacity of the food regulatory system was a lack of accountability within the Ministerial Council of the food regulatory system and the establishment of the Expert Panel. When making concessions to certain food manufacturers, notably the MBCM, during the review of Standard A9, the NFSC did not declare its voting pattern or reasons for its policy advice. In so doing, the Ministerial Council sanctioned the undermining of the procedure for open and transparent consultation laid down in the NFA Act 1991. As such, it made the policy process less democratic and more political. The Ministerial Council was not subject to Commonwealth or other freedom of information legislation as it is not an ‘agency’ under the Freedom of Information Act 1982. Hence the ministers’ policy advice was made without the opportunity for parliamentary scrutiny even though their decision had an impact on constituencies for which they
had no democratic representation (Wright 1998). Similarly, the establishment and operation of the Expert Panel lacked openness and transparency. For example, there was no formal selection process or criteria for selecting the members of the Expert Panel beyond the discretion of bureaucrats within the Nutrition Section of the DHSH.

The case study findings also indicate that the dominant ideology within the political climate of neoliberalism resonated with the positivist-reductionist approach to the interpretation and application of the public health policy objectives in a food regulation setting. The political climate was characterised by an ideology of individualism and placing responsibility for health onto the individual. Consistent with this ideology was the notion of encouraging food product innovation to develop the food supply to offer technical ‘solutions’ and increased ‘choice’ to individuals to address health problems. The legitimation of the positivist-reductionist approach privileged those stakeholder arguments that invoked scientific evidence that related to relatively immediate and readily quantifiable health indicators which were exemplified by the powerful emotional nature of arguments associated with the prevention of NTDs. Stakeholder arguments that invoked scientific evidence related to longer term and more holistic and abstract health indicators were not appealing in this environment. It was from this perspective that the policy objective to protect public health and safety was interpreted and applied in terms of evidence obtained from technical risk analysis procedures.

In addition, to these external events, several characteristic internal policy subsystem factors of the ACF were observed in the case study findings. In particular, among subsystem actors there was a disparity in resources and differences in participating and accessing the food regulatory system.

The food regulatory system favoured those coalition members with the greater capacity to fully access and utilise the procedures to their advantage. Consulting and participating with the food regulatory system did not occur on a level playing field during the case study. The MBCM invested substantial resources advocating for the liberalising of the food fortification permissions. The advocacy ranged from direct lobbying of decision makers through to employing a PR agency to organise seminars.
These seminars involved co-opting local and international nutrition scientists to make presentations. This allowed them to make media statements opposing the NFA policy in relation to the review of Standard A9. Public health and consumer groups had less capacity to participate in the review process. For example, they had less financial resources to attend meetings or to access ANZFA's public register in Canberra. Others have noted that relative resource advantage within and between coalitions is a useful and accurate characterisation of the politics involved in affecting dietary change (Mills 1992).

In addition to the disparity in resources, findings also highlight differences among subsystem actors in participating and accessing the food regulatory system. Whereas the MBCM employed staff whose job description included participating in the procedures of the food regulatory system, public health and consumer agencies relied on a small number of professionals to prepare submissions in addition to their 'core' work. Representation of consumer and public health interests in the policy process generally has been noted as problematic because they "...lack both continuity and expertise, in large part because few individuals have sufficient ideological or material incentives to bear the enormous costs of organizing large numbers of people." (Sabatier 1977: 444).

One finding from the case study that is not explained by the ACF was the influence of the global context. Policy developments occurring in selected countries were emphasised by members of the dominant coalition to argue in support of policy change in Australia. The argument was that Australia was not keeping pace with the international benchmark for food fortification policy generally and folate fortification specifically. The global perspective was exploited by stakeholders to pick and choose the policy profile of selected countries that matched their core values.

In this section I have shown that the ACF provides a powerful theoretical explanation of the findings. The explanation is that the case study was a competition between two advocacy coalitions with different core values. These either aligned with the folate fortification policy option or the policy option of targeted folic acid supplementation complemented with nutrition education. The advocacy coalitions sought to
manipulate both the procedures and the interpretation and application of the policy objectives of the food regulatory system to achieve their agendas. Evidence based practice was mediated by the meaning acquired by the public health policy objectives. External and internal subsystem factors were critical in creating a non-level playing field that determined whose core values were privileged or obscured within the food regulatory system and hence how and why scientific evidence was used. The case study illustrates that the governance of the Australian food regulatory system is operating within a contemporary political environment of neoliberalism and globalisation. This governance is legitimising the core values of a dominant coalition comprising a confluence in the interests of corporate stakeholders and scientists with a positivist-reductionist approach to public health in the making of public health policy.

10.4 Program logic: comparing observed and predicted outcomes

Given the relevance and powerful explanatory capacity of the ACF for the case study, it is possible to predict certain outcomes from the folate fortification policy. Outcomes that have emerged since the launch of the policy can be compared for their consistency with outcomes predicted from the theory. Yin refers to this as a ‘program logic’ strategy and it offers a further test of rigour of the relevance of applying the ACF to the case study (Yin 1994). In this section I investigate the ‘program logic’ of the theory. There are three predicted outcomes:

i) The policy’s implementation and impact.

ii) The exploitation of the policy to amend health claims policy.

iii) The relationship between the food Authority and coalition members.

10.4.1 The policy’s implementation and impact

It is outside the scope of this thesis to evaluate the impact of the folate fortification policy. Nevertheless, data regarding the implementation and impact of the policy is available from preliminary evaluations undertaken in Australia and internationally.
Policy implementation

It would be logical to predict that those stakeholders who advocated for the folate fortification policy are likely to be most involved with the policy’s implementation. In response to the publication of revised Standard A9, myself, under the auspices of the then NFA, coordinated the planning, implementation and analysis of an Australia-wide survey. This baseline survey monitored the availability and price of food products permitted to be fortified with folate. Data were collected over a three-year period from late-1995, prior to the appearance of folate fortified food product in Australian stores. Community nutritionists and health workers collected the data from over 50 locations in all States and Territories ranging from capital cities to remote locations. The primary objectives of the survey were to monitor the availability and cost of folate-fortified food products. A published paper reporting the method, results and discussion of this survey is attached at Appendix 12 (Lawrence et al. 1999).

Based on the data collected in this survey, the implementation of the NHMRC’s recommendation on folate fortification was modest and uneven. In the three-year period following the gazetted of revised Standard A9, a total of 47 folate-fortified food products became available. Sixty percent of the folate-fortified products were breakfast cereals (28 products). In fact, 9 of the 10 most popular breakfast cereals were among the brands fortified with folate. Yet only about 30% of women of childbearing age (i.e. the target group) report consuming breakfast cereal on a given day (Australian Bureau of Statistics 1998). It is noteworthy that one manufacturer, MBCM, was responsible for 23 of these folate fortified breakfast cereals. The latest evaluation, in late-1999 reported only 104 of the recommended foods had been fortified with folate and these were mainly breakfast cereals (Abraham and Webb 2000). Having been most intensively involved in the review of Standard A9, breakfast cereal manufacturers were now dominating the policy’s implementation. This supports the predicted outcome.

Policy impact

Given the policy was being implemented without a risk-benefit assessment of policy options being undertaken, it is not possible to evaluate the relative impact
effectiveness of the various policy options. Since this research began there have been several evaluations of the folate fortification policy at the national and state level. The preliminary findings emerging from these evaluation studies are mixed. The report of the interim evaluation of the folate fortification policy by the NFNMU concluded, “Three years after gazettal, fortification has not … had a major impact on folate intakes of the target population, and the incidence of NTDs has not been measurably reduced. Thus, the public health objectives of this program are not being met.” (Abraham and Webb 2000: 85). Conversely, data from population-based birth defect registers in three Australian states have documented a 30% to 45% fall in prevalence of NTDs since 1996 (Owen et al. 2000; Chan et al. 2001; Bower et al. 2002). However, this trend began before folate fortified food products were widely available in Australia. With folate fortification now in place, it will be difficult to separate the attributable fraction of different policy options to this fall in prevalence. For example, data from the evaluations of health promotion campaigns in these three states have demonstrated effectiveness of these campaigns in improving women’s and health professionals’ knowledge and practice in relation to folate (Watson et al. 2001; Chan et al. 2001; Bower et al. 1997).

In the United States, where folate fortification of staple foods was mandated from 1 January 1998, studies have since reported that serum folate concentrations have dramatically increased among the population (Jacques et al. 1999). There has also been a 19% reduction in NTD birth prevalence (Honien 2000). The authors comment that the significance of their findings depends upon what pre-fortification period is used as the reference for comparison with the post-fortification cohort. Given the long-term downward trend in NTD prevalence, “… factors other than fortification may have contributed to this decline.” (Honien 2000: 2981). Similarly, it has been reported that, “The decline in NTD prevalence observed in all British and Irish populations since the early 1970s continued with the introduction of folate fortification of cereals” (Murphy et al. 2000: 885). Researchers are now interpreting these evaluation data to argue that the consumption of 5 mg folic acid on a daily basis may be needed to reduce the risk of NTDs by 50-70% (Wald et al. 2001).
The findings emerging from the evaluation studies support the predicted outcomes. The proportion of the measured benefit that can be attributed to folate fortification relative to other initiatives such as the promotion of folic acid supplements to target individuals cannot be determined. The significance of the findings reported in several studies depended upon what pre-fortification period was used as the reference for comparison with the post-fortification cohort because of the long-term downward trend in NTD prevalence. Now that the policy is being implemented it is no longer possible to assess the relative cost-effectiveness of alternative policy options and to learn the best policy approach to reduce the prevalence of NTDs.

10.4.2 The exploitation of the policy to amend health claims policy

The dominant coalition was founded on a coming together of the values of clinical epidemiologists and the commercial interests of food manufacturers. Consistently during the review of Standard A9, the NFA and consumer and public health stakeholders argued that the food manufacturers advocacy for liberalising food fortification was motivated primarily by marketing objectives, rather than public health needs. From this perspective, it would be predicted that the folate fortification policy would be exploited, by the MBCM in particular, to facilitate a transformation in policy regarding the promulgation of information of the relationship between food and health.

On 18 March 1998, the Commonwealth Minister for Health announced that a folate health claim would be piloted in the second half of 1998. The announcement was made by the Minister at a ‘nutrition summit’ organised by the MBCM to launch a report based on the MBCM’s own national survey of consumer attitudes to health and nutrition. In referring to the findings from the MBCM’s research, the Minister stated that the Federal government was considering a move to amend the Food Standards Code to allow health claims “... in the wake of research which found that six in ten consumers are confused by nutrition messages” [D184-18/3/98, Media release, ‘Confusion about nutrition, diet and food messages: Government and industry to explore new approach’, Commonwealth Minister for Health].
Within two weeks of the MBCM’s launch, the Parliamentary Secretary with responsibility for the food Authority, wrote to the Chair and members of ANZFA enclosing a Direction in relation to the proposed pilot [D185-30/3/98, Direction from Worth to McCaughey]. ANZFA was directed, in accordance with section 11 of the ANZFA Act 1991, to exercise its power under section 37 of the Act to omit to invite public submissions in relation to the Proposal. Section 37 refers to emergency procedures that permit critical issues to be addressed as a matter of urgency.

In response to the directive, ANZFA raised proposal P170 - Pilot for a Management Framework for Health Claims. The folate-NTD relationship was to be used for the pilot. The experience gained from conducting the pilot was to be used to guide decision making for the review of the prohibition on health claims (Australia New Zealand Food Authority 2000). On 18 November 1998, P170 was launched at another nutrition meeting hosted by the MBCM. For the first time a health claim was legally permitted on food products available in Australia and New Zealand. The Parliamentary Secretary responsible for ANZFA announced that the pilot folate health claim trial “… represented the beginning of an exciting chapter in public health education and research.” [D186-19/11/98, Media release ‘Folate health message – it’s legal on food: Major milestone in public health history’, Tambling].

The Directive to implement the approval of the pilot folate health claim trial raises several concerns regarding the transparency of the process. The folate health claim trial created a precedent for health claims. Yet the invoking of the Section 37 procedure denied the opportunity for public consultation. The rationale for invoking the emergency procedures, to minimise delays in preventing NTDs, is questionable. It is difficult to understand why a pilot health claim trial is an emergency intervention. In particular, if the health claim trial was an emergency, it is not logical that its evaluation was confined to assessing its management process, rather than its impact on NTD rates.

The interim evaluation report of the folate trial concluded that the folate-NTD health claim had had little impact on increasing knowledge of folate or the purchase of foods carrying the claim. The report stated, “… written educational material is the
preferred preference for conveying information about folate and NTDs, rather than food labelling.” (Australia New Zealand Food Authority 2000: 10). Despite this insignificant outcome, the Commonwealth Minister for Health made a speech in May 2001 in which he stated: “I believe the Folate Health Claim pilot program has demonstrated that we can shake off the ancient prohibition that stopped the snake oil salesmen and peddlers of patent nostrums from making untrue claims about the efficacy of their potions. … we have an opportunity to move on from our previous blanket ban on linking specific foods to specific health conditions.” [D200-23/5/01, MinisterSpeech, http://www.health.gov.au/mediarel/yr2001/mw/mwsp010523a.htm]. One year later, the ANZFRMC approved, in principle, a policy to permit health claims with a final decision on the form of the policy to be made in November 2002 [D201-24/5/02, ANZFRMC media release].

The evidence that has emerged since the launch of the folate fortification policy indicates that the policy has indeed turned out to have been the ‘stalking horse’ for health claims predicted by the Chairperson of the NFA several years earlier. The policy has served to open the door to initially review and ultimately amend the policy prohibiting health claims in Australia in accordance with the interests of the MBCM. The process that has led from the folate fortification policy launch to the in principle approval of health claims has displayed similar characteristics to those observed for the case study. The process lacked openness and transparency and in the absence of evidence of effectiveness has progressed on the principle of no-harm.

The Expert Panel did not recommend the folate-NTD health claim. Nevertheless, it was naïve in failing to consider the longer term implications of its actions on the health claims policy agenda. The irony being that the broader policy changes that the folate fortification policy has facilitated may be to the Expert Panel’s own detriment. Food manufacturers have acknowledged that the folate-NTD relationship does not make for a ‘sexy’ health claim and the more liberal food fortification policy has provided opportunities for fortifying food products with other nutrients that can be marketed to a larger target audience. As the MBCM’s former Director of Scientific and Consumer Affairs commented,
"... we saw it [folate health claim trial] as very important strategic move to develop the whole long term health claims debate. That was the company's international policy ... So the investment in folate, and it was substantial, was not really to do anything about folate really, in the end it was about progressing health claims generally." [16/5-6].

10.4.3 The relationship between the food Authority and coalition members

Central to the theoretical understanding is that coalitions seek to manipulate the interpretation of the policy objectives of the food regulatory system to achieve their core values. That the policy outcome did not match that originally recommended by the NFA illustrates that it was instructed to change its interpretation of policy objectives to support a different set of core values to that which existed when it first initiated its review of Standard A9. It would be predicted that since the launch of Standard A9 the food Authority's relationship with different coalition members would have changed significantly.

There is evidence that public health and consumer representatives who previously supported the food Authority and its interpretation of policy objectives are now expressing concern that ANZFA has an inappropriately 'close' relationship with food manufacturers to the detriment of public health interests. For example, at its annual food conferences in 1999 and 2001, the Public Health Association of Australia recommended the need for reform of the governance of the food Authority in each conference's Outcome Statements (Eat Well SA and Public Health Association Australia 1999) (Public Health Association of Australia 2001).

Conversely, the corporate entities that previously had lobbied against the NFA policy stance on the review of Standard A9 and had publicly criticised NFA staff, especially its nutritionists, are now publicly defending the Authority and its staff. For example, in response to criticisms directed at the food Authority following its perceived failure to adequately protect public health interests, the MBCM's Director of Scientific and Consumer Affairs commented, "We should support our dietitian colleagues at ANZFA. They are working on our behalf to ensure that there is a scientific basis to the food regulations we have and that public health interests are taken into account."
[D188-July 1999, Williams, 'Genetically modified food', DAA newsletter]. Similarly, the Chief Executive Officer of the AFGC has commented that,

"I have seldom witnessed such a mischievous, unsubstantiated attack on a regulatory authority as we are currently witnessing on the Australian New Zealand Food Authority, which is being charged with being sycophantic to industry, anti-consumer and incompetent. ... One could explain some of that aggression in terms of a wish to return to the early days of that authority, when there was a strong predisposition to use food regulation for social engineering." [D187-April 1999, Hooke 'The food industry as honest broker'. National Science & Industry Forum Report].

These observations support the prediction that since the launch of the folate fortification policy there has been a significant change in the food Authority’s relationship with different coalition members.

The observed outcomes that have emerged since the launch of the folate fortification policy are consistent with those predicted from knowledge of the theory. These observations support the program logic strategy and add further confidence to the theoretical explanation for the case study.

10.5 Generalising the theoretical understandings to the food regulatory system

Earlier in this thesis I described the food regulatory system as an inherently political setting for making public health policy. Food’s role as both a fundamental public health resource and a valuable commercial commodity invariably lead to different expectations among stakeholders about how the food supply should be regulated. Policy agendas associated with using food regulation as a policy instrument to effect public health outcomes have emerged to be particularly vexatious for the contemporary food regulatory system. In this section I discuss what the theoretical understandings gained from the analysis of the case study mean to public health policy-making in the food regulatory system more generally.
Neural tube defects are not the only health related issue for which food regulation is being proposed as a public health policy intervention. Many stakeholders are arguing that issues such as health claims on food labels, genetically modified food and novel foods more generally, illustrate the nature and scope of the role food regulation can play as a public health policy instrument. These contemporary issues are attracting similar coalitions of stakeholders to those that existed for the case study. The coalitions are forming around shared core values towards the relationship between food and health. Against this background the State claims that the role of the food regulator is that of the ‘policy broker’ who mediates between coalitions.

However, the external and internal policy subsystem factors of the ACF highlight that it is naïve to assume that the food regulator has the independence to act as a neutral umpire in public policy-making. The theoretical understanding that emerges from the case study highlights the need to conceptualise the policy-making process associated with a food regulation setting as a component within a wider political environment as represented by Easton’s model of a political system (Easton 1965). Easton’s model draws on political system’s theory that at its core explains public policy as the product of the political system responding to demands arising from its environment. Coalitions attempt to manipulate the procedures and interpretation of policy objectives within the food regulatory system to serve their respective agendas. Evidence based practice is being presented as the harbinger of truth for the policy-making process when mediating between the demands of coalitions. Yet, as the theoretical understandings illustrate, the use of scientific evidence is itself an integral component of the policy-making process.

The case study demonstrated what happens when the stability of the food regulatory system is threatened. During the review of Standard A9 the NFA resisted the demands being placed upon the policy-making process from the broader political environment. Dominant coalitions and the government perceived the NFA as a recalcitrant agency and its actions as threatening to destabilise the functioning of the food regulatory system. The actions of the Ministerial Council in intervening to exert its influence over the policy-making process restored stability. This experience highlights that the governance and procedures of the food regulatory system are shaped by the political environment and are subservient to higher political agendas.
Essentially, the role of the food regulator is concerned with managing processes and maintaining the system’s stability, within the wider political system, rather than independently making public health policy. The food regulator is positioned to respond to political agendas. In such circumstances it is difficult for the food regulator to assert leadership and adopt a long term vision for the development of the food supply.

The manipulation of the governance and procedures of the food regulatory system involves a political balancing act. The system cannot be structured to privilege one coalition so that its credibility is undermined. For example, Nixon refers to an ‘ideological fervor’ to review the FDA that is described as a ‘right wing agenda to demonize regulators and government’ (Nixon 1996). Despite this aggressive assault on the FDA, he observes that many corporate representatives and deregulation politicians express doubts about the wisdom in dismantling the FDA. If the strategy was so effective and taken to its logical conclusion regulatory responsibility would be handed to the private sector which may prove to be counterproductive and akin to “… throwing the baby out with the bathwater.” (Nixon 1996: 563).

In the contemporary political environment, public health policy-making in government is devolving to bureaucracies that lack specialist expertise. As a consequence, they have a reduced capacity to influence and manage public health outcomes. Instead they manage processes such as the establishment of expert panels (Di Francesco 2001). As outlined in Chapter 2, since the launch of Standard A9 a program of legislative and regulatory review culminating in the Inter-Governmental Agreement 2000 for the new regulatory system has been undertaken. These developments have imposed a number of structural and procedural changes onto the food standards setting process that have the potential to exacerbate the flaws in the governance of the food regulatory system observed with the case study. For example, the latest arrangements have reconstituted the statutory authority with its responsibilities being confined to technical matters and established the ANZFRSC to assume responsibility for policy matters. This formal separation of technical and policy roles appears likely to introduce inefficiencies and further diminish the openness and transparency and consultative process of the policy-making process (Lawrence 2001).
Also, in the contemporary political environment of neoliberalism and globalisation, the food regulatory system is being subjected to ongoing reforms of its structural and administrative arrangements. These reforms are characterised by the dominance of market values and measures of economic efficiency in directing the governance of the food regulatory system. The emphasis is upon developing innovative food technologies and products rather than conserving the integrity and sustainability of the food supply.

In accordance with the external and internal subsystem factors explained by the ACF these reform agendas for the food regulatory system are creating a non-level playing field and serving to privilege those stakeholders and coalitions whose core values are aligned with the medical model of public health. The medical model of public health is able to generate political support because it promotes the notion of food products serving the dual roles of being value added commodities as well as offering solutions for health problems.

The medical model offers relatively immediate tangible results that can be measured. Also, it focuses on the individual and tends to be less threatening to existing power relations. Alternatively, policy-makers can be frustrated by the uncertainty associated with the effectiveness of the relatively long term and multicausal benefits of the health promotion model of public health (Labonte 1998). There are technical obstacles in developing indicators and collecting data to provide evidence in support of abstract concepts associated with social and environmental principles. As Miller, a former senior official at the FDA has commented,

"The human mind has great difficulty in comprehending the totality of complex, dynamic systems and as a result moves in the direction of simplification and reduction. ... [This has increased knowledge of mechanisms explaining submolecular systems, but] ... has been less successful in providing a base for public health policy, largely because reductionist approaches to science do not encourage the kind of integrative, constructionist 'gestalt' required for successful public policy. This is particularly true for public health policy related to the food supply." (Miller 1993: 411).
In Chapter 2 the description of the food regulatory system highlighted that policymakers were confronted with a diversity of conceptual, scientific and ethical dilemmas when using scientific evidence in making public health policy in this setting. The case study captured these dilemmas. In the previous two sections theoretical understandings emerged that illuminated how and why scientific evidence was used and the dilemmas were resolved when using food regulation as a public health policy instrument to reduce the risk of NTDs. This is important because the food regulatory system is the unit of analysis for this thesis. So, what do these insights contribute to understanding the resolution of the conceptual, scientific and ethical dilemmas associated with evidence based practice when making public health policy in the food regulatory system?

The policy-making process that resulted in the folate fortification policy, and revised Standard A9 more broadly, has ushered in a new era of evidence based practice for making public health policy in a food regulation setting. Conceptually the protection of public health and safety policy objective in the food regulatory system is being interpreted in terms of technical risk analysis procedures. The resolution of the scientific uncertainty associated with evidence largely is explained by the policy-making process adopting the no-harm principle. For example, in the absence of evidence of harm, the composition and labelling of food can be manipulated irrespective of a public health need for such change. This new era has replaced ‘principles-oriented’ evidence based practice with ‘risk analysis-oriented’ evidence based practice. Risk analysis procedures are concerned with relatively short term safety issues for individuals rather than accounting for longer term collective consequences.

The no-harm principle presents new challenges for protecting public health and safety. Although there is no evidence that the policy decision will harm individuals, it has laid open the potential for indiscriminate addition of nutrients to food products in the form of a ‘power race’ among food manufactures for food fortification (Sindall et al.). A management approach to complement the shift in public health policy-making is to instigate ‘protective’ measures, for example, providing resources for monitoring and nutrition education. However, there is an inherent contradiction in
adopting this approach. Governments are reducing their commitment to such public programs. They also are abrogating responsibilities for public health nutrition to the private sector (Lawrence 1998).

Understanding the resolution of the ethical dilemmas in public health policy-making involves recognising the weakening of the role and influence of the State and a progressive decline in collectivist ideals and a corresponding rise in the ideology of individualism. Individualism holds individuals responsible for their actions and consequences, including health. The dominant ideology is to provide for individual choice rather than necessarily to protect ‘collective goods’. This resolves the ‘promotion of individual autonomy versus protection of collective interests’ ethical dilemma and how the assessment of potential paternalism is explained. As illustrated by the case study, in a food regulation setting this equates to permitting food innovation to provide an individual with an increased choice of food products and increased information to construct a healthy diet.

These observations of the relevance of the ACF theory to the food regulatory system extend to food and nutrition policy in Australia more generally. In his analysis of food and nutrition policy in Australia, particularly that made by the NHMRC, Duff has concluded that policies consistently reflect the core values of the medical model to the ignorance of the health promotion model. He criticises the NHMRC for institutionalising the medical model in its policy statements and research funding, “The priority accorded medical positivism as the only way to produce valid knowledge, and the emphasis on medical authority, has meant that where public health issues have been raised, there has been little support for forms of research which do not confirm medical strategies and authority.” (Duff 1996: 50). Earlier reviews of the NHMRC also noted that a disproportionate emphasis is placed on core values aligned with the medical model rather than those aligned with the health promotion model of public health (Sax 1984; Bienenstock 1993). Brian Howe, a former Commonwealth Minister for Health, addressed the NHMRC directly with issues raised by certain critics when stating, “At its sharpest, the criticism is that the Council is dominated by the medical profession, and that the Council’s solutions to health problems therefore tend to represent the profession’s view of the world” (National Health and Medical Research Council 1990: 53).
10.6 Implications predicted from the theoretical understanding

In the previous section I discussed that the theoretical understanding could be used to explain the resolution of the conceptual, scientific and ethical dilemmas associated with evidence based practice when making public health policy in the food regulatory system. In this section I discuss the implications that can be predicted from the theoretical understanding in relation to the future profile of the food supply and the nature of evidence based policy-making.

10.6.1 The future profile of the food supply

The NFSC decision to base the policy review of Standard A9 on the no-harm principle rendered redundant the concept of nutritional integrity as a basis to public health policy principles. The nutrient profile and nutritional ‘behaviour’ of certain foods will no longer be able to be predicted from historical experience. Conventional public health nutrition policy concepts such as balance, variety and moderation to select a healthy diet are now less straightforward. In addition, nutrition education tools such as food selection guides now have a diminished relevance as their conceptual basis was founded on categorising foods on their characteristic nutrient profiles.

The corollary of the policy decision is that there is increased regulatory flexibility for food manufacturers and scientists with a positivist-reductionist approach to public health research to pursue food product development. Against this background it is likely that the future profile of the food supply will be characterised by a proliferation of new products that reflect a convergence in conventional food and therapeutic properties. As the Managing Director of ANZFA commented during the period that this thesis was being finalised,
"We have seen but the tip of the iceberg, representing an industry that now has the freedoms – and I hope the incentives – to experiment with its products. To produce foods that have not yet been thought of. To create markets where none exist today. ... It is a most exciting time for everyone connected with the industry – and I count myself alongside you." 66

10.6.2 The future of evidence based policy-making

A fundamental challenge with the new era of risk analysis-oriented evidence based practice is that a secure and predictable policy base for food and health relationships has been replaced by a policy framework that permits evidence to be used with greater flexibility to drive food product development. The ‘risk with risk analysis’ as the policy basis to evidence based practice is that regulators cannot anticipate unforeseen circumstances, especially over the longer term. In the context of folate fortification, Mills comments, “…the absence of evidence of toxicity is not evidence of the absence of toxicity.” (Mills 2000: 1443).

Beck critiques the concept of scientific knowledge and risk analysis as the basis for informing technological development (Beck 1992). Beck’s thesis is that scientific rationality and its collusion with technological development is legitimating the production of risk, for example, the construction of acceptable levels of risk. Science is then being positioned to assess and manage the risks and problems it has created. Clearly, there is a contradiction.

Easton’s systems model of the policy-making process is characterised by its feedback loop. For example, a policy outcome feeds back into the political environment to then influence the inputs into the decision-making process and the cycle continues. One implication that emerges from applying Beck’s thesis to the new era of evidence based practice that is informing policy-making within the food regulatory system is that the process inevitably is non-sustainable.

66 Lindenmayer I, ‘The opportunities and threats of the new Food Standards Code’, keynote presentation at the 4th Annual Food Composition and Labelling Standards Conference, Sydney, June 2002
Also, there are two potential developments that may have significant implications for public health policy-making in the food regulatory system that are forecast from the theoretical understandings. Firstly, the ongoing development of international trade and the role of the WTO (and Codex) likely will place further pressure for the global harmonisation of food regulation. The implication of such globalisation of food regulation on the capacity and integrity of national food regulatory systems remains unclear. Secondly, the logical extension of the political system’s model is that if coalitions believe that the food regulatory system is marginalizing their core values they may resort to activities that do not recognise the authority of the system and direct their demands externally. For example, if coalitions lose confidence in the system their ultimate weapon is to withdraw support for its role and agitate to destabilise its legitimacy with the intention of replacing it with an alternative approach.

Australians are fortunate to enjoy a food supply that is abundant, diverse, safe and relatively cheap. National surveys consistently indicate that the food supply contains more than adequate amounts of nutrients to satisfy the nutrient requirements of all Australians (Australian Bureau of Statistics 1993). There are few nutritional deficiencies among the population. Rather than conserving the nutritional integrity of the food supply, and thereby protect its public health resource capacity, much of the justification for developing the food supply is based on arguments that it is change that will help achieve public health benefits. From a public health perspective this situation raises the question, when do we stop developing the food supply, or is it in perpetual development?

10.7 Strengths and limitations of the research

The research findings presented in this thesis shed light on many aspects of public health policy-making in a food regulation setting. Nonetheless, it is critical to recognise the strengths and limitations, in applying the interpretation from this case study to a wider setting.
10.7.1 The influence of my role in the study as an observing participant

There is an inherent paradox in undertaking research that relies on the use of scientific evidence to test the plausibility of a theory at the core of which is the notion that evidence based practice is value-laden. The reader will remember from the explanation in the methods chapter that it cannot be assumed that the observations for this investigation began from an objective base. Although it may be an illusion to be objective in data collection, analysis and interpretation, I was aware of the importance of identifying this subjective influence. Throughout this thesis I have attempted to reflect continually on my own presence in the field of analysis and to address my personal involvement with the case study as well as my judgements in conducting the data collection, analysis and interpretation to ensure that any influence is clearly visible to the reader. I have attempted to expose these and consider alternatives and do not claim that the thesis was the product of a disinterested and neutral observer. I address the credibility of the analysis by being transparent with logic, data and analysis procedures and expose any assumptions.

10.7.2 The rationality of the theory

This thesis operates from a social constructivist ontology. All knowledges are social products dependent on those who produce them and the social and political contexts in which they are produced. As such there may be multiple constructions of the policy process (Baum 1995). Social knowledge is not 'falsifiable' in scientific terms, that is, knowledge of the public policy process cannot be 'disproved' as such. Instead, the aim of the policy analysis was to interpret the research findings against a theoretic framework synthesised from the policy and social science literature to identify the most plausible theoretical explanation. Although the theory that was applied to the analysis of the case study cannot be proved, its plausibility was able to be judged according to how well it explained the data, how comprehensive it was to informed participants, and how well it cohered with existing knowledge (Mays and Pope 1995).

There are no ways of resolving truths about competing views of the world. The idea that policy analysis, or in the instance of this thesis, what might more accurately be described as the analysis of the policy-making process, is neutral is a myth.
(Hogwood and Gunn 1984). Because rational analysis is not possible, then claims of truth and proof are meaningless. Nevertheless, I reject the notion that the intermingling of facts, theories and values means that the stories that emerge from policy analysis are bound inevitably to a relativist position wherein all interpretations are valid and theory cannot be conceived or its plausibility assessed. Instead, in demonstrating the relevance of the ACF to the case study I have explained the value-laden nature of evidence based practice in public health policy-making and exposed the hidden political processes to provide a base for further theory development. As Parsons notes, “Although the models and metaphors of public policy are not testable in a ‘scientific’ sense, they provide a way in which the values, assumptions and beliefs which frame the analysis of problems and processes can be made clear and open to critical understanding.” (Parsons 1995: 67).

10.7.3 The generalisability of the findings
There is an inherent conundrum between the rationale for selecting a case study and its generalisability. As the unique and revelatory nature of a case study increases, so too does the rationale for the case study method. Yet, such case studies are especially context dependent and as a result are less generalisable to other cases and their theoretical relevance assumes a smaller frame of relevance. I have attempted to mediate between the two phenomena in conducting the research presented in this thesis.

The case study coincided with the existence of scientific and ethical dilemmas associated with the epidemiological evidence of the folate-NTD relationship and meant that competing core values emerged and were expressed in policy-making. It was through the existence of these competing core values that this case study provided an opportunity to investigate deeper insights into the policy-making process. Without this opportunity otherwise deeper insights into the policy-making process probably would remain hidden from investigation.

Also, the analysis of the case study at each of the levels of the food regulatory system coincided with peculiar circumstances that provided opportunities for otherwise hidden aspects of the policy-making process to be revealed. At the decision-making
level members of the Expert Panel were empowered to interpret and apply the statutory objectives. At the procedural level the timing of the review of Standard A9 engaged the policy debate with the broader food fortification agenda and a wider diversity of stakeholders. At the political environment level the establishment of the NFA was a component of the microeconomic reform agenda. The NFA originally chose to interpret the public health and safety policy objective in a way that was contrary to the prevailing political interests. The NFA then asserted this position so that a highly visible adversarial and truncated process was created. The NFA’s policy stance and its persistence in pursuing this stance forced the dominant coalition to be more visible in exercising its power.

The existence of the peculiar dilemmas and circumstances for this case study raises several questions about the generalisability of the thesis findings, including:

- Given the peculiar circumstances, how generalisable is the Australian response to the folate-NTD evidence to another country at another time?
- Given the revelatory and unique case study, how generalisable is the case study to public health policy-making in a food regulation setting more broadly?
- Given the conceptual, scientific and ethical dilemmas of the food regulatory system that the case study captured, how generalisable is the theory to public health policy-making more broadly?

From a naturalistic inquiry perspective it is meaningless to avoid revelatory and unique case studies or to attempt to control for peculiar circumstances and to presume that there is a more ‘normal’ case study for policy analysis and from which to generalise theory. In assessing the plausibility of theory and its potential generalisability, I argue that the opportunities for policy analysis provided by the peculiar dilemmas and circumstances associated with this case study are a strength, not a weakness. There is a fundamental paradox in attempting to reveal hidden policy processes and agendas for analysis. By definition they are difficult to observe and you will never know if you have found them all as you don’t know what you cannot find. The peculiar dilemmas and circumstances have provided the opportunity for many otherwise hidden phenomena to be exposed and made more visible to observation and analysis.
10.7.4 The rigour in conducting the research

There are many interpretations of how and why scientific evidence was used in the making of the folate fortification policy. Rather than accept the interpretation on the basis of indisputable evidence, my analysis purports to provide the most plausible theoretical explanation of the public health policy-making process relative to other explanations. Using the principle of judicial review, the balance of evidence indicates that there was a strategic pattern to the policy-making process across the three levels of the food regulatory system. The alternative explanation that the pattern was circumstantial cannot be sustained given the coherent link between the three levels of analysis and the consistency of individual data from multiple data sources.

There are reservations about the plausibility of the thesis argument. I cannot assume that I captured all the information relevant to the case study, nor that the information collected was always an accurate representation of events. Similarly, I cannot assume that I accounted for all possible interpretations of the data. At the time of the policy-making process, many events and processes were quite unpredictable and fickle. Elegant theories of the policy-making process are attractive, but need to be interpreted and applied with caution. As Gardner observes,

"Although policy analysis and research can be rational and objective, the policy process, or more properly processes, are more chaotic. Decisions are subject to the vagaries of individual, interest group, public service, and political party preferences and values, and to their relative power and authority." (Gardner 1998: 2).

With due recognition to these matters, procedures were put in place at each stage of the research design from data collection to analysis and reporting to minimise bias and improve rigour. These procedures were outlined in Chapter 5.
10.8 Conclusion

This chapter has interrogated the data obtained from the analysis of each of the three levels of the food regulatory system. The data were analysed to prepare a coherent assessment of what happened in the making of the folate fortification policy. The themes that emerged from each of the analyses were interpreted against the theoretical framework presented in Chapter 3 to identify the most plausible explanation of the case study findings. The application of the ACF provided a powerful explanation for making sense of the findings by putting back together into a plausible story the data that had emerged from the pulling apart of the case study. The validity of the theoretical understanding was reinforced when the observed outcomes since the launch of revised Standard A9 are consistent with those predicted from the theory.

In accordance with the thesis aim the theoretical understandings were generalised to the public health policy-making process in a food regulation setting. The discussion focussed on addressing the issues identified in Chapter 2 as relevant to the unit of analysis, that is, the conceptual, scientific and ethical dilemmas in using evidence in the policy-making process in this setting. In the current political environment it would be expected that the theoretical understandings would apply to the food regulatory system more generally. Then the implications of the combination of the theoretical understandings and the policy outcome were discussed. Finally, the research was discussed in terms of the strengths and limitations of the findings.

In the next chapter conclusions are drawn regarding the findings and arguments presented in this discussion chapter. A series of recommendations are prepared in response to the findings from this research. It is intended that these recommendations will contribute to improving the practice of public health policy-making in a food regulation setting.
CHAPTER 11

Conclusion

This study has investigated how and why scientific evidence is used in the making of public health policy in a food regulation setting. In this chapter I draw together the research's rationale, conduct, analysis and interpretation to present the conclusion to the thesis. I explain how I have fulfilled the aim posed in the introduction to the thesis. I then describe why the research is important and what the research contributes to the practice of using food regulation as a policy instrument for public health. The investigation was a form of applied evaluation research and in the final section of this conclusion I respond to the thesis findings by proposing a series of recommendations for improving public health policy practice in a food regulation setting.

This thesis began with a critique of the concept of evidence based practice as the 'policy for making policy'. Evidence based practice promises rationality, objectivity and accountability for informing the policy-making process and assisting in the arbitration of political debates. Consequently, there has been a substantial investment in assembling scientific evidence and developing appraisal criteria to inform policy-making. Despite the priority accorded evidence based practice it was noted that there has been relatively little research into the use of evidence in the making of public health policy generally and in a food regulation setting specifically. Research primarily has been directed towards the science, rather than the art, of using evidence in the policy-making process and there is a lack of theoretical understanding regarding how and why scientific evidence is used in public health policy-making in a food regulation setting. The aim of the thesis was to test theory to gain a theoretical understanding of the use of scientific evidence in the policy-making process in a food regulation setting.

The policy-making process that led to the selection of the policy option of folate fortification of staple food products in Australia in response to epidemiological evidence of a folate-NTD relationship provided a unique and revelatory case study
against which to test theory. Easton’s model of a political system was employed as a heuristic device to pull apart the case study and thereby identify otherwise hidden insights into the policy-making process. A pattern of interaction was shown between the political environment, procedural and decision-making process levels of the policy-making process of the food regulatory system when the data were interrogated and iterations were conducted across these three levels. The pattern provides a coherent assessment of what happened in response to the folate-NTD evidence that caused the folate fortification policy option to prevail over other policy options.

Although the exact physiological mechanism by which folate reduces the risk of NTDs remains unknown, the epidemiological evidence strongly suggests that NTDs are the outcome of a metabolic disorder arising from a genetic predisposition in certain at risk individuals. The typology presented in Chapter 4 indicates that the promotion of folate supplements to the target individuals would have been the policy response consistent with the epidemiological evidence for the aetiology of NTDs. Nevertheless, given the uncertainties and dilemmas associated with the epidemiological evidence it cannot be said that there was an incontrovertible right or wrong policy response. Moreover, to evaluate a particular policy decision as more or less ‘correct’ violates one of the basic premises of the social constructivist approach to policy analysis. Such an assessment would rely on the assumptions of the positivist ontology that there are clearly delineated criteria representing truth and against which the policy-making processes’ rationalisation of the case study’s uncertainties and dilemmas can be analysed and a judgement made regarding its ‘correctness’.

What this thesis has demonstrated can be said about the folate fortification policy is that there was a strategic process that led to this policy outcome. Specifically, the thesis has shown that the making of the folate fortification policy was inherently political. Integral to the political nature of the policy-making was the existence of competing core values among stakeholders regarding the relationship between food and health. It was the explanation of the strategic process that resolved the debate surrounding the competing core values that has provided a theoretical understanding of the mechanism within the food regulatory system that is responsible for how and
why scientific evidence is used in the making of public health policy. This theoretical understanding was gained because when the data were interpreted against the theoretical framework, the ACF provided an informed base for putting the data back together and offering a plausible and powerful explanation of the case study findings.

The theory was then generalised to the unit of analysis to show why the understandings are important to the food regulatory system and to offer explanations for the conceptual, scientific and ethical dilemmas identified for the food regulation setting in Chapter 2. By demonstrating the high explanatory value of existing policy science theory to public health policy-making in the food regulatory system, the thesis has established theory confirmation in a new setting. In gaining this theoretical understanding the study fulfils the research aim of this thesis.

This research is important because often the political nature of the policy-making process is hidden, the existence of competing core values among stakeholders is not acknowledged and the policy outcomes are presented as non-controversial. The ACF theory that was applied to the case study findings produced new insights into the making of public health policy in a food regulation setting. In particular, the theoretical understandings that were gained contribute to explaining the use of scientific evidence in the making of public health policy in a food regulation setting by providing details of the mechanism that shaped the policy-making process. These theoretical understandings provide an informed basis to challenge the inherently political nature of policy-making and to expose the value-laden assumptions in evidence based practice.

The following significant conclusions can be drawn from this study:
1. Evidence based practice for the case study was mediated by the meaning acquired from the interpretation and application of the complementary food regulation policy objectives intended to effect public health while upholding the protection of public health and safety.
2. Different meanings of the complementary food regulation public health policy objective are captured in different core values of stakeholders. The typology in Chapter 4 provides a classification scheme to organise different core values associated with using food regulation as a public health policy instrument.
3. During the case study coalitions formed around shared core values associated with the use of food regulation as a public health policy instrument. These coalitions attempted to manipulate the food regulatory system to achieve policy outcomes consistent with their core values.

4. Internal and external policy subsystem factors manipulate the governance and procedures of the food regulatory system. In the case study these factors served to privilege the interests of certain food manufactures and the values of certain scientists with a positivist-reductionist approach to public health research while diminishing other core values.

5. All else being equal, in the current political environment it would be anticipated that a similar use of scientific evidence in the policy-making process would occur for other food regulation public health policy issues in Australia.

6. All else being equal, in the current political environment it would be anticipated that a similar use of scientific evidence in the policy-making process likely would occur for broader food and nutrition policy issues in Australia.

As we look towards the future, there will be an ongoing investment in research to generate an expanding quantity and quality of scientific evidence for making public health policy in a food regulation setting. The challenge is that irrespective of the quantity and quality of the scientific evidence that is being made available, scientific evidence cannot be assumed to speak for itself. In this thesis I have shown that policy-making is an inherently political and value-laden process and the potential for politically motivated interpretation and application of otherwise value-neutral scientific evidence can undermine the investment in its generation. Without due attention to the political nature of policy-making, scientific evidence can be abused to legitimise vested interests and to attack opponents. From this perspective, evidence based practice, far from liberating policy-making from political influence, can itself become part of the problem rather than the solution.

The theoretical understandings gained from this thesis can be used to challenge many of these current assumptions and practices in public health policy-making in the food
regulatory system. However, just because theoretical understandings have been gained, I do not assume that politics will be removed from public health policy-making and that evidence based practice will be transformed to a state of complete rationality. The political nature of the policy-making process and the value-laden nature of evidence based practice are immutable. As Parsons, comments, "The inherent messiness of politics militates against the naïve belief that decision-making can somehow be made more 'rational'.” (Parsons 1995: 433).

Nevertheless, it is important that policy-making in a food regulation setting is evidence based. I believe that rational evidence based practice is an ideal worth striving for. This will require the value-laden nature of the use of evidence in the policy-making process to be made more explicit and the interpretation and application of policy objectives to be complemented with more democratic processes.

The theory that has been applied in this thesis can make a significant practical contribution to improving policy-making practice in a food regulation setting. This theory elucidates the mechanism by which scientific evidence is used in the policy-making process. It also provides an informed basis for identifying and predicting relationships, processes and outcomes from knowledge of contextual circumstances and stakeholders engaged with the policy. With this understanding practitioners will be better placed to engage with the policy-making process to uphold public health principles in the interpretation and application of policy objectives intended both to protect and promote public health.

Also, the theory can be used in conjunction with lessons learned from the case study observations, to prepare recommendations that can help to make the policy-making process more transparent and democratic and therefore less vulnerable to political forces. To this end a series of recommendations are presented in the final section of this chapter. Transparent and democratic processes will increase confidence in the food regulatory system and help evidence based practice to be used as a tool to improve the integrity of policy-making rather than being exploited to disguise policy-making's political nature. As a key informant commented,
“It’s about the process and the philosophy of how we can do it [policy-making] better in the future. We can’t unfortunately recover the lost ground with this business [folate fortification] ... This wont be the last food component associated with health profiles, there are umpteen phytonutrients that are going to be addressed in a similar way in the future. ... This is the sort of analysis that one ought to bring to bear on this sort of process over and over again.” [120/6-7].
Recommendations

Many lessons that have relevance for policy-making practice emerge from this study. In this section I propose a series of recommendations.

1. Improving the governance of the food regulatory system - legislative arrangements

The case study observations indicate that the governance of the food regulatory system from the perspective of the legislative arrangements within which it operates, was flawed. Whereas the protection of public health and safety is the priority objective within the food standards setting environment, the food regulatory system operates within a political environment where it is positioned below trade and economic portfolios in a hierarchy of departmental importance. The legislative establishment of a food regulatory agency completely independent of government intervention and the influence of economic portfolios is not feasible as food regulatory agencies must be appointed and funded by someone with authority to spend public money (McKee and Lang 1997). Nor is complete independence an ideal arrangement as it may shift the issue of lack of independence to one of lack of accountability. Therefore, in seeking to reform the current governance arrangements, a solution must be found from within the government structure.

The legislative arrangements for the Australian food regulatory system originated within food law and not public health law. This historical context has a major bearing on the capacity of the contemporary food regulatory system to interpret and apply public health policy objectives. It provides an explanation for the existence of the contradictory policy objectives that must take into account both public health and economic agendas in balancing the role of food as a public health resource and a commercial commodity. Several commentators have argued that locating the food regulatory system within the legislative framework of a separate Public Health Act, rather than a Food Act, would increase its capacity to uphold the protection of public health and safety and enable food regulation to be more readily used as a policy tool to support the objectives of a food and nutrition policy (Lang et al. 1997; Reynolds 1997).
The Commonwealth could instigate legislative reform to pass a Public Health Act that established a dedicated public health agency within cabinet that reports directly to a cabinet minister, not a Parliamentary Secretary, and therefore has direct access to the legislature (Reynolds 1997). This legislative reform would enable an alternative form of governance of the food regulatory system to be introduced. Within the jurisdiction of the public health agency a separate statutory agency devoted to the public health and consumer information objectives of food regulation could be established. Responsibility for food trade objectives would remain with ANZFA. The advantages offered to public health from such a legislative reform are three-fold. Firstly, it lifts the portfolio status within the government hierarchy. Secondly, it provides the opportunity for a clear separation between objectives intended to protect public health and consumer interests and those promoting industry interests. Thirdly, it provides the opportunity to expand the interpretation of the public health and safety objective to encompass social and environmental criteria and to replace the no-harm principle with the precautionary principle in the assessment process.

**Recommendation 1**

That legislative reform be enacted to provide for a separate Public Health Act that enables an alternative form of governance of the food regulatory system to be introduced in Australia. To accompany the legislative reform a dedicated public health agency within cabinet that reports directly to a cabinet minister and hosts a separate statutory agency devoted to public health and consumer information objectives of food regulation be established.

2. **Improving the governance of the food regulatory system – procedural arrangements**

The case study observations indicate that the governance of the food regulatory system from the perspective of its procedural arrangements also was flawed. The technical procedures associated with setting food standards, that were the responsibility of the statutory authority, were subject to consultation and public accountability requirements prescribed in the NFA Act 1991 and were relatively open and transparent. Conversely, the final interpretation and application of the policy
objectives and the intense lobbying took place at the Ministerial Council stage of the procedures. The Ministerial Council operated within the bureaucracy and was not subject to the same statutory provisions prescribed in the *NFA Act 1991* and therefore the policy setting stage in the procedural arrangements was not open and transparent.

Food is one of the few matters in Australia where legislation is not made by a decision of parliament. The need for openness and transparency of the procedures are particularly important given this arrangement as there is little recourse for appeal and the members of the Ministerial Council are not directly accountable to any jurisdiction. Subject to recommendation 1 above, a subservient recommendation is required to amend a particular aspect of the procedural arrangements of the food regulatory system. An amendment needs to be introduced requiring the voting pattern of the Ministerial Council to be disclosed and the individual members to provide reasons for their vote. Such an amendment will help to improve the openness and transparency of the Ministerial Council and increase accountability, predictability and confidence in the food regulatory system more generally.

**Recommendation 2**

That, subject to the provisions of recommendation 1, an amendment to relevant Commonwealth freedom of information legislation be introduced to define the Ministerial Council as an agency and thereby require the voting pattern of the Ministerial Council to be disclosed and the individual members to provide reasons for their vote.

3. **Developing minimum standards of selection for expert panels**

The observations of the Expert Panel's establishment and operation highlighted the unaccountable and selective nature of these phenomena. This circumstance served to privilege the values of certain stakeholders while diminishing the values of other stakeholders. Similar concerns have been raised in relation to other public health committees by Gaughwin who has proposed that such concerns be addressed by developing 'minimum standards of deliberation' (Gaughwin 1998). A similar concept in the form of minimum standards of selection needs to be adopted when establishing food regulation advisory committees and should account for:
• Formal and transparent selection criteria
• Conflict of interest criteria that are rigorously enforced
• Strategies to promote a plurality of independent and relevant expertise

In addition, there must also be a disclosure requirement whereby bureaucrats responsible for the selection of advisory committees are identifiable so that an audit trail can readily be undertaken to trace accountability for decisions, rather than the present practice of enabling individual bureaucrats to merge anonymously within bureaucratic structures.

Recommendation 3
That minimum standards of selection be developed for food regulation expert panels and that bureaucrats responsible for managing the selection process be disclosed in advisory committee documentation.

4. Reorienting evidence based practice for public health policy-making
The conclusions in this thesis highlight the following challenges for the concept of evidence based practice in relation both to effecting public health outcomes using food regulation as a policy instrument and to protecting public health and safety in response to food regulation.

i) Effecting public health outcomes using food regulation as a policy instrument
In Australia there have been initiatives to adapt the principles of evidence based medicine to a public health context, e.g. the concept of the levels of evidence is being extended to recognise the legitimacy of social science methods to generate data relevant to public health policy (Rychetnik and Frommer 2000). Nevertheless, confusion persists regarding the application of evidence based practice to public health nutrition policy. For example, in the context of health claims policy, a prominent Australian nutritionist has commented, "Agreement to apply appropriate principles of evidence-based medicine to public-health nutrition will bring welcome objectivity and the opportunity to have rules of evidence for claims and disputes." (my emphasis) (Truswell 2001: 1062). Others have highlighted the need to challenge
the interpretation that holds onto the reductionist approach to evidence based practice and attempts to make public health nutrition fit in with it, i.e. there is a need to ‘cut the cloth to fit the dress’ (Brunner et al. 2001).

ii) Protecting public health and safety when using food regulation as a policy instrument

As food regulation continues to be used as a policy instrument to effect public health, new and innovative ways will be needed to assess and then monitor and evaluate the public health and safety implications of these developments. Currently, various food regulatory authorities are directing a relatively substantial investment towards preparing principles and procedures for risk analysis to uphold the protection of public health and safety (Australia New Zealand Food Authority 1996) (Joint FAO/WHO Food Standards Programme 1997)). However, regardless of how sophisticated the risk analysis procedures are of themselves, if they are confined to microbiological and toxicological criteria they represent a narrow interpretation of public health and safety confined to an immediate impact on individuals rather than on the population in total and broader public health outcomes in the longer term. Given the emergence of a new era of risk analysis procedures to replace the concept of protecting the nutritional integrity of food, the challenge will be to develop policy based on risk analysis orthodoxies that incorporate a public health scope inclusive of the environmental and social consequences of food regulation policy.

**Recommendation 4**

That the principles espoused in the typology presented in Chapter 4 be applied to guide the policy response to scientific evidence when informing policy decisions intended either to effect or to protect public health in a food regulation setting.
5. Promoting access to, and participation in, the food regulatory system

This thesis has highlighted the non-level nature of the playing field within which policy-making in a food regulation setting is conducted. Generally, public health and consumer organizations and individual consumers have fewer opportunities to access and to participate in the food regulatory system relative to other stakeholders. Consumers are interested in what is happening with the food supply and public health and consumer organizations strive to have their opinions heard within the food regulatory system. Yet, the food regulatory arrangements are setting barriers to these stakeholders’ access to, and participation in, the policy-making process. The barriers range from a general lack of visibility of the mechanisms of the food regulatory system through to financial, technical and time burdens placed on consumers. Consequently, many consumers are increasingly removed, sceptical and confused by the mechanisms by which food is regulated.

In recognition of previous deficiencies in community access to and participation on the food standards setting process, several activities have recently been initiated. The Board of ANZFA identified improving community involvement in standards setting as a key priority for 1999/2000. This identification led to the development of a community involvement policy and protocol statement (Australia New Zealand Food Authority 2001). As at June 2002, the ANZFRSC has released a discussion paper seeking views and comments from stakeholders on consultative mechanisms to apply to the development of policy guidelines by the Ministerial Council (Australia New Zealand Food Regulation Standing Committee 2002) and the FAO and WHO are undertaking an independent evaluation of their food standards work including the Codex programme (World Health Organization 2002). Such activities will need to be followed up with practical strategies that actively strengthen community access to, and participation in, the food regulatory system. In Australia, greater investment is required from the DoHA (formerly DSHS) in particular, to inform, motivate and empower consumers, and to reduce the barriers to participating in the food regulatory system.

**Recommendation 5**

That strategies be developed and implemented to promote community access to, and participation in, the food regulatory system in Australia.
6. Promoting leadership in public health policy in a food regulation setting

The observations of the case study highlight the lack of leadership towards public health policy in Australia's food regulation setting, both within government and external to government. Within government there was disunity between the nutrition sections of the NFA and the DHSH and a failure to present a coordinated policy response to the review of Standard A9 and the case study. External to government there were several individuals and public health and consumer agencies that presented a public health policy response to the case study as a countervailing position to that being presented by food manufacturers and certain professors of nutrition. However, the response from these public health and consumer stakeholders lacked coordination and ostensibly was reactionary to an agenda that was framed by food manufacturers.

Since the launch of Standard A9 the lack of leadership in public health nutrition in Australia, especially within government, has become more pronounced. Ostensibly, the Nutrition Section of the DHSH has been disbanded and there is no longer a nutrition committee within the NHMRC. In the current leadership vacuum within government, other areas of government are assuming responsibility for advising on public health policy matters related to Codex agenda items and in the case of the ANZFRSC, health claims policy. External to government the allegiance of certain traditional public health agencies is becoming less predictable. For example, the DAA is currently presided over by a former Scientific and Marketing Director of the MBCM and the DAA’s Food Standards Advisory Committee now is chaired by a consultant to the MBCM. Similarly, the immediate past president of the Nutrition Society of Australia currently is the Scientific Director of the AFGC.

**Recommendation 6**

That a dedicated public health nutrition section be established within the Commonwealth department of health and each of the state health departments with the mandates to coordinate and promote public health policy interests for food regulation across Australia.
7. Monitoring and evaluating the folate fortification policy

Now that folate fortification of food products is being implemented it is important that adequate and timely monitoring of all potential risks and benefits of folate fortification for the target individuals as well as the population in general are undertaken. The Expert Panel stressed that timely and sufficient monitoring be undertaken to ensure that the review of the folate fortification intervention would be based on sound scientific information (National Health and Medical Research Council 1994). However, a sobering note has been issued by the NFMNU with their comment “Current mechanisms in place to monitor the implementation of the fortification program are inadequate” (Abraham and Webb 2000: 86).

In addition to the monitoring and evaluation of the policy, research into the folate-NTD relationship needs to be maintained, so that we continue to learn the nature of this relationship and plan for the best way to prevent NTDs. This may include refining the folate fortification policy where necessary. The research priorities to be coordinated by the NHMRC will need to be to investigate the mechanism by which folate exerts its protective effect, the dose-response relationship, the potential influence of other nutrients in mediating the folate-NTD relationship, and technical information regarding food composition and folate stability in food products.

Recommendation 7

That the NHMRC be resourced to coordinate both the adequate and timely monitoring and evaluation of the folate fortification policy so as to assess the potential risks and benefits of this policy, and the ongoing research to learn the best way to prevent NTDs.

8. Further research

This thesis is unique in its demonstration of the relevance of ACF theory to explain the use of scientific evidence in public health policy-making process in a food regulation setting. The conclusions are initial and tentative and the theoretical understanding that emerges from this study is necessarily crude in the sense that it is investigating an area that is new. No single theory can be expected to explain all the aspects of how and why scientific evidence is used in the public health policy-
making process. There remain many uncertainties and dilemmas regarding evidence-based practice. Debates about evidence based policy-making continue and the practice is still evolving.

The theory applied to the case study and presented in this thesis is heuristic in the sense that in providing new and important information it can be critiqued and modified to guide further research for the building of understanding into the making of public health policy theory. According to McCool, it is imperative that analysis continues, because if research ends "... we stop theory building, we stop learning, we stop improving our understanding of public policy." (McCool 1995: 176). In relation to the extension of the ACF theory to the food regulation setting, further research is needed to build deeper insights into the nature of coalitions and the influence of various internal and external policy subsystem factors associated with the ACF.

The scope of the findings is restricted to one case study of one public health policy issue in one political setting. It is important that further research is conducted to validate the plausibility of the theory as it applies to other case studies to replicate the findings reported in this thesis. Replication logic was beyond the scope of this thesis. If support for the ACF theory applied to this case study, as distinct from a plausible rival theory, can be replicated from the evaluation of additional case studies then the empirical results are more robust and the theory gains more credibility. This replication logic may then be used to make analytic generalisations about the policy-making process for other folate fortification experiences, other public health policy issues in a food regulation setting and public health policy issues in other political settings. Examples of cases to test replication logic for each of these situations include the policy-making process associated with the:

i) Folate fortification policy outcome of overseas countries as an example of another folate fortification experience.

ii) Mandatory fortification of bread-making flour with thiamin to reduce the risk of Wernicke-Korsakoff syndrome as an example of another public health policy issue in a food regulation setting.

iii) Fluoridation of water to prevent dental caries as an example of a public health policy issue in another political setting.
Recommendation 8

That further research be undertaken to build deeper insights into aspects of the ACF theory as it applies to public health policy-making in a food regulation setting and other case studies be analysed to test the replication logic of the theory.
References


Hancock, L. (1997). Analysing Health Policy, Deakin University.


Health and Medical Research Strategic Review Committee (1999). The Virtuous Cycle - Working Together For Health and Medical Research. Canberra, National Health and Medical Research Council.


Herbert, V. (1996). "Food fortification should be with both folic acid and vitamin B12." Nutrition Today 31: 175.


Lang, T., E. Millstone and M. Rayner (1997). Food Standards and the State: A fresh start. London, Centre for Food Policy, Wolfson School of Health Sciences, Thames Valley University.


US Food and Drug Administration (1980). "Folic acid preparations, oral and parenteral for therapeutically use; drugs for human use; drug efficacy study implementation; amendment. (Notice)." Federal Register 45: 69043.


Appendix 1

Codex Alimentarius Commission

‘General Principles for the Addition of Essential Nutrients to Foods’
GENERAL PRINCIPLES FOR THE ADDITION OF ESSENTIAL NUTRIENTS TO FOODS

1. PURPOSE

1.1 To provide guidance to those responsible for developing guidelines and legal texts pertaining to the addition of essential nutrients to foods.

1.2 To establish a uniform set of principles for the rational addition of essential nutrients to foods.

1.3 To maintain or improve the overall nutritional quality of foods.
1.4 To prevent the indiscriminate addition of essential nutrients to foods thereby decreasing the risk of health hazard due to essential nutrient excesses, deficits or imbalances. This will also help to prevent practices which may mislead or deceive the consumer.

1.5 To facilitate acceptance in international trade of foods which contain added essential nutrients.

2. **SCOPE**

These principles are intended to apply to all foods to which essential nutrients are added.

3. **DEFINITIONS**

For the purpose of these guidelines:

3.1 **Nutrient** means any substance normally consumed as a constituent of food:

   (a) which provides energy; or

   (b) which is needed for growth and development and maintenance of healthy life; or

   (c) a deficit of which will cause characteristic bio-chemical or physiological changes to occur.

3.2 **Essential nutrient** means any substance normally consumed as a constituent of food which is needed for growth and development and the maintenance of healthy life and which cannot be synthesized in adequate amounts by the body.

3.3 **Nutritional equivalence** means being of similar nutritive value in terms of quantity and quality of protein and in terms of kinds, quantity and bioavailability of essential nutrients. For this purpose, nutritional equivalence means that essential nutrients provided by the food being substituted, that are present in a serving or portion or 100 kcal of the food at a level of 5% or more of the recommended intake of the nutrient(s) are present in the substitute or partially substituted food (extender) in comparable amounts.

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

3.5 **Fortification or enrichment** means the addition of one or more essential nutrients to a food over and above the levels normally contained in the food or the levels after restoration for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

3.6 **Restoration** means the addition to a food of essential nutrient(s) which are lost during the course of good manufacturing practice, or during normal storage and handling procedures, in amounts which will result in the presence in the food of the levels of the nutrient(s) present in the edible portion of the food before processing, storage or handling.

3.7 **Special purpose foods** are foods that have been designed to perform a specific function, such as to replace a meal which necessitates a content of essential nutrients which cannot be achieved except by addition of one or more of these nutrients. These foods include but are not limited to foods for special dietary use.

4. **BASIC PRINCIPLES**

4.1 Essential nutrients may be added to foods for the purpose of:

4.1.1 restoration;
4.1.2 nutritional equivalence of substitute foods;

4.1.3 fortification;

4.1.4 ensuring the appropriate nutrient composition of a special purpose food.

4.2 The essential nutrient should be present at a level which will not result in either an excessive or an insignificant intake of the added essential nutrient considering amounts from other sources in the diet.

4.3 The addition of an essential nutrient to a food should not result in an adverse effect on the metabolism of any other nutrient.

4.4 The essential nutrient should be sufficiently stable in the food under customary conditions of packaging, storage, distribution and use.

4.5 The essential nutrient should be biologically available from the food.

4.6 The essential nutrient should not impart undesirable characteristics to the food (e.g. colour, taste, flavour, texture, cooking properties) and should not unduly shorten shelf-life.

4.7 Technology and processing facilities should be available to permit the addition of the essential nutrient in a satisfactory manner.

4.8 Addition of essential nutrients to foods should not be used to mislead or deceive the consumer as to the nutritional merit of the food.

4.9 The additional cost should be reasonable for the intended consumer.

4.10 Methods of measuring, controlling and/or enforcing the levels of added essential nutrients in foods should be available.

4.11 When provision is made in food standards, regulations or guidelines for the addition of essential nutrients to foods, specific provisions should be included identifying the essential nutrients to be considered or to be required and the levels at which they should be present in the food to achieve their intended purpose.

5. NUTRIENT ADDITION FOR PURPOSES OF RESTORATION

5.1 Where the food has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, restoration of the essential nutrients of concern lost during processing, storage or handling should be strongly recommended.

5.2 A food should be considered a significant source of an essential nutrient if the edible portion of the food prior to processing, storage or handling contains the essential nutrient in amounts equal to or greater than 10% of the recommended nutrient intake in a reasonable daily intake (or in the case of an essential nutrient for which there is no recommended intake, 10% of the average daily intake). 1/

6. NUTRIENT ADDITION FOR PURPOSES OF NUTRITIONAL EQUIVALENCE

6.1 Where a substitute food is intended to replace a food which has been identified as a significant source of energy and/or essential nutrients in the food supply, and particularly where there is demonstrated evidence of public health need, nutritional equivalence in terms of the essential nutrients of concern should be strongly recommended.

1/ This section remains under review.
6.2 A food being substituted or partially substituted should be considered a significant source of an essential nutrient if a serving or portion or 100 kcal of the food contains the essential nutrient in amounts equal to or greater than 5% of the recommended nutrient intake.

6.3 Where there is a clear public health reason to moderate the intake of a specific nutrient, the level of this nutrient need not be equivalent.

7. NUTRIENT ADDITION FOR PURPOSES OF FORTIFICATION

7.1 Fortification should be the responsibility of national authorities since the kinds and amounts of essential nutrients to be added and foods to be fortified will depend upon the particular nutritional problems to be corrected, the characteristics of the target populations, and the food consumption patterns of the area.

7.2 The following conditions should be fulfilled for any fortification programme:

7.2.1 There should be a demonstrated need for increasing the intake of an essential nutrient in one or more population groups. This may be in the form of actual clinical or subclinical evidence of deficiency, estimates indicating low levels of intake of nutrients or possible deficiencies likely to develop because of changes taking place in food habits.

7.2.2 The food selected as a vehicle for the essential nutrient(s) should be consumed by the population at risk.

7.2.3 The intake of the food selected as a vehicle should be stable and uniform and the lower and upper levels of intake should be known.

7.2.4 The amount of the essential nutrient added to the food should be sufficient to correct or prevent the deficiency when the food is consumed in normal amounts by the population at risk.

7.2.5 The amount of the essential nutrient added should not result in excessive intakes by individuals with a high intake of a fortified food.

8. NUTRIENT ADDITION TO SPECIAL PURPOSE FOODS

8.1 Nutrients may be added to special purpose foods including foods for special dietary uses to ensure an appropriate and adequate nutrient content.
Appendix 2

List of field note sources
<table>
<thead>
<tr>
<th>Field note code</th>
<th>Date</th>
<th>Event with which field note associated</th>
<th>Context of information collected in field note</th>
</tr>
</thead>
<tbody>
<tr>
<td>FN01</td>
<td>22/6/92</td>
<td>NHMRC FHC meeting</td>
<td>Transition in food regulation policy-making process</td>
</tr>
<tr>
<td>FN02</td>
<td>8/7/93</td>
<td>Internal NFA memo</td>
<td>Lobbying of an influential clinical epidemiologist</td>
</tr>
<tr>
<td>FN03</td>
<td>1/10/93</td>
<td>International Union of Nutrition Sciences conference</td>
<td>Hostility towards NFA</td>
</tr>
<tr>
<td>FN04</td>
<td>23/3/94</td>
<td>NFSC vote on food Standard A9</td>
<td>No harm versus precautionary principle</td>
</tr>
<tr>
<td>FN05</td>
<td>6/4/94</td>
<td>Comment from CAFTA president</td>
<td>Lobbying of food industry</td>
</tr>
<tr>
<td>FN06</td>
<td>14/4/94</td>
<td>Lunchtime seminar at NFA by DITARD representative</td>
<td>ACIL Economics Pty Ltd lobbying process</td>
</tr>
<tr>
<td>FN07</td>
<td>3/5/94</td>
<td>NFA23 Board Member’s discussion</td>
<td>The NFSC was directing the NFA about what policy decision to make</td>
</tr>
<tr>
<td>FN08</td>
<td>19/5/94</td>
<td>NHMRC Expert panel 3rd meeting</td>
<td>i) Lack of consideration of policy options ii) Consumer representative being intimidated</td>
</tr>
<tr>
<td>FN09</td>
<td>24/5/94</td>
<td>Comment from NFA Members in response to NFSC teleconference</td>
<td>The viability of the NFA was under threat</td>
</tr>
<tr>
<td>FN10</td>
<td>12/6/94</td>
<td>NFA24 Board Member’s discussion</td>
<td>NFA Members commenting that their “hands were tied” by NFSC</td>
</tr>
<tr>
<td>FN11</td>
<td>28/10/94</td>
<td>NFSC vote on food Standard A9</td>
<td>A Health Minister being directed to change her voting intention on the way to the NFSC meeting</td>
</tr>
<tr>
<td>FN12</td>
<td>25/5/95</td>
<td>Reconsideration of food Standard A9</td>
<td>Threat by MBCM as strategy to influence policy-making process</td>
</tr>
<tr>
<td>FN13</td>
<td>14/6/95</td>
<td>Television interview regarding folate fortification</td>
<td>Influence of corporate sector over ABC story on folate</td>
</tr>
<tr>
<td>FN14</td>
<td>2/11/95</td>
<td>Meeting with the MBCM</td>
<td>Implementation of folate fortification and the review of health claims</td>
</tr>
<tr>
<td>FN15</td>
<td>21/11/95</td>
<td>Telephone call with ANZFA nutritionist</td>
<td>i) Monitoring the policy ii) Industry involvement</td>
</tr>
<tr>
<td>FN16</td>
<td>22/11/95</td>
<td>Meeting with ANZFA Board Member</td>
<td>Significance of food Standard A9 policy position to the authority of ANZFA</td>
</tr>
<tr>
<td>-------</td>
<td>---------</td>
<td>---------------------------------</td>
<td>--------------------------------------------------------------------------</td>
</tr>
<tr>
<td>FN17</td>
<td>4/2/96</td>
<td>Deakin Nutrition Summer School</td>
<td>Opposition from Nutrition Section of DSHS towards NFA</td>
</tr>
<tr>
<td>FN18</td>
<td>20/8/96</td>
<td>ANZFA staff meeting</td>
<td>Capacity of and support for food regulation personnel</td>
</tr>
</tbody>
</table>

* Due to confidentiality requirements outlined in the ethics approval for this research the actual name of each individual associated with a field note has been withheld. However, in the research database stored at Deakin University for a 5-year period the original field note is available and the name of a responsible individual is identified and linked with the relevant data.
Appendix 3

List of document sources
<table>
<thead>
<tr>
<th>Document code and name</th>
<th>Date</th>
<th>Event with which document is associated</th>
<th>Relevance of data to analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>D001 NHMRC Nutrition Committee letter to Food Standards Section of Federal Bureau of Consumer Affairs</td>
<td>10/9/88</td>
<td>At its meeting of 20-21 July 1988 the Nutrition Committee of NHMRC affirmed its philosophy of restoration and nutrition education rather than fortification.</td>
<td>Compare with the later NHMRC submission to 1992 review of A9 The influence of key individuals.</td>
</tr>
<tr>
<td>D002 NHMRC Nutrition Committee extract of report of meeting held</td>
<td>13-14 August 1990</td>
<td>At its meeting of 13-14 August, 1990 the Nutrition Committee of NHMRC confirmed its policy of limited restoration rather than fortification.</td>
<td>Compare with the later NHMRC submission to 1992 review of A9 The influence of key individuals.</td>
</tr>
<tr>
<td>D003 Original draft revised Standard A9</td>
<td>4/3/92</td>
<td>Full assessment</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D004 NFA Explanatory Notes on Draft Revised Standard A9</td>
<td>4/3/92</td>
<td>Full assessment</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D005 NFA Format for Application to Amend Draft Revised Standard A9</td>
<td>4/3/92</td>
<td>Full assessment</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D007 Minutes of NHMRC teleconference of 10/3/92</td>
<td>22-23 June 1992</td>
<td>Full assessment</td>
<td>The role of certain profosors of nutrition during the NHMRC process for the review of A9</td>
</tr>
<tr>
<td>D008 Agenda papers for NHMRC meeting</td>
<td>22-23 June 1992</td>
<td>Full assessment</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D009 Newspaper clipping ‘Food body takes aim at cereals’ added goodness’</td>
<td>28/6/92</td>
<td>Full assessment</td>
<td>Lobbying</td>
</tr>
<tr>
<td>D010 NHMRC Statement on the relationship between dietary folic acid and neural tube defects such as spina bifida</td>
<td>June 1992</td>
<td>Released independently at time of full assessment</td>
<td>Did not recommend folic acid fortification</td>
</tr>
<tr>
<td>D011 P24 – Fax from WARICH</td>
<td>19/8/92</td>
<td>A9 Public submission process</td>
<td>First mention of folic acid in the context of Standard A9 and flagging that it will be put onto the agenda</td>
</tr>
<tr>
<td>D012 Submission from PHC NHMRC</td>
<td>3/9/92</td>
<td>A9 Public submission process</td>
<td>No reference to folic acid Referance to export potential</td>
</tr>
<tr>
<td>D013 Letter from a professor of nutrition (and signed by a group of professors and medical nutritionists)</td>
<td>3/9/92</td>
<td>A9 Public submission process</td>
<td>1. How public health defined 2. Link to breakfast cereals 3. Lobbying by key individuals - folic fortification used as rationale for more liberal fortification approach - Supports principle of no-harm - Cautions against impeding trade and commerce.</td>
</tr>
<tr>
<td>D014 Submission from a professor of nutrition</td>
<td>3/9/92</td>
<td>A9 Public submission process</td>
<td>Influence of an individual Brief mention of folic acid</td>
</tr>
<tr>
<td>D015 P24 – Submission from WARICH</td>
<td>4/9/92</td>
<td>A9 Public submission process</td>
<td>Scientific evidence of benefit (addresses folic fortification only and not principles for fortification)</td>
</tr>
<tr>
<td>Date</td>
<td>Event Description</td>
<td>Supporting Evidence</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>10/9/92</td>
<td>Submission from medical nutritionist via professor of nutrition</td>
<td>A9 Public submission process</td>
<td></td>
</tr>
<tr>
<td>24/9/92</td>
<td>Submission from medical nutritionist</td>
<td>A9 Public submission process</td>
<td></td>
</tr>
<tr>
<td>September 1992</td>
<td>Submission from Roche</td>
<td>A9 Public submission process</td>
<td></td>
</tr>
<tr>
<td>September 1992</td>
<td>Submission from ABCIA via MBCM</td>
<td>A9 Public submission process</td>
<td></td>
</tr>
<tr>
<td>5/9/92</td>
<td>Newspaper clipping 'Battle looms over the breakfast table'</td>
<td>A9 Public submission process</td>
<td></td>
</tr>
<tr>
<td>10/9/92</td>
<td>Letter from professor of nutrition</td>
<td>A9 Public submission process</td>
<td></td>
</tr>
<tr>
<td>October 1992</td>
<td>Update on the inquiry process for A9, NFA11</td>
<td>Summary on the submissions to draft A9</td>
<td></td>
</tr>
<tr>
<td>7/10/92</td>
<td>NFA Announcement of Public Hearing</td>
<td>Summarises the A9 review process and the basis for the proposed Standard</td>
<td></td>
</tr>
<tr>
<td>22/10/92</td>
<td>Letter from MBCM</td>
<td>Full assessment</td>
<td></td>
</tr>
<tr>
<td>23-24 November 1992</td>
<td>Summary report Meeting of the Subcommittee on folate acid, Food Advisory Committee, FDA</td>
<td>US experience on folate fortification</td>
<td></td>
</tr>
<tr>
<td>February 1993</td>
<td>Article in The Food Standard ‘The Vitamins and Minerals debate’</td>
<td>Preliminary Inquiry report</td>
<td></td>
</tr>
<tr>
<td>May 1993</td>
<td>NFA literature review: 'A review of the case for the fortification of the food supply with folate to prevent neural tube defects'</td>
<td>Preliminary Inquiry report</td>
<td></td>
</tr>
<tr>
<td>26-27 May 1993</td>
<td>Draft report FHC meeting</td>
<td>Preliminary Inquiry report</td>
<td></td>
</tr>
<tr>
<td>31/5/93</td>
<td>Submission from Professor of nutrition</td>
<td>Preliminary Inquiry report</td>
<td></td>
</tr>
<tr>
<td>2/6/93</td>
<td>Submission from WA Health Department</td>
<td>Preliminary Inquiry report</td>
<td></td>
</tr>
<tr>
<td>2/6/93</td>
<td>Submission from Goodman Fielder Pty Ltd</td>
<td>Preliminary Inquiry report</td>
<td></td>
</tr>
<tr>
<td>2/6/93</td>
<td>Submission from ABC/A</td>
<td>Preliminary Inquiry report</td>
<td></td>
</tr>
<tr>
<td>7/6/93</td>
<td>Submission from ACA</td>
<td>Preliminary Inquiry report</td>
<td></td>
</tr>
</tbody>
</table>

- **D016**: Submission from medical nutritionist via professor of nutrition
- **D017**: Submission from medical nutritionist
- **D018**: Submission from Roche
- **D019**: Submission from ABCIA via MBCM
- **D020**: Newspaper clipping 'Battle looms over the breakfast table'
- **D021**: Letter from professor of nutrition
- **D022**: Update on the inquiry process for A9, NFA11
- **D023**: NFA Announcement of Public Hearing
- **D024**: Letter from MBCM
- **D025**: NFA Inquiry into vitamins and minerals standard. Transcript of Proceedings of Public Hearing.
- **D026**: Summary report Meeting of the Subcommittee on folate acid, Food Advisory Committee, FDA
- **D027**: Article in The Food Standard ‘The Vitamins and Minerals debate’
- **D028**: Preliminary inquiry report. Item 6.1, NFA 16, Subject: proposal 24 – Revision of Standard A9
- **D029**: NFA literature review: 'A review of the case for the fortification of the food supply with folate to prevent neural tube defects'
- **D030**: Draft report FHC meeting
- **D031**: Submission from Professor of nutrition
- **D032**: Submission from WA Health Department
- **D033**: Submission from Goodman Fielder Pty Ltd
- **D034**: Submission from ABC/A
- **D035**: Submission from ACA
<table>
<thead>
<tr>
<th>Document ID</th>
<th>Date</th>
<th>Type</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>D036</td>
<td>8/6/93</td>
<td>Preliminary Inquiry report</td>
<td>Comments that it would be premature to act on folate</td>
</tr>
<tr>
<td>D037</td>
<td>10/6/93</td>
<td>Preliminary Inquiry report</td>
<td>Prioritising public health versus economic and trade objectives</td>
</tr>
<tr>
<td>D038</td>
<td>10/6/93</td>
<td>Preliminary Inquiry report</td>
<td>Does not mention folate</td>
</tr>
<tr>
<td>D039</td>
<td>June 1993</td>
<td>Preliminary Inquiry report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D040</td>
<td>11/6/93</td>
<td>Preliminary Inquiry report</td>
<td>Lobbying</td>
</tr>
<tr>
<td>D041</td>
<td>16/6/93</td>
<td>Preliminary Inquiry report</td>
<td>Lobbying</td>
</tr>
<tr>
<td>D042</td>
<td>June 1993</td>
<td>Release coincided with Preliminary Inquiry report</td>
<td>Independent recommendations on folate fortification</td>
</tr>
<tr>
<td>D043</td>
<td>June 1993</td>
<td>Inquiry</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D044</td>
<td>June 1993</td>
<td>Inquiry</td>
<td>NFA links certain professors with food industry</td>
</tr>
<tr>
<td>D045</td>
<td>June 1993</td>
<td>Inquiry</td>
<td>A review of the case for the fortification of the food supply with folate to prevent neural tube defects</td>
</tr>
<tr>
<td>D046</td>
<td>June 1993</td>
<td>Inquiry</td>
<td>Power relations over responsibility for food regulation policy</td>
</tr>
<tr>
<td>D047</td>
<td>June 1993</td>
<td>Inquiry</td>
<td>Regulations in other countries concerning the addition of vitamins and minerals to foods</td>
</tr>
<tr>
<td>D048</td>
<td>21/6/93</td>
<td>Inquiry</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D049</td>
<td>25/6/93</td>
<td>Inquiry</td>
<td>NFA being criticised in the media</td>
</tr>
<tr>
<td>D050</td>
<td>25/6/93</td>
<td>Inquiry</td>
<td>MBCM lobbying Ministers for Health</td>
</tr>
<tr>
<td>D051</td>
<td>June 1993</td>
<td>Inquiry</td>
<td>Illustrates a difference between FHC and HCC of the NHMRC and the FHC supported HCC position</td>
</tr>
<tr>
<td>D052</td>
<td>1/7/93</td>
<td>Inquiry</td>
<td>Disagreement within ABCIA over lobbying strategy</td>
</tr>
<tr>
<td>D053</td>
<td>27/7/93</td>
<td>Inquiry</td>
<td>Lobbying of Health Ministers by MBCM (and clinical epidemiologists)</td>
</tr>
<tr>
<td>Document</td>
<td>Date</td>
<td>Inquiry Type</td>
<td>Description</td>
</tr>
<tr>
<td>----------</td>
<td>------</td>
<td>--------------</td>
<td>-------------</td>
</tr>
<tr>
<td>D054 NFA Questions and Answers on Vitamins and Minerals</td>
<td>2/7/93</td>
<td>Inquiry</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D055 Letter from ABCIA to Sanitarium</td>
<td>9/7/93</td>
<td>Inquiry</td>
<td>Illustrates that trade prioritised over public health in lobbying</td>
</tr>
<tr>
<td>D056 Letter from NFA Chairperson to MBCM</td>
<td>19/7/93</td>
<td>Inquiry</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D057 Letter from professors of nutrition to the Commonwealth Minister for Health</td>
<td>21/7/93</td>
<td>Inquiry</td>
<td>Alliance between professors of nutrition and food industry</td>
</tr>
<tr>
<td>D058 Letter from Sanitarium to Commonwealth Minister for Health</td>
<td>26/7/93</td>
<td>Inquiry</td>
<td>Disagreement within ABCIA over lobbying strategy</td>
</tr>
<tr>
<td>D059 Fax from DITAC Dept executive to NFA 'Issues in the fortification of breakfast cereals'</td>
<td>28/7/93</td>
<td>Inquiry</td>
<td>Lobbying of DITAC by ABCIA</td>
</tr>
<tr>
<td>D060 Letter from Minister for Primary Industry and Energy to NFA Chairperson</td>
<td>5/8/93</td>
<td>Inquiry</td>
<td>Hierarchy of government policy (trade versus public health) Regulation and its impact on export performance</td>
</tr>
<tr>
<td>D061 Newspaper clipping 'Cereal giants snap at tougher rules'</td>
<td>19/9/93</td>
<td>Inquiry</td>
<td>Commonwealth Minister for Health reported to be 'sliding' with food industry over NFA</td>
</tr>
<tr>
<td>D062 Food for Thought: A Report to the Agri-Food Council Working Group on Regulatory Regimes ACIL Economics &amp; Policy Pty Ltd</td>
<td>September 1993</td>
<td>Inquiry</td>
<td>How public health defined Interpretation of nutrition role Trade versus public health policy priorities Defining role and responsibilities of the regulator</td>
</tr>
<tr>
<td>D063 Newspaper clipping 'Regulation of business is still growing'</td>
<td>29/11/93</td>
<td>Inquiry</td>
<td>NFA being criticised by economic portfolio within government</td>
</tr>
<tr>
<td>D064 Newspaper clipping 'Richardson lightens up for the sake of his form'</td>
<td>14/10/93</td>
<td>Inquiry</td>
<td>Evidence of association between Commonwealth Minister for Health and MBCM</td>
</tr>
<tr>
<td>D065 NFA Minute to the Commonwealth Minister for Health</td>
<td>27/10/93</td>
<td>Inquiry</td>
<td>NFA adopted a policy position &quot;... predicated on conserving the inherent nutritional integrity of the food supply&quot;</td>
</tr>
<tr>
<td>D066 Transcript of radio interview CSIRO-MBCM</td>
<td>23/11/93</td>
<td>Inquiry</td>
<td>Suggests alliance between professors of nutrition and food industry</td>
</tr>
<tr>
<td>D067 Letter from MBCM to the Commonwealth Minister for Health</td>
<td>21/12/93</td>
<td>Inquiry</td>
<td>Evidence of association between Commonwealth Minister for Health and MBCM</td>
</tr>
<tr>
<td>D068 Response to Aspects of ACIL 'Food for Thought' report by academic</td>
<td>9/2/94</td>
<td>Inquiry</td>
<td>Role of public health in food regulation and responsibility of food regulator</td>
</tr>
<tr>
<td>D069 Outcomes of the NFSC meeting</td>
<td>28/3/94</td>
<td>NFSC meeting</td>
<td>NFSC instructed NFA to consider 'no-harm' not efficacy, ie burden of proof on NFA not industry</td>
</tr>
<tr>
<td>D070 Minutes of NFA 24 meeting reporting NFSC outcome</td>
<td>March 1994</td>
<td>NFSC meeting</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D071 Extract from National Food Standards Council Agenda papers, Attachment 2, B2 Folic Acid: Associated with protection against birth defects. Is food fortification the solution?</td>
<td>March 1994</td>
<td>NFSC meeting</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>Document ID</td>
<td>Description</td>
<td>Date</td>
<td>Event/Meeting</td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------</td>
<td>---------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>D072</td>
<td>GMA Newslines: ‘Health and Safety: Also at Issue with Vitamins and Minerals’</td>
<td>April</td>
<td>Outcome of the NFSC meeting</td>
</tr>
<tr>
<td>D073</td>
<td>Letter from NFA to NHMRC</td>
<td>5/4/94</td>
<td>Establishment of the Expert Panel</td>
</tr>
<tr>
<td>D074</td>
<td>Letter from DHSH to NHMRC</td>
<td>15/4/94</td>
<td>Establishment of the Expert Panel</td>
</tr>
<tr>
<td>D075</td>
<td>NFA Briefing paper – Reconsideration of draft amended Standard A9 – Vitamins and Minerals, as agreed by NFSC</td>
<td>April</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>D076</td>
<td>Balanced Fare: National Food Authority response to the ACIL Report</td>
<td>April</td>
<td>General review of A9</td>
</tr>
<tr>
<td>D077</td>
<td>Facsimile from Nutrition Section of DHSH to Executive of DHSH</td>
<td>19/4/94</td>
<td>Establishment of the Expert Panel</td>
</tr>
<tr>
<td>D078</td>
<td>Gazette notice in the Australian</td>
<td>20/4/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>D079</td>
<td>Facsimile from NHMRC to DHSH</td>
<td>21/4/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D080</td>
<td>Letter from NHMRC Secretariat to panel members</td>
<td>22/4/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D081</td>
<td>Agenda papers for NHMRC Panel's teleconference</td>
<td>25/4/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D083</td>
<td>Letter from NHMRC inviting Panel Members</td>
<td>4/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D084</td>
<td>Agenda papers for 2nd Panel meeting</td>
<td>5/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D085</td>
<td>Background papers prepared by Panel members for discussion at 2nd meeting</td>
<td>5/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D086</td>
<td>Draft report of the Expert Panel's 2nd meeting</td>
<td>5/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D087</td>
<td>Internal NFA memo</td>
<td>6/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D088</td>
<td>Newspaper clipping ‘Breakfast battle over what comes naturally’</td>
<td>17/5/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>D089</td>
<td>Agenda papers for Expert Panel's 3rd meeting</td>
<td>19/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D090</td>
<td>Blackboard recommendation at Expert Panel's 3rd meeting</td>
<td>19/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D091</td>
<td>Draft report of the Expert Panel's 3rd meeting</td>
<td>May 1994</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>Reference</td>
<td>Brief Description</td>
<td>Date</td>
<td>Type of Document</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------</td>
<td>------</td>
<td>------------------</td>
</tr>
<tr>
<td>D092</td>
<td>Facsimile from Bower to Jefferson providing information for panel</td>
<td>24/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D093</td>
<td>Report of the Senate Estimates Committee C, p111</td>
<td>24/5/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>D094</td>
<td>Questions taken on notice – Senate Estimates Committee (C) Hearing</td>
<td>24-25 May, 1994</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>D095</td>
<td>Letter from Bread Manufacturers Industrial Association of Australia to NFA Chairperson</td>
<td>24/5/94</td>
<td>Submission regarding folate fortification of bread</td>
</tr>
<tr>
<td>D096</td>
<td>Submission from Bread Research Institute of Australia Inc to NHMRC panel</td>
<td>24/5/94</td>
<td>Submission regarding folate fortification of bread</td>
</tr>
<tr>
<td>D097</td>
<td>NFA response to draft minutes of 3rd Expert Panel meeting</td>
<td>25/5/94</td>
<td>Detailed critique and request for more dietary modelling and note that NFA wanted 25% RDI</td>
</tr>
<tr>
<td>D098</td>
<td>Letter from the Australian College of Paediatrics to NFA</td>
<td>25/5/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D099</td>
<td>Facsimile from WARICH</td>
<td>May 1994</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D100</td>
<td>Copy of a fax from The Flour Millers' Council of Australia to NHMRC fortification panel, via NFA Chairperson</td>
<td>26/5/94</td>
<td>Submission regarding folate fortification of bread</td>
</tr>
<tr>
<td>D101</td>
<td>Attachment 4, NFA OOS ‘Consultative meeting with industry representatives to discuss the revised draft Standard A9’</td>
<td>27/5/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>D102</td>
<td>Commentary on further amendments to draft Standard A9</td>
<td>May 1994</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>D104</td>
<td>NFA response to Questions taken on notice – Estimates (C) Hearing 24-25 May, 1994</td>
<td>2/6/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>D105</td>
<td>Covering letter for NHMRC Panel’s Report to the 117th session of the NHMRC</td>
<td>1-2 June 1994</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D106</td>
<td>Expert panel on folate fortification of the NHMRC, Report to the 117th Session of Council, 1-2 June 1994, Agenda item 10.5</td>
<td>2/6/94</td>
<td>Expert Panel meeting</td>
</tr>
<tr>
<td>D107</td>
<td>NHMRC policy document</td>
<td>1-2 June 1994</td>
<td>NHMRC policy recommendations</td>
</tr>
<tr>
<td>Date</td>
<td>Source/Event</td>
<td>Date/Reference</td>
<td>Type</td>
</tr>
<tr>
<td>-------</td>
<td>---------------------------------------------------</td>
<td>-------------------</td>
<td>-------------------------------------</td>
</tr>
<tr>
<td>2/6/94</td>
<td>NHMRC News release</td>
<td>2/6/94</td>
<td>NHMRC policy recommendations</td>
</tr>
<tr>
<td></td>
<td>'Folate should be in our food to protect babies against spina bifida'</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/6/94</td>
<td>Letter from DHSH to NFA Chairperson</td>
<td>3/6/94</td>
<td>NHMRC policy recommendations</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/6/94</td>
<td>Transcript of radio interview – 2RN interviewing Expert Panel member</td>
<td>3/6/94</td>
<td>Follow on from NHMRC News release</td>
</tr>
<tr>
<td>3/6/94</td>
<td>Transcript of radio interview – 2RN</td>
<td>3/6/94</td>
<td>Follow on from NHMRC News release</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3/6/94</td>
<td>Newspaper clipping 'Baby food may get vitamin additive'</td>
<td>3/6/94</td>
<td>Follow on from NHMRC News release</td>
</tr>
<tr>
<td>3/6/94</td>
<td>Newspaper clipping 'Vitamin may be added to food'</td>
<td>3/6/94</td>
<td>Follow on from NHMRC News release</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4/6/94</td>
<td>Newspaper clipping 'Add folate to foods, says council'</td>
<td>4/6/94</td>
<td>Follow on from NHMRC News release</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7/6/94</td>
<td>Foodweek newsletter, 'NFA and food industry relations hit new low'</td>
<td>7/6/94</td>
<td>Draft reconsideration report</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>12/6/94</td>
<td>P14 - Vitamins and Minerals, Attachment 1, Item 1, NFA 24</td>
<td>12/6/94</td>
<td>Draft Reconsideration report</td>
</tr>
<tr>
<td>13/6/94</td>
<td>Newspaper clipping 'Limits on additives proposed'</td>
<td>13/6/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>13/6/94</td>
<td>Newspaper clipping 'Suspect vitamin additive faces ban'</td>
<td>13/6/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>13/6/94</td>
<td>Newspaper clipping 'Cereal makers win battle over nutrient additives'</td>
<td>13/6/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>13/6/94</td>
<td>Newspaper clipping 'Tough limits on additives'</td>
<td>13/6/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>13/6/94</td>
<td>Newspaper clipping 'New limits on food additives'</td>
<td>13/6/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>13/6/94</td>
<td>Newspaper clipping 'Food additives limits proposed'</td>
<td>13/6/94</td>
<td>Reconsideration report</td>
</tr>
<tr>
<td>22/6/94</td>
<td>Newspaper clipping, 'Kennett slams Canberra on food'</td>
<td>22/6/94</td>
<td>Review of functional foods</td>
</tr>
<tr>
<td>Document Code</td>
<td>Date</td>
<td>Type</td>
<td>Description</td>
</tr>
<tr>
<td>---------------</td>
<td>------------</td>
<td>---------------------------</td>
<td>-----------------------------------------------------------------------------</td>
</tr>
<tr>
<td>D126</td>
<td>June 1994</td>
<td>Reconsideration report</td>
<td>Different interpretation of evidence (safety concerns expressed)</td>
</tr>
<tr>
<td>D127</td>
<td>1/7/94</td>
<td>Reconsideration report</td>
<td>Opposing folate fortification policy recommendation</td>
</tr>
<tr>
<td>D128</td>
<td>Faxed 8/7/94</td>
<td>Reconsideration report</td>
<td>Protests about the NFSC decision. Asserts Ministers reordered the NFA objectives to favour trade over health. Folate fortification is a public health experiment without consent.</td>
</tr>
<tr>
<td>D129</td>
<td>July 1994</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D130</td>
<td>July 1994</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D132</td>
<td>July 1994</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D133</td>
<td>5/8/94</td>
<td>Reconsideration report</td>
<td>Illustrates the ongoing difference between NFA and NHMRC</td>
</tr>
<tr>
<td>D134</td>
<td>10/8/94</td>
<td>Reconsideration report</td>
<td>Applauds the NFA's revised position on A9</td>
</tr>
<tr>
<td>D135</td>
<td>6/9/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D136</td>
<td>15/9/94</td>
<td>Reconsideration report</td>
<td>Lobbying in opposition to folate</td>
</tr>
<tr>
<td>D137</td>
<td>22/9/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D138</td>
<td>23/9/94</td>
<td>Reconsideration report</td>
<td>Policy chronology, State Minister for Health opposing folate fortification policy</td>
</tr>
<tr>
<td>D139</td>
<td>3/10/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D140</td>
<td>8/11/94</td>
<td>Responding to NFA letter</td>
<td>Illustrates the difference between NFA and NHMRC. Claims that the effectiveness of folate fortification proven and monitoring is a priority</td>
</tr>
<tr>
<td></td>
<td></td>
<td>of 5/6/94 regarding folate monitoring</td>
<td></td>
</tr>
<tr>
<td>D141</td>
<td>11/11/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D142</td>
<td>22/11/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D143</td>
<td>30/11/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D144</td>
<td>6/12/94</td>
<td>Reconsideration report</td>
<td>Lobbying, Challenging NFSC's authority</td>
</tr>
<tr>
<td>D145</td>
<td>8/12/94</td>
<td>Reconsideration report</td>
<td>State Minister for Health opposing folate fortification policy, State Minister lobbied by ACA</td>
</tr>
<tr>
<td>Document Title</td>
<td>Date</td>
<td>Type</td>
<td>Subject</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------------</td>
<td>---------</td>
<td>---------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>D146 Foodweek newsletter 'NFA leadership never in doubt, says Pincus'</td>
<td>13/12/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D147 NFA letter in response to Foodweek article</td>
<td>14/12/94</td>
<td>Letter complaining about Foodweek article</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D148 NFA Media release 'NFA Chairperson announces resignation'</td>
<td>14/12/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D149 Theophanus media release 'Resignation of chairperson of National Food Authority'</td>
<td>14/12/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D150 NFA internal Office memo</td>
<td>15/12/94</td>
<td>Reconsideration report</td>
<td>Discusses strategy in relation to story on Chairperson's resignation</td>
</tr>
<tr>
<td>D151 Newspaper clipping 'Connolly reviews stand on food fortification'</td>
<td>16/12/94</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D152 Newspaper clipping, 'No tears for Pincus'</td>
<td>17/12/94</td>
<td>Reconsideration report</td>
<td>Questions whether the NFA Chairperson's resignation was due to pressure from within government as a result of industry pressure over A9</td>
</tr>
<tr>
<td>D153 Letter from WA Minister for Health to NFA Chairperson</td>
<td>2/1/95</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D154 Letter from Connolly to Crowie</td>
<td>3/1/95</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D155 MBCM article in Food Australia</td>
<td>January 1995</td>
<td>Reconsideration report</td>
<td>Outlines MBCM policy on fortification and health claims</td>
</tr>
<tr>
<td>D156 Letter from Tasmanian Minister for Health to NFA Chairperson</td>
<td>27/1/95</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D157 Current Issue Brief NFSC reconsideration</td>
<td>7/2/95</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D158 Newspaper clipping 'Food rules may keep out cereal'</td>
<td>10/2/95</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D159 Ministerial from NZ Minister for Health to Parliamentary Secretary</td>
<td>15/2/95</td>
<td>Reconsideration report</td>
<td>Policy chronology</td>
</tr>
<tr>
<td>D160 Media release 'New Ministers for transport, education and health'</td>
<td>21/2/95</td>
<td>Reconsideration report</td>
<td>Replacement of Health minister opposing folate fortification</td>
</tr>
<tr>
<td>D161 Transcript of interview of ACA on radio station 4QR</td>
<td>24/4/95</td>
<td>Commenting on folate in the context of the NFSC decision</td>
<td>ACA supports supplements. If must have fortification, then should be mandatory -- ministers are having a 50:50 bet and it is not well targeted</td>
</tr>
<tr>
<td>D162 News Release from Dr Andrew Theophanus, MP 'Clear new standard for adding vitamins and minerals to food'</td>
<td>8/6/95</td>
<td>Launch of revised Standard A9</td>
<td>Claims that: - fortified food will provide increased consumer choice - the revised Standard will give industry flexibility to meet consumer demand - based on solid evidence</td>
</tr>
<tr>
<td>D163 Speech of Dr Andrew Theophanus, 'Launch of new food Standard A9 – Vitamins and Minerals'</td>
<td>8/6/95</td>
<td>Launch of revised Standard A9</td>
<td>Food Standard A9 presented as a public health intervention</td>
</tr>
<tr>
<td>D164 ACA media release, 'Health Ministers sell out Consumers'</td>
<td>8/6/95</td>
<td>Launch of revised Standard A9</td>
<td>Protests about revised food Standard A9</td>
</tr>
<tr>
<td>Code</td>
<td>Title</td>
<td>Date</td>
<td>Description</td>
</tr>
<tr>
<td>------</td>
<td>-----------------------------------------------------------------------</td>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>D165</td>
<td>Newspaper clipping, 'New vitamin law comes under attack'</td>
<td>8/6/95</td>
<td>Launch of revised Standard A9</td>
</tr>
<tr>
<td>D166</td>
<td>Newspaper clipping, 'New food additives code'</td>
<td>9/6/95</td>
<td>Launch of revised Standard A9</td>
</tr>
<tr>
<td>D167</td>
<td>Newspaper clipping, 'Food industry shake-up to restrict vitamin use'</td>
<td>9/6/95</td>
<td>Launch of revised Standard A9</td>
</tr>
<tr>
<td>D168</td>
<td>Newspaper clipping, 'New standard on food additives'</td>
<td>9/6/95</td>
<td>Launch of revised Standard A9</td>
</tr>
<tr>
<td>D169</td>
<td>Foodweek newsletter, 'Disputed food standard starts with joint blessing'</td>
<td>13/6/95</td>
<td>Launch of revised Standard A9</td>
</tr>
<tr>
<td>D170</td>
<td>National Food Authority – Amendment No. 27 to the Food Standards Code</td>
<td>14/6/95</td>
<td>Gazetted</td>
</tr>
<tr>
<td>D171</td>
<td>Article in Food Australia, 'New vitamins and minerals standard'</td>
<td>July 1995</td>
<td>Launch of revised Standard A9</td>
</tr>
<tr>
<td>D173</td>
<td>Cablegram from NZ to Department of Foreign Affairs and Trade</td>
<td>9/8/95</td>
<td>Gazetted of Standard A9</td>
</tr>
<tr>
<td>D174</td>
<td>Briefing memo for NHMRC for Quantum interview</td>
<td>25/9/95</td>
<td>Background briefing for NHMRC representative for ABC Quantum program to explain reasons for voluntary and not mandatory folate fortification</td>
</tr>
<tr>
<td>D175</td>
<td>Fax from Chairperson of Expert Panel to NFA Board Member</td>
<td>30/11/95</td>
<td>Implementing folate fortification policy</td>
</tr>
<tr>
<td>D176</td>
<td>Kellogg's news release, 'Kellogg's in public health move'</td>
<td>7/12/95</td>
<td>Implementing folate fortification policy</td>
</tr>
<tr>
<td>D177</td>
<td>Newspaper clipping, 'Vitamins in cereals to save babies'</td>
<td>8/12/95</td>
<td>Implementing folate fortification policy</td>
</tr>
<tr>
<td>D178</td>
<td>NFA response to Federal Bureau of Consumer Affairs</td>
<td>22/1/96</td>
<td>Gazetted of Standard A9</td>
</tr>
<tr>
<td>D179</td>
<td>Letter from NFA Board Member to NHMRC</td>
<td>6/2/96</td>
<td>Implementing folate fortification policy</td>
</tr>
<tr>
<td>D180</td>
<td>Letter from AFC to NFA</td>
<td>29/2/96</td>
<td>Implementing folate fortification policy</td>
</tr>
<tr>
<td>D181</td>
<td>Letter from DISSH to AIHW</td>
<td>20/3/96</td>
<td>Implementing folate fortification policy</td>
</tr>
<tr>
<td>D182</td>
<td>Transcript of ADA meeting, 'Folic acid – a rich case in science policy'</td>
<td>27-30 October 1997</td>
<td>US experience</td>
</tr>
<tr>
<td>D183</td>
<td>Transcript of House of Lords session</td>
<td>26/11/97</td>
<td>UK experience</td>
</tr>
<tr>
<td>Date</td>
<td>Description</td>
<td>Action</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------------</td>
<td>------------------------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>18/3/98</td>
<td>Implementing folate fortification policy</td>
<td>Folate as the ‘stalking horse’ for health claims</td>
<td></td>
</tr>
<tr>
<td>30/3/98</td>
<td>Implementing folate fortification policy</td>
<td>Folate as the ‘stalking horse’ for health claims</td>
<td></td>
</tr>
<tr>
<td>19/11/98</td>
<td>Implementing folate fortification policy</td>
<td>Folate as the ‘stalking horse’ for health claims</td>
<td></td>
</tr>
<tr>
<td>November 1998</td>
<td>Launch of folate pilot trial</td>
<td>Commonwealth Minister for Health’s personal interest in folate</td>
<td></td>
</tr>
<tr>
<td>July 1999</td>
<td>Implementing folate fortification policy</td>
<td>Shaping of the food regulatory system by interest groups</td>
<td></td>
</tr>
<tr>
<td>April 1999</td>
<td>Implementing folate fortification policy</td>
<td>Shaping of the food regulatory system by interest groups</td>
<td></td>
</tr>
<tr>
<td>June 2000</td>
<td>Implementing folate fortification policy</td>
<td>Using folate-NTDs to lead onto other agendas</td>
<td></td>
</tr>
<tr>
<td>8/8/00</td>
<td>Implementing folate fortification policy</td>
<td>Commonwealth Minister for Health launching food industry symposium</td>
<td></td>
</tr>
<tr>
<td>August 2000</td>
<td>Implementing folate fortification policy</td>
<td>Folate as the ‘stalking horse’ for health claims</td>
<td></td>
</tr>
<tr>
<td>September 1999</td>
<td>Post-review Standard A9</td>
<td>Accessibility Openness and transparency</td>
<td></td>
</tr>
<tr>
<td>September 2000</td>
<td>Post-review Standard A9</td>
<td>1. Remarks on inequitable access to the review process</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>2. Comments on potential for political influence</td>
<td></td>
</tr>
<tr>
<td>September 2000</td>
<td>Post-review Standard A9</td>
<td>Comments on potential for political influence Assessment criteria</td>
<td></td>
</tr>
<tr>
<td>8/9/00</td>
<td>Implementing folate fortification policy</td>
<td>Folate as the ‘stalking horse’ for health claims</td>
<td></td>
</tr>
<tr>
<td>26/9/00</td>
<td>Policy impact</td>
<td>Reports a decline in Victoria in spina bifida prevalence, but large fall before fortification available</td>
<td></td>
</tr>
<tr>
<td>December 2000</td>
<td>Post-review Standard A9</td>
<td>Defining the role and responsibilities of the regulator</td>
<td></td>
</tr>
<tr>
<td>2/4/02</td>
<td>Implementing folate fortification policy</td>
<td>Folate as the ‘stalking horse’ for health claims</td>
<td></td>
</tr>
<tr>
<td>March 2001</td>
<td>Post-review Standard A9</td>
<td>Defining the role and responsibilities of the regulator</td>
<td></td>
</tr>
<tr>
<td>23/5/01</td>
<td>Implementing folate fortification policy</td>
<td>Folate as the ‘stalking horse’ for health claims</td>
<td></td>
</tr>
<tr>
<td>24/5/02</td>
<td>Implementing folate fortification policy</td>
<td>Announcement that Ministers have agreed to policy principles for health and related claims</td>
<td></td>
</tr>
</tbody>
</table>
Appendix 4

List of key informants
## List of key informants*  

<table>
<thead>
<tr>
<th>Key informant (Informant number, gender and approximate age)</th>
<th>Place of employment at time of interview</th>
<th>Role played in case study**</th>
</tr>
</thead>
<tbody>
<tr>
<td>I1, Female, 48</td>
<td>University lecturer (public health and nutrition)</td>
<td>iii), iv)</td>
</tr>
<tr>
<td>I2, Female, 54</td>
<td>Private consultant (legal)</td>
<td>iii), iv), v)</td>
</tr>
<tr>
<td>I3, Male, 58</td>
<td>University professor (public health)</td>
<td>i), ii), vi)</td>
</tr>
<tr>
<td>I4, Female, 70</td>
<td>Private consultant (food and nutrition policy)</td>
<td>i), ii), iv), v)</td>
</tr>
<tr>
<td>I5, Female, 47</td>
<td>Clinical epidemiologist</td>
<td>i), ii), vi)</td>
</tr>
<tr>
<td>I6, Male, 50</td>
<td>University lecturer (nutrition and dietetics)</td>
<td>iii), iv)</td>
</tr>
<tr>
<td>I7, Female, 50</td>
<td>Food industry legal adviser</td>
<td>iii), iv)</td>
</tr>
<tr>
<td>I8, Female, 54</td>
<td>Private consultant (public health)</td>
<td>iii), iv)</td>
</tr>
<tr>
<td>I9, Male, 52</td>
<td>University professor (epidemiology)</td>
<td>i), v)</td>
</tr>
<tr>
<td>I10, Female, 48</td>
<td>Food industry nutritionist</td>
<td>iii), v)</td>
</tr>
<tr>
<td>I11, Female, 47</td>
<td>Public servant (Therapeutics Good Administration)</td>
<td>iii), iv)</td>
</tr>
<tr>
<td>I12, Male, 62</td>
<td>Public servant (Therapeutics Goods Administration)</td>
<td>iii), iv)</td>
</tr>
<tr>
<td>I13, Male, 50</td>
<td>Food industry lobbyist</td>
<td>iii), iv)</td>
</tr>
<tr>
<td>I14, Female, 63</td>
<td>Private consultant (nutrition and dietetics)</td>
<td>iii), v)</td>
</tr>
<tr>
<td>I15, Male, 58</td>
<td>Public servant (NHMRC)</td>
<td>ii), iii), iv), vii)</td>
</tr>
<tr>
<td>ID</td>
<td>Gender, Age</td>
<td>Occupation</td>
</tr>
<tr>
<td>------</td>
<td>-------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>I16</td>
<td>Female, 38</td>
<td>Public servant (FSANZ)</td>
</tr>
<tr>
<td>I17</td>
<td>Female, 51</td>
<td>Public servant (FSANZ)</td>
</tr>
<tr>
<td>I18</td>
<td>Male, 49</td>
<td>Barrister</td>
</tr>
<tr>
<td>I19</td>
<td>Male, 58</td>
<td>Commonwealth Member of Parliament</td>
</tr>
<tr>
<td>I20</td>
<td>Male, 56</td>
<td>University professor (medicine)</td>
</tr>
<tr>
<td>I21</td>
<td>Female, 44</td>
<td>Nutritionist at ACA</td>
</tr>
<tr>
<td>I22</td>
<td>Female, 38</td>
<td>Nutritionist at MBCM</td>
</tr>
<tr>
<td>I23</td>
<td>Male, 68</td>
<td>University professor (nutrition) Declined to be interviewed</td>
</tr>
<tr>
<td>I24</td>
<td>Male, 51</td>
<td>Public servant (WA Health Department) Declined to be interviewed</td>
</tr>
<tr>
<td>I25</td>
<td>Female, 54</td>
<td>Clinical epidemiologist Declined to be interviewed</td>
</tr>
<tr>
<td>I26</td>
<td>Male, 59</td>
<td>Food industry director Declined to be interviewed</td>
</tr>
</tbody>
</table>

* Due to confidentiality requirements outlined in the ethics approval for this research the actual name of each key informant has been withheld. However, in the research database stored at Deakin University for a 5-year period the actual name of each key informant is identified and linked with the relevant data.

** Key to the role played in the case study:

i) Expert knowledge of the relationship between folate and NTDs.
ii) Knowledge of historical association of the NHMRC with folate-NTD issue.
iii) Knowledge of the contexts within which food regulation policy decisions were shaped at the time of the folate fortification policy decision.
iv) Knowledge of the political environment within which the folate fortification policy decision operated.
v) Member of NFA staff involved in reviewing and developing policy recommendations for food Standard A9.
vii) Member of the NHMRC Expert Panel on folate fortification.
ivii) Member of the NFSC that voted on both the NFA and the NHMRC folate fortification recommendations.
Appendix 5

Theme list for key informant interviews
Theme list for key informant interviews

The theme list was developed around a list of topics that were discussed, but neither the wording nor the order of questions was fixed. The interview was modified in accordance with the selection criteria for particular informants to enable a particular line of questioning to receive greater attention.

The epidemiological evidence for the folate-NTD relationship
- What is your opinion of the quality and quantity of the epidemiological evidence?
- Do you have any concerns regarding the scientific evidence?
- What additional scientific evidence do you believe is required?
- Do you believe neural tube defects are of public health significance?

The policy-making environment
- What has been the background to the policy interest in folate-NTDs in Australia?
- Who were the individuals, interest groups associated with this issue?
- Why were these individuals and interest groups involved?
- What was the role, if any, of the food industry in this policy debate?
- Were there any other events, agendas and influences shaping the policy-making process? In what way?

The decision-making process
- What is your opinion of the membership of the Expert Panel?
- How were the members of the Expert Panel selected?
- What is your opinion of the way that the meetings of the Expert Panel were conducted?
- How could the decision-making process have been improved?

The folate fortification policy
- What is your opinion of the policy?
- Are there any changes you believe should be made to the policy?
- Are there any safety implications of the policy recommendations?
- Do you believe there are any ethical issues raised with this policy?
- Is there an alternative policy option that you would recommend? Why?

Implications
- What do you believe are the implications of the policy for food regulation?
- What should be done now that the policy has been launched?
- What lessons do you believe can be learned from the policy-making experience?

The food regulatory system
- What is your opinion of the NFA and its role in the policy-making process?
- How can food regulation be used as a public health policy instrument?
- What is your opinion of the food regulatory system in Australia?
- What do you believe are the major challenges facing the food regulatory system?
- How could the food regulatory system be improved?

Closing probes
- Can you suggest additional informants who should be interviewed?
- Is there anything else you would like to add?
Appendix 6

Deakin University Ethics Approval
and Plain language statement
EMORANDUM

To: Mr Mark Lawrence
Nutrition & Public Health
Burwood Campus

OM: Secretary, Deakin University Ethics Committee (DUEC)

TE: 24/11/97

BJEKT: PROJECT EC 174-97 (Please quote this project number in all correspondence)

AN EVALUATION OF POLATE FORTIFICATION OF THE FOOD SUPPLY AS A CASE STUDY OF PUBLIC HEALTH POLICY DEVELOPMENT AND IMPLEMENTATION

ish to advise that your project was considered at DUEC Meeting 6/97 held on 17 November 1997.

> relevant decision is reproduced here for your information.

THAT APPROVAL BE GIVEN FOR MR MARK LAWRENCE TO UNDERTAKE THIS PROJECT AS PRINCIPAL INVESTIGATOR (UNDER THE SUPERVISION OF PROF JOHN CATFORD, DEAKIN HEALTH STRATEGIES) FROM 1 FEBRUARY 1998 TO 31 DECEMBER 1999 SUBJECT TO SUBMISSION OF QUESTIONNAIRE/LINE OF QUESTIONING FOR CONSIDERATION AND ENDORSEMENT.

NB Project approved subject to conditions/revisions to be attended to as soon as possible. See below.

Questionnaire/Line of Questioning to be submitted to DUEC Secretary asap for consideration/endorsement.
[possible endorsement by Chair of DUEC].*******
[PI may consider integrating Plain Language Statement with introductory letter, and if so forward copy of revision to DUEC Secretary.]

Please note that the standard conditions for projects given ethical clearance are as outlined below:

) Limit of Approval: the approval is limited to the research proposal as submitted. If an extension of time is required please act the Secretary either by mail, fax or email with the revised completion date;

) Variation to Project: any modifications or alterations must be submitted to the Committee for consideration and approval. Please provide the relevant extract(s) of the approved project proposal together with a brief description of the proposed changes and the rationale behind those changes plus any supporting documentation that directly relates to the variation sought. If the committee considers the changes to be significant it may request that a new application be submitted;

) Project Reports: these are required annually and at the conclusion of the project (usually end of data collection). Unless otherwise arranged, progress reports must reach the Secretary, no later than 31 October each year, on the prescribed format.ailure to submit the required reports will lead to approval of the project lapsing. The Committee may also exercise its authority to withhold approval for new applications while progress reports on previous projects are still outstanding.

) Data storage: the principal investigator/academic supervisor (for student projects) is responsible for secure data storage for a period of not less than 5 years after date of publication, or longer depending on the nature of the research.

Signature Redacted by Library

Keith Wilkins,
Secretary, DUEC
Tel: 03 5227 3412; Fax: 03 5227 2789; Email: keithwil@deakin.edu.au
Dear

My name is Mark Lawrence and I am a National Health and Medical Research Council (NHMRC) Scholar undertaking a PhD at Deakin University evaluating the NHMRC policy on folate fortification of staple foods as an intervention to help reduce the risk of neural tube defects. This evaluation study will contribute directly to the proposed review by the NHMRC of this policy and it will help inform related food regulation policy matters including the current consideration of policy in relation to health claims and food fortification.

One of the methods that I will be using in this research is key informant interviews. These interviews will provide information to help explain the 'how' and 'why' of the policy’s development and implementation. As a key stakeholder/expert involved in the development and/or implementation of this policy I am writing to you to invite you to participate in this important research.

The aims of the project are to:

i) Analyse the decision making process involved in the development and implementation of the NHMRC policy;

ii) Examine the implementation of the folate fortification policy;

i) Evaluate the effectiveness of folate fortification on dietary intake as a public health intervention;

ii) Contribute to the review of the folate fortification intervention by the NHMRC; and

iii) Develop theory regarding public health policy development and implementation in a food regulation setting.

The research will be conducted in the form of semi-structured interviews. This means that I will be asking people who agree to participate to answer questions about the development and implementation of the folate fortification policy. There will be an opportunity to elaborate on other issues that are relevant to this topic. With approval, I intend to use a tape recorder to assist with my writing up of the interview. The interview will take approximately one hour. All participants in this study will be informed of the results upon the completion of the research.

A number of provisions will be put in place to preserve the confidentiality of the information that you provide. These include:

i) All records of your interview including any tapes will only be identified by a number or an alias and your name and address kept separately.
ii) Original records of your interview and the coded information will be stored in a locked filing cabinet in an office at Deakin University.

iii) Any information that you provide will not be made public in any form that could reveal your identity to an outside party ie. you will remain anonymous.

iv) Only aggregated results will be used for research purposes and may be reported in scientific and academic journals.

v) Individual results will not be released to any person except at your request and on your authorisation.

vi) That you are free to withdraw your consent at any time during the study in which event your participation in the research study will immediately cease and any information obtained from you will not be used ie. will be destroyed.

Could you please indicate your interest, or otherwise, in participating in this research by crossing out the appropriate word(s) on the enclosed sheet and returning to me at the address above, or on fax (03) 9244 6808, by ...................... If you have any questions regarding this invitation, or the research in general, please contact me on telephone (03) 92443789 or e-mail: malawren@deakin.edu.au. Should you have any concerns about the conduct of this research project, please contact the Secretary, Ethics Committee, Research Services, Deakin University, 221 Burwood Highway, BURWOOD VIC 3125. Tel (03) 9251 7123.

If you agree to participate in this research, I will contact you within two weeks of receiving your response to arrange an interview time and location convenient to you. At the interview I will ask you to sign a consent form to acknowledge the conditions under which I am conducting this research.

I thank you in advance for your support of this research and look forward to your response and to arranging an interview with you.

Yours sincerely

Mark Lawrence
NHMRC Scholar
October 1999
Appendix 7

Summary of the types of studies and trials conducted on folate and neural tube defects and the relative risks associated with supplementary and dietary folate (Excerpt from the report of the NHMRC Expert Panel on Folate Fortification)
**FIGURE 2.1. SUMMARY OF THE TYPES OF STUDIES AND TRIALS CONDUCTED ON FOLATE AND NEURAL TUBE DEFECTS AND THE RELATIVE RISKS ASSOCIATED WITH SUPPLEMENTARY AND DIETARY FOLATE**

<table>
<thead>
<tr>
<th>RANDOMISED CONTROLLED TRIALS</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laurence et al 1981</td>
<td>0.42 [0.04, 2.97]</td>
</tr>
<tr>
<td>FA (4 mg)</td>
<td></td>
</tr>
<tr>
<td>MRC 1991</td>
<td>0.29 [0.10, 0.74]</td>
</tr>
<tr>
<td>FA (4 mg)</td>
<td></td>
</tr>
<tr>
<td>Kirke et al 1992</td>
<td>0.00 [0.00, 1.00]</td>
</tr>
<tr>
<td>FA (0.36 mg)</td>
<td></td>
</tr>
<tr>
<td>Czeizel &amp; Dudas 1992</td>
<td>0.00 [0.00, 0.35]</td>
</tr>
<tr>
<td>MV/FA (0.8 mg)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>NON-RANDOMISED TRIALS</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smithells et al 1980</td>
<td>0.14 [0.03, 0.47]</td>
</tr>
<tr>
<td>MV/FA (0.36 mg)</td>
<td></td>
</tr>
<tr>
<td>Vergel et al 1990</td>
<td>0.00 [0.00, 2.13]</td>
</tr>
<tr>
<td>FA (3 mg)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>COHORT STUDY</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Milunsky et al 1989</td>
<td>0.29 [0.15, 0.55]</td>
</tr>
<tr>
<td>MV/FA</td>
<td></td>
</tr>
<tr>
<td>Milunsky et al 1989</td>
<td>0.42 [0.15, 1.13]</td>
</tr>
<tr>
<td>Dietary FA (≥100μg)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CASE CONTROL STUDIES</th>
<th>Relative Risk (95% CI)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multinare et al 1986</td>
<td>0.41 [0.26, 0.66]</td>
</tr>
<tr>
<td>MV/FA</td>
<td></td>
</tr>
<tr>
<td>Bower (unpublished data)</td>
<td>0.35 [0.14, 0.66]</td>
</tr>
<tr>
<td>Dietary FA</td>
<td></td>
</tr>
<tr>
<td>Bower &amp; Stanley 1992</td>
<td>0.11 [0.01, 1.33]</td>
</tr>
<tr>
<td>MV/FA</td>
<td></td>
</tr>
<tr>
<td>Mills et al 1989</td>
<td>0.87 [0.73, 1.02]</td>
</tr>
<tr>
<td>MV/FA</td>
<td></td>
</tr>
<tr>
<td>Werler et al 1993</td>
<td>0.40 [0.20, 0.60]</td>
</tr>
<tr>
<td>MV/FA</td>
<td></td>
</tr>
<tr>
<td>Werler et al 1993</td>
<td>0.60 [0.40, 1.10]</td>
</tr>
<tr>
<td>Dietary FA</td>
<td></td>
</tr>
</tbody>
</table>

Figure prepared by Mr David Smith (Wolfson Institute for Preventive Medicine, Medical College of St Bartholomew's Hospital, London) in association with Professor N. J. Wald and Dr C. Bower.
Appendix 8

Executive summary, Recommendations and Background to the establishment, of the NHMRC Expert Panel on Folate Fortification
FOLATE FORTIFICATION

Report of the Expert Panel on Folate Fortification

ENDORSED AT THE 117TH SESSION OF THE NATIONAL HEALTH AND MEDICAL RESEARCH COUNCIL

Sydney, 1-2 June 1994

National Health and Medical Research Council

NHMRC
Recommendations

In making the following recommendations, the Expert Panel on Folate Fortification agreed that:

- Increasing the amount of folate in the Australian diet will reduce the rate of neural tube defects (NTDs).
- There is sufficient evidence to recommend as a public health measure the mandatory fortification of flour (including breads and savoury biscuits), and voluntary fortification of breakfast cereals, rice, pasta, yeast extracts and fruit and vegetable juices to 50 per cent of the recommended dietary intake (RDI) for folate.
- However, as a practical first step, it is recommended that fortification be voluntary for all the foods listed above, and that this be reviewed three years after gazetted to determine whether voluntary fortification has been effective, or whether mandatory fortification of flour is necessary.
- At the levels of increased folate proposed there is no foreseeable risk to any population group.

Therefore the Panel recommends that the Council recommend the following:

Recommendation

The Council recommends:

1. That the National Food Authority, in its revision of Standard A9 of the Australian Food Standards Code, permit the addition of folate in the following manner:

   i) Voluntary fortification to 50 per cent RDI per reference quantity of:
      - Flour
      - Savoury biscuits
      - Bread
      - Breakfast cereals
      - Pasta
      - Rice
      - Yeast extracts
      - Fruit and vegetable juices

   ii) Nutritional equivalence of beverages derived from legumes (such as soy beverages) and textured vegetable protein.
2. That voluntary fortification be reviewed three years after the date of gazettal to determine its effectiveness and whether there is a need for mandatory fortification to be introduced. The NHMRC will coordinate the monitoring to determine the effectiveness of voluntary fortification.

3. That a nutrition message such as:

   A diet rich in the vitamin folate is important for women in their child-bearing years. This food is a good source of folate.

be permitted to be used on those foods fortified with at least 25 per cent RDI folate per reference quantity.

4. That priority be given to the undertaking of analyses of the folate content of foods in Australia as part of the 'Composition of Foods, Australia' series.

The Panel also recommends that the Council recommend the following:

Recommendation

The Council recommends:

1. That the food industry and other researchers give priority to determining the following for the foods identified for fortification:
   - method development and validation for analyses of folate;
   - the feasibility of adding folate;
   - the stability of added folate in processing and subsequent storage;
   - the bioavailability of the added folate;
   - any organoleptic problems associated with the fortification of foods with folate; and
   - the cost of adding folate to the identified foods.

The Council notes that some of this information may be available from other countries where fortification of some of the identified foods has been in place for a number of years.

2. That State and Territory Health Authorities and other appropriate organisations give consideration to developing and implementing appropriate education campaigns to inform the public and health professionals of the relationship between NTDs and folate and the importance of consuming folate-containing foods for both the general population and women of child-bearing age.

3. The NHMRC encourages the establishment of monitoring activities outlined in section 8 of the report.

4. The NHMRC coordinates, through an appropriate committee, the results of the monitoring activities established to evaluate the effectiveness of folate fortification.

The effectiveness should be judged by whether, three years after the date of gazettal of the revised Standard A9:

   • there has been a reduction in the incidence of NTDs of 25 per cent or more;
• there has been a 50 per cent uptake in the fortified cereal products by the target group; and
• at least 70 per cent of women in the target group are consuming more than 400 μg folate/day.

In addition, the Panel recommends that Council note:

1. The Panel recommends that blood samples be collected in the National Nutrition Survey 1995-96 for the analysis of folate.

2. The Panel recommends that the RDI for folate for pregnancy (400μg) be extended to cover the time between the last menstrual period and conception and that consideration be given to extending the period of the RDIs for other nutrients for pregnancy in a similar manner.
Executive summary

The National Health and Medical Research Council (NHMRC) established the Expert Panel on Folate Fortification after the National Food Authority (NFA) requested in April 1994 that NHMRC assess the issue of folate fortification of foods to prevent neural tube defects (NTDs). The request followed the revision by the NFA of food Standard A9—Vitamins and Minerals. The findings of the Panel and its recommendations, based on its terms of reference, are explained in detail in this report. The major issues are summarised below.

Relationship between folate, other nutrients and neural tube defects (NTDs)

Numerous studies and major trials have established that there is a negative association between folate and NTDs: the risk of NTDs decreases as folate intakes increase. The amount of supplemental folate found to be effective ranges from 360 µg to 4000 µg a day.

An estimated 400 to 500 pregnancies are affected by NTDs in Australia each year. From models of food consumption, in which selected foods are fortified with folate, an estimated 50 per cent to 66 per cent of these NTDs could be prevented. Despite certain assumptions which are inherent in these calculations, it is conservatively estimated that $2 315 300 in total costs could be averted each year by increasing the folate intakes of the population.

Estimated folate intakes and upper targets for intake

There is a lack of Australian data on folate levels in foods. However, reasonable approximations of folate intake can be obtained by using data from overseas.

The current Australian RDIs for folate are: 200 µg for people aged 12 years and over, 400 µg in pregnancy, and 350 µg for lactating women. Comparison of the estimated dietary folate intakes from a 1990 Victorian survey with the RDIs indicated that 29 per cent of the population surveyed consumed less than the RDI for folate. Mean intakes were above the RDI, but only a minority of women consumed folate at the level of the RDI for pregnancy.

The Panel adopted an upper target for folate intake of 1 000 µg a day, based on the available evidence, and consideration of areas of potential concern, namely the vitamin B12/folate interaction; interactions with zinc metabolism; interactions with
folic acid antagonist drugs, and interactions with anticonvulsant medication.

The target group for increasing folate intakes to prevent NTDs is women of child-bearing age. The target for folate consumption for this group is 400 µg (the RDI for pregnancy) at the 10th percentile of intake, with a mean of approximately 600-700 µg and the 95th percentile of consumption less than 1 000 µg. In estimates of intake, the target group had the highest margin of safety (i.e. their intakes were considerably below 1 000 µg a day). Therefore, with folate fortification at the levels considered, their total folate intakes should fall within the upper target of 1 000 µg a day, even if they do take folate supplements.

**Methods for reducing NTDs**

The following options for reducing the incidence of NTDs were considered:

- nutrition education of women intending to become pregnant;
- mass supplementation of women intending to become pregnant;
- mandatory fortification, or
- voluntary fortification.

After consideration of the various options, the Panel agreed that as a practical first step, voluntary fortification be recommended. The Panel recommends voluntary fortification to 50 per cent RDI per reference quantity of flour, savoury biscuits, bread, breakfast cereals, pasta, rice, yeast extracts, and fruit and vegetable juices. This is to be reviewed three years after gazettal, to determine whether voluntary fortification has been effective, or whether alternative and, or additional identified options should then be considered.

**Effects of fortification on the population**

The expected intake that would result from fortification was modelled and is presented tabulated in section 4 of the report. At a level of 50 per cent fortification of the identified foods, it was estimated that females aged 25-34 years would be consuming a mean folate intake of 500 µg a day, with intakes of about 290 µg a day and 730 µg a day at the 10th and 90th percentiles respectively. Estimates for other population groups were also made, as were estimates of the potential effects of fortification for consumers who follow the ‘Dietary guidelines for Australians’.

In addition to preventing up to 66 per cent of NTDs, the following advantages of fortification of selected foods with folate were identified:

- The availability of increased folate to all women in the target population, regardless of economic or educational status.
- Increasing folate intake without the need to change food selection practices or to remember to take a supplement.
- Provision of folic acid in a continuous and passive manner.
- Improved nutritional status of other population subgroups, such as disadvantaged groups and Aboriginal and Torres Strait Island peoples.
Technical and economic implications of fortification

The possible technical and economic implications of fortification were considered. The method of fortification, the stability of folate in foods, bioavailability, potential organoleptic changes, safety, methods of analysis and cost, and additional costs of fortification are all discussed in detail in the report. Given the lack of experience in Australia with the addition of folate to foods, the introduction of fortification may initially bring about the need to undertake some feasibility testing.

Health claims

A health claim per se is not considered desirable in Australia. A nutrition message such as:

A diet rich in the vitamin folate is important for women in their child-bearing years.
This food is a good source of folate

is considered to be appropriate.

Monitoring and surveillance

A system to monitor and assess the effects of fortification of foods with folate to lower the incidence of NTDs in Australia is documented in this report. This system essentially highlights the need to:

- monitor the incidence of neural tube defects,
- monitor current and changing food composition values for folate,
- monitor intakes and blood values of folate in specific population subgroups, and
- coordinate the monitoring activities as outlined.
1. Expert Panel on Folate Fortification

Background to the establishment of the Panel

Following the recommendation of the former Health Care Committee (HCC) of the National Health and Medical Research Council (NHMRC), Council approved a statement on the relationship between dietary folic acid and neural tube defects (NTDs) such as spina bifida in June 1992.

In the light of recommendations produced by the US Department of Health and Human Services, the Expert Group to the UK Department of Health and recent research, HCC recommended that Council endorse a revised statement on the relationship. The revised statement was endorsed by Council in June 1993.

The revised statement differed from the first in several ways, but one of the most important differences is that it recommended that staple foods such as breads and cereals be fortified with folate. However, no level of fortification was recommended.

At the same time that the NHMRC was considering the issue of folate and NTDs, the National Food Authority (NFA) commenced a review of Standard A9 — Vitamins and Minerals. The basis for the revision was the adoption of the Codex principle that, in general, vitamins and minerals should only be added to foods on the basis of restoring the nutrients lost in processing, except for nutritional equivalence of substitute foods and fortification where there is an identified and proven public health need. Foods proposed by the NFA to be restored were cereal-based foods, extracts, fruit and vegetable juices and juice products, as well as specialty foods such as formula dietary foods, food aid biscuits and foods classified as substitute foods-soy beverages and textured vegetable protein.

Standard A9 is a voluntary standard and manufacturers of food products are not required to add the permitted vitamins and minerals to the specified levels. However, if they do choose to add vitamins and minerals to foods, they are limited to the amount that can be claimed by maximum claims per reference quantity specified in the standard.

The level at which folate can be added to foods has varied over the different drafts of the standard. The maximum claim for folate per reference quantity at a restoration level was 15 per cent of the recommended dietary intake (RDI) for adults. This intake is equivalent to 30 μg of folate.

The draft Standard A9 proposed by NFA to the National Foods Standards Council
(NFSC), comprising Federal, State and Territory Ministers for Health, at its March 1994 meeting was referred back to the NFA for reconsideration.

In addition, the NFSC referred the issue of folate fortification of foods to the NHMRC for an assessment of the matter and to make recommendations to the NFA. A period of three months was given for the NFA to submit a revised recommendation to the NFSC by 23 June 1994, and this recommendation was to include details of any proposal to fortify foods with folate.

To assist the NFA to meet its deadline, the NHMRC was requested to report its findings and recommendations to the Authority by 10 June 1994.

The letter from Dr Burch of the NFA to the Chair of Council is at appendix 1.

As a result of this request, the Expert Panel on Folate Fortification was established with the following membership and terms of reference.

**Membership**

<table>
<thead>
<tr>
<th>Name</th>
<th>Affiliation</th>
<th>Expertise/Role</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prof Colin Binns</td>
<td>School of Public Health, Curtin University of</td>
<td>(expertise in public health nutrition) (Chair)</td>
</tr>
<tr>
<td></td>
<td>Technology</td>
<td></td>
</tr>
<tr>
<td>Dr Carol Bower</td>
<td>Institute for Child Health Research in Western</td>
<td>(expertise in folate research in women and children)</td>
</tr>
<tr>
<td></td>
<td>Australia</td>
<td></td>
</tr>
<tr>
<td>Prof Stewart Truswell</td>
<td>Human Nutrition Unit, University of Sydney</td>
<td>(expertise in the implications of folate fortification for the whole population)</td>
</tr>
<tr>
<td>Prof John McNeil</td>
<td>Social and Preventive Medicine, Monash Medical</td>
<td>(expertise in epidemiology and toxicology)</td>
</tr>
<tr>
<td></td>
<td>Centre</td>
<td></td>
</tr>
<tr>
<td>Ms Janine Lewis</td>
<td>National Food Authority</td>
<td>(expertise in food regulation)</td>
</tr>
<tr>
<td>Mrs Barbara Brown</td>
<td>Nutrition Section, HSH</td>
<td>(expertise in the food and nutrition patterns of the Australian population)</td>
</tr>
<tr>
<td>A/Prof Heather Greenfield</td>
<td>Dept of Food Science and Technology, University of NSW</td>
<td>(expertise in nutrition and food analysis)</td>
</tr>
<tr>
<td>Ms Wendy Morgan</td>
<td>Representative of the Food Industry Council of</td>
<td>(expertise in technical aspects of folate fortification for the food industry)</td>
</tr>
<tr>
<td></td>
<td>Australia, Goodman Fielder Pty Ltd</td>
<td></td>
</tr>
<tr>
<td>Ms Valorie Cocksedge</td>
<td>National Council of Women</td>
<td>(AFCO nominee)</td>
</tr>
</tbody>
</table>
Secretariat
Ms Michelle Fraser
Mrs Sue Jeffreson (Secretary/convenor)
Mr Paul van Belkom

Terms of reference

1. To report on the relationship between folate, other nutrients and the incidence of neural tube defects.
2. To report on the current estimated intakes of folate in different population subgroups in Australia, and make recommendations on safe upper levels of folate intake.
3. To recommend the most appropriate method for reducing the incidence of neural tube defects, including food fortification.
4. To identify the effects of any proposed fortification program on population subgroups other than the target group.
5. To identify the likely technical and economic implications of any fortification program to the food industry.
6. To make recommendations as to whether health claims should be permitted for folate and, if so, to recommend suitable types of claims.
7. To make recommendations for appropriate methods of monitoring and surveillance of the effects of any recommended intervention.
STANDARD A9 VITAMINS AND MINERALS

PURPOSE

This Standard regulates the addition of vitamins and minerals to foods, and the claims which can be made about the vitamin and mineral content of foods, other than those special purpose foods standardised in Standards R5, R6, R7 and R9.

Nothing in this Standard permits claims which state or imply that vitamins and minerals have or may have a therapeutic or prophylactic effect. In the absence of an express permission, therapeutic or prophylactic claims are prohibited by clause (19) of Standard A1.

Claims cannot state or suggest, in the absence of an express permission, that a food containing added vitamins and minerals can replace primary foods.

TABLE OF PROVISIONS

Clause

1. Interpretation
2. Prohibition on adding vitamins and minerals unless permitted
3. Permitted addition of vitamins and minerals
4. Claims about vitamins and minerals
5. Restrictions on claims about vitamins and minerals
6. Labelling

Schedule

Permitted forms of and recommended dietary intakes (RDI) for vitamins and minerals

Interpretation

1. In this Standard-

‘average quantity’ has the meaning assigned to it in clause (13) of Standard A1;

‘claim’ does not include a reference to a vitamin or mineral in a statement required elsewhere by this Code to be included in the label on or attached to food, unless that reference includes information in addition to that required by this Code;
'claimable food' means a food which consists of at least 90 per cent by weight of primary foods, foods listed in the Table to clause 3, added water, or a mixture of these;

for the purposes of determining whether an artificially sweetened food is a 'claimable food', the composition of the food is to be calculated as if sucrose were substituted for the artificial sweetening substance to an equivalent sweetness;

'permitted form' means a form of a vitamin or mineral specified in column 2 of the Schedule;

'primary food' means fruit, vegetables, grains, legumes, meat, milk, yoghurt, eggs, nuts, seeds and fish;

'RDI', for a vitamin or mineral in column 1 of the Schedule, means the recommended dietary intake for that vitamin or mineral specified in column 3 of the Schedule, calculated and expressed in the form specified in the Schedule;

'reference quantity' means-

(a) in relation to a food specified in the Table to clause 3, either the quantity specified in that Table for that food or, in relation to a food which requires dilution or reconstitution according to directions, the quantity of the food which when diluted or reconstituted produces the quantity specified in that Table;

(b) in relation to all other foods, either a normal serving or, in relation to a food which requires dilution, reconstitution or preparation according to directions, the quantity of the food which when diluted, reconstituted or prepared produces a normal serving;

**Prohibition on adding vitamins and minerals unless permitted**

2. A vitamin or mineral must not be added to a food unless-

(a) the addition is specifically permitted either by this Standard or elsewhere in this Code; and

(b) except where the contrary intention appears, the vitamin or mineral is in a permitted form.

**Permitted addition of vitamins and minerals**

3. (1) A vitamin or mineral specified in column 3 of the Table to this clause may be added to the food specified in column 1 in relation thereto.

(2) If a proportion is specified in column 5 in the Table to this clause, the vitamin or mineral specified in
column 3 in relation to that proportion must not be added to the food specified in column 1 so that the total level of that vitamin or mineral in the food exceeds the proportion specified.

**TABLE TO CLAUSE 3**

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
<th>Column 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Food</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reference quantity</td>
<td>Vitamins and minerals that may be added</td>
<td>Maximum claim per reference quantity (proportion RDI)*</td>
<td>Maximum permitted level of vitamin or mineral per reference quantity</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>thiamin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>niacin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin E</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iron</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>magnesium</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>zinc</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin A</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>thiamin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>niacin</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B6</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B12</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin C</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin D</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin E</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>calcium</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iodine</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iron</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>magnesium</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>phosphorus</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>zinc</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Biscuits containing not more than 200 g/kg fat and not more than 50 g/kg sugar</td>
<td>35g</td>
<td></td>
<td>0.55 mg (50%)</td>
<td></td>
</tr>
<tr>
<td>Biscuits formulated to contain not less than 200 g/kg protein (gN/kg x 6.25) nor less than 200 g/kg fat [biscuits specially formulated for food aid programs]</td>
<td>40g</td>
<td></td>
<td>750 μg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.10 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.7 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>19 mg (1.9 times)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1.6 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>2.0 μg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>40 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 μg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>10 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 μg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>800 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>150 μg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>320 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>1000 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>12 mg (100%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1500 μg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>10 μg</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>150 μg</td>
</tr>
<tr>
<td>Food</td>
<td>Reference quantity</td>
<td>Vitamins and minerals that may be added</td>
<td>Maximum claim per reference quantity (proportion RDI)*</td>
<td>Maximum permitted level of vitamin or mineral per reference quantity</td>
</tr>
<tr>
<td>------</td>
<td>-------------------</td>
<td>----------------------------------------</td>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>Bread, brown bread, wholemeal bread, rye bread</td>
<td>50 g</td>
<td>thiamin</td>
<td>0.55 mg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin</td>
<td>0.4 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>niacin</td>
<td>2.5 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B6</td>
<td>0.4 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin E</td>
<td>2.5 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td>100 µg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iron</td>
<td>3.0 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>magnesium</td>
<td>80 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>zinc</td>
<td>1.8 mg (15%)</td>
<td></td>
</tr>
<tr>
<td>Breakfast cereals, as purchased</td>
<td>a normal serving</td>
<td>carotene forms of vitamin A</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>200 µg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>thiamin</td>
<td>0.55 mg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin</td>
<td>0.4 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>niacin</td>
<td>2.5 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B6</td>
<td>0.4 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin C</td>
<td>10 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin E</td>
<td>2.5 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td>100 µg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>calcium</td>
<td>200 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iron</td>
<td>3.0 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>magnesium</td>
<td>80 mg (25%)</td>
<td></td>
</tr>
<tr>
<td>Flour, wholemeal, rye flour, rye meal, oatmeal, maize meal, rice flour, mixtures thereof</td>
<td>35 g</td>
<td>thiamin</td>
<td>0.55 mg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin</td>
<td>0.4 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>niacin</td>
<td>2.5 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B6</td>
<td>0.4 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin E</td>
<td>2.5 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td>100 µg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iron</td>
<td>3.0 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>magnesium</td>
<td>80 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>zinc</td>
<td>1.8 mg (15%)</td>
<td></td>
</tr>
<tr>
<td>Pasta</td>
<td>that amount which is equivalent to 35 g of uncooked dried pasta</td>
<td>thiamin</td>
<td>0.55 mg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin</td>
<td>0.4 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>niacin</td>
<td>2.5 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B6</td>
<td>0.4 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin E</td>
<td>2.5 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td>100 µg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iron</td>
<td>3.0 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>magnesium</td>
<td>80 mg (25%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>zinc</td>
<td>1.8 mg (15%)</td>
<td></td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
<td>Column 4</td>
<td>Column 5</td>
</tr>
<tr>
<td>---------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>Food</td>
<td>Reference quantity</td>
<td>Vitamins and minerals that may be added</td>
<td>Maximum claim per reference quantity (proportion RDI)*</td>
<td>Maximum permitted level of vitamin or mineral per reference quantity</td>
</tr>
<tr>
<td>DAIRY PRODUCTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dried milk, dried skim milk</td>
<td>200 mL</td>
<td>vitamin A 110 µg (15%)</td>
<td>125 µg</td>
<td></td>
</tr>
<tr>
<td>Modified milk (including low fat modified milk), skim milk</td>
<td>200 mL</td>
<td>riboflavin 0.4 mg (25%)</td>
<td>no claim permitted</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin D</td>
<td>125 µg</td>
<td></td>
</tr>
<tr>
<td>Foods standardised in Standard 119 - Cheese and Cheese Products</td>
<td>25 g</td>
<td>vitamin A 110 µg (15%)</td>
<td>125 µg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>calcium 200 mg (25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>phosphorus 150 mg (15%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EDIBLE FATS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Butter, table spreads, margarine</td>
<td>10 g</td>
<td>vitamin A 110 µg (15%)</td>
<td>125 µg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin D 1.0 µg (10%)</td>
<td>1.6 µg</td>
<td></td>
</tr>
<tr>
<td>EXTRACTS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Extracts of meat, vegetables or yeast (including modified yeast)</td>
<td>5 g</td>
<td>thiamin 0.55 mg (30%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin 0.43 mg (25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>niacin 2.5 mg (25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B₆ 0.4 mg (25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B₁₂ 0.5 µg (25%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate 100 µg (50%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iron 1.8 mg (15%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
<td>Column 4</td>
<td>Column 5</td>
</tr>
<tr>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
<td>----------</td>
</tr>
<tr>
<td>Food</td>
<td>Reference quantity</td>
<td>Vitamins and minerals that may be added</td>
<td>Maximum claim per reference quantity (proportion RDI)*</td>
<td>Maximum permitted level of vitamin or mineral per reference quantity</td>
</tr>
<tr>
<td>FORMULA DIETARY FOODS</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Formula dietary foods</td>
<td>Amount recommended to replace one meal</td>
<td>vitamin A</td>
<td>375 μg (50%)</td>
<td>375 μg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>thiamin</td>
<td>0.55 mg (50%)</td>
<td>0.85 mg (50%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin</td>
<td>9.5 mg (95%)</td>
<td>9.5 mg (95%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>niacin</td>
<td>0.8 mg (50%)</td>
<td>1.0 mg (50%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B6</td>
<td>20 mg (50%)</td>
<td>20 mg (50%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B12</td>
<td>2.5 μg (25%)</td>
<td>2.5 μg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin C</td>
<td>5.0 mg (50%)</td>
<td>75 μg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td>100 μg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>calcium</td>
<td>400 mg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iodine</td>
<td>75 μg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>iron</td>
<td>6.0 mg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>magnesium</td>
<td>160 mg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>phosphorus</td>
<td>500 mg (50%)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>zinc</td>
<td>6.0 mg (50%)</td>
<td></td>
</tr>
<tr>
<td>FRUIT JUICE, VEGETABLE JUICE, FRUIT DRINK AND FRUIT CORDIAL</td>
<td></td>
<td>vitamin C</td>
<td>refer to subclause 5(4)</td>
<td></td>
</tr>
<tr>
<td>Fruit drinks containing at least 250 mL/L of the juice, puree or comminution of the fruit; fruit drink concentrate which contains in a reference quantity at least 250 mL/L of the juice, puree or comminution of the fruit</td>
<td></td>
<td>carotene forms of vitamin A</td>
<td>refer to subclause 5(4)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td>refer to subclause 5(4)</td>
<td></td>
</tr>
<tr>
<td>Food</td>
<td>Column 2 Reference quantity</td>
<td>Column 3 Vitamins and minerals that may be added</td>
<td>Column 4 Maximum claim per reference quantity (proportion RDI)*</td>
<td>Column 5 Maximum permitted level of vitamin or mineral per reference quantity</td>
</tr>
<tr>
<td>----------------------------------------------------------------------</td>
<td>-----------------------------</td>
<td>-----------------------------------------------</td>
<td>---------------------------------------------------------------</td>
<td>--------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Fruit juice, reconstituted fruit juice, concentrated fruit juice:</td>
<td>200 mL</td>
<td>folate</td>
<td>100 µg (50%)</td>
<td></td>
</tr>
<tr>
<td>Blackcurrant</td>
<td></td>
<td>vitamin C</td>
<td>500 mg (12.5 times)</td>
<td></td>
</tr>
<tr>
<td>Guava</td>
<td></td>
<td>carotene forms of vitamin A</td>
<td>400 mg (10 times)</td>
<td></td>
</tr>
<tr>
<td>Other fruit juice</td>
<td></td>
<td></td>
<td>120 mg (3 times)</td>
<td></td>
</tr>
<tr>
<td>Mango</td>
<td></td>
<td></td>
<td>800 µg (1.1 times)</td>
<td></td>
</tr>
<tr>
<td>Pawpaw</td>
<td></td>
<td>vitamin C</td>
<td>300 µg (40%)</td>
<td></td>
</tr>
<tr>
<td>Other fruit juice</td>
<td></td>
<td>carotene forms of vitamin A</td>
<td>200 µg (25%)</td>
<td></td>
</tr>
<tr>
<td>Tomato juice, concentrated tomato juice</td>
<td>200 mL</td>
<td>folate</td>
<td>60 mg (1.5 times)</td>
<td></td>
</tr>
<tr>
<td>Vegetable juice</td>
<td>200 mL</td>
<td>vitamin C</td>
<td>200 µg (25%)</td>
<td></td>
</tr>
<tr>
<td>Fruit cordial, fruit cordial base</td>
<td>200 mL</td>
<td>carotene forms of vitamin A</td>
<td>100 µg (50%)</td>
<td>refer to subclause 5(4)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td>60 mg (1.5 times)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin C</td>
<td>200 µg (25%)</td>
<td></td>
</tr>
<tr>
<td>Column 1</td>
<td>Column 2</td>
<td>Column 3</td>
<td>Column 4</td>
<td>Column 5</td>
</tr>
<tr>
<td>-----------------------</td>
<td>----------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td><strong>Food</strong></td>
<td>Reference</td>
<td>Vitamins and minerals that may be added</td>
<td>Maximum claim per reference quantity (proportion RDI)*</td>
<td>Maximum permitted level of vitamin or mineral per reference quantity</td>
</tr>
<tr>
<td><strong>BEVERAGES DERIVED FROM LEGUMES</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Beverages containing not less than 30 g/kg protein derived from legumes</td>
<td>200 mL</td>
<td>vitamin A thiamin</td>
<td>110 µg (15%)</td>
<td>no claim permitted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>riboflavin vitamin B6</td>
<td>0.4 mg (25%)</td>
<td>no claim permitted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B12 vitamin D</td>
<td>0.8 µg (40%)</td>
<td>no claim permitted</td>
</tr>
<tr>
<td></td>
<td></td>
<td>folate</td>
<td>calcium magnesium</td>
<td>240 mg (30%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>phosphorus zinc</td>
<td>iodine</td>
<td>200 mg (20%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>thiamin</td>
<td>riboflavin niacin vitamin B6</td>
<td>0.16 mg (15%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>vitamin B12 folate</td>
<td>iron magnesium</td>
<td>20 µg (10%)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>zinc</td>
<td>15 µg</td>
</tr>
</tbody>
</table>

*Maximum claim only applies where the vitamin and mineral has been added (refer clause 5(2)).

**Claims about vitamins and minerals**

4. (1) Subject to clauses 5 and 6, a claim may be made in relation to the presence of a vitamin or mineral in a food if-

(a) the claim is specifically permitted elsewhere in the Code; or
(b) (i) the vitamin or mineral is listed in column 1 of the Schedule; and

(ii) the food is a claimable food; and

(iii) the food contains in a reference quantity at least 10 per cent of the RDI for that vitamin or mineral derived from those ingredients in the food which are primary foods or foods listed in the Table to clause 3.

(2) A claim that a food is a good source of a vitamin or mineral can only be made if a reference quantity of the food contains at least 25 per cent of the RDI for that vitamin or mineral derived from those ingredients in the food which are primary foods or foods listed in the Table to clause 3.

Restrictions on claims about vitamins and minerals

5. (1) The label on or attached to a package containing a food must not claim-

(a) that a vitamin or mineral is present in the food unless the claim is permitted by clause 4;

(b) that the food is enriched or fortified with a vitamin or mineral;

(c) any comparison, whether expressed or implied, between the vitamin or mineral content of the food with that of any other food except where expressly permitted in the Code; or

(d) that a vitamin or mineral is present in the food if such a claim is prohibited elsewhere in the Code.

(2) The label on or attached to a package containing a food listed in Column 1 of the Table to clause 3 to which a vitamin or mineral has been added must not include a claim that the food contains in a reference quantity that vitamin or mineral in greater proportion than that specified in column 4 of the Table to clause 3.

(3) In relation to a claimable food, the maximum amount of a vitamin or mineral which may be claimed in a reference quantity is calculated by adding together an amount calculated for each ingredient by multiplying-

(a) (i) in relation to an ingredient to which the vitamin or mineral has not been added, the
amount of the vitamin or mineral in a reference quantity of the ingredient which is a primary food or a food listed in the Table to clause 3; or

(ii) in relation to an ingredient to which the vitamin or mineral has been added, the amount of the vitamin or mineral in a reference quantity of the ingredient or the maximum claim for the vitamin or mineral in a reference quantity of the ingredient, whichever is the lesser;

(b) the proportion of the ingredient in the food; and

(c) the ratio of the reference quantity of the claimable food to the reference quantity of the ingredient.

(4) For the purposes of subclause (2), the maximum claim for vitamin A, vitamin C or folate in respect of fruit drinks, and vitamin C in respect of fruit cordial and fruit cordial bases is calculated by:

(a) for each juice present in the food, multiplying the maximum claim for the vitamin per reference quantity permitted in respect of that juice (specified in column 4 of the Table to clause 3) by the proportion of that juice in the food (in the case of cordial bases, after dilution as directed in the label);

(b) summing all the values thus obtained; and

(c) rounding the result, in the case of vitamin C, to the nearest multiple of 5 mg, or in the case of vitamin A and folate, to the nearest multiple of 10 μg.

EXAMPLE CALCULATION

Vitamin C claim for an apple and blackcurrant fruit drink (42 per cent juice, apple 40 per cent, blackcurrant 2 per cent) in a reference quantity of 200 mL:

(a) Apple juice: 120 mg (max claim) × 40/100
(proportion of juice in final product) = 48 mg
Blackcurrant juice: 500 mg (max claim) × 2/100
(proportion of juice in final product) = 10 mg

(b) 48 mg + 10 mg = 58 mg
(c) Maximum claim for the food is 60 mg (result rounded to nearest multiple of 5 mg)

(5) A claim about vitamin C in a food must not include any vitamin C which has been added to the food, or to an ingredient of the food, as an antioxidant.

Labelling

6. (1) Where a claim is made in relation to the presence of a vitamin or mineral in a food, the label on or attached to a package containing the food must include a statement containing the following information:

(a) the serving size of the food;

(b) the number of servings per package of the food;

(c) the vitamin or mineral in respect of which the claim is made;

(d) the average quantity of that vitamin or mineral in 100 g or 100 mL of the food as the case may be; and

(e) the proportion of the RDI of that vitamin or mineral contributed by one serving of the food.

EXAMPLES

(a) 'Servings per package: 20
Serving size 50 g

<table>
<thead>
<tr>
<th>Vitamin</th>
<th>Proportion of RDI* per serving</th>
<th>Per 100 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>thiamin</td>
<td>15%</td>
<td>0.33 mg</td>
</tr>
<tr>
<td>niacin</td>
<td>20%</td>
<td>4.0 mg</td>
</tr>
</tbody>
</table>

* Recommended dietary intake'

OR

(b) 'One 50 mL serving of Ozfood contains 25 per cent of the recommended dietary intake of vitamin C. 100 mL of Ozfood contains not less than 20 mg of vitamin C. 20 servings per pack'.

(2) The statement required by subclause (1) may be an entry in a nutrition information panel for the vitamin or mineral, provided both the average quantity of the vitamin or
mineral in, and the proportion of the RDI contributed by, a serving of the food are specified.

**EXAMPLE**

<table>
<thead>
<tr>
<th></th>
<th>Per serving (50 mL)</th>
<th>Per 100 mL</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Energy</strong></td>
<td>86 kJ</td>
<td>172 kJ</td>
</tr>
<tr>
<td><strong>Protein</strong></td>
<td>LESS THAN 1 g</td>
<td>LESS THAN 1 g</td>
</tr>
<tr>
<td><strong>Fat</strong></td>
<td>LESS THAN 1 g</td>
<td>LESS THAN 1 g</td>
</tr>
<tr>
<td><strong>Carbohydrate - total</strong></td>
<td>5 g</td>
<td>10 g</td>
</tr>
<tr>
<td><strong>- sugars</strong></td>
<td>5 g</td>
<td>10 g</td>
</tr>
<tr>
<td><strong>Vitamin C</strong></td>
<td>10 mg (25% RDI*)</td>
<td>20 mg</td>
</tr>
<tr>
<td><strong>Sodium</strong></td>
<td>LESS THAN 5 mg</td>
<td>LESS THAN 5 mg</td>
</tr>
<tr>
<td><strong>Potassium</strong></td>
<td>LESS THAN 5 mg</td>
<td>LESS THAN 5 mg</td>
</tr>
</tbody>
</table>

* Recommended dietary intake.*
Appendix 10

Lawrence, M., I. Rutishauser and J. Lewis (2001). "Knowledge about folate and the contribution of nutrient supplements to the intake of folic acid and vitamin B_{12} in Australian adults in 1995-96."

Knowledge about folate and the contribution of nutrient supplements to the intake of folic acid and vitamin B12 in Australian adults in 1995 and 1996

Mark A. Lawrence, Ingrid H.E. Rutishauser and Janine L. Lewis

Abstract The present paper reports knowledge about folate and the contribution of supplements to the intake of folic acid and vitamin B12 in Australian adults during 1995 and 1996. Data were obtained from two population survey monitors surveys conducted in a sample of 4422 adults in 1995-96. The surveys were designed to complement food intake data from the 1995 National Nutrition Survey and to provide an estimate of total folic acid intake prior to the implementation of voluntary fortification of foods with folic acid. The proportion with knowledge about folate increased with education level and socioeconomic status and was greater in women than men. It was also greater in those who were married, and in those residing in Western Australia and the Australian Capital Territory than in other states and territories. Five per cent of men and 10% of women had taken a supplement containing folic acid on the previous day. The equivalent figures for vitamin B12 were 7.5% for men and 12.5% for women. On average, intake of folic acid from supplements was 11 µg per day for men and 28 µg per day for women and intake of vitamin B12 was 2.6 µg per day for men and 4.5 µg per day for women. For individuals who consumed a supplement containing folic acid on the day before the survey the median folic acid contribution was 200 µg. In 1995 and 1996 only one in two adults Australians had heard of folate and only one in ten women of child-bearing age had taken a supplement containing folic acid. (Aust J Nutr Diet 2001;58:12–18)

Key words: folate fortification, nutrient supplements, food regulation, knowledge, behaviour

Introduction

The main purpose of the nutrient supplement survey was to document the contribution of nutrient supplements to dietary intake as part of a program to monitor the effect of changes to food Standard A9. Under the amended food Standard A9, gazetted in June 1995, a limited number of foods are permitted to be fortified with folic acid on a voluntary basis up to a claimable level of 50% of the recommended dietary intake (RDI) per reference quantity. The reference quantity for these foods generally means a ‘normal’ serving as specified in the Table to clause 3 of amended food Standard A9. Food Standard A9 was amended in response to National Health and Medical Research Council (NHMRC) recommendations intended to reduce the risk of neural tube defects (NTD) in the Australian population (1).

Previous nutrient-related interventions in Australia have not always been monitored adequately (1,2). For this reason the nutrient supplement survey was designed specifically to collect baseline data on folic acid prior to the introduction of voluntary fortification. Data were obtained for all adults, and not only the target group of women of child-bearing age, i.e. 18 to 44 years, since the NHMRC expert panel had noted that excess folic acid has the potential to mask the clinical symptoms of pernicious anaemia in the elderly and to lead to irreversible neurologic damage (3,4).

A further reason for assessing folic acid intake from supplements separately from folate found in food, is the difference in bio-availability (5). In nature folate occurs with different numbers of conjugated glutamate residues but the typical synthetic form of the nutrient used in vitamin supplements and for fortification of foods is the mono-glutamic acid form, folic acid, which has approximately twice the bio-availability. The US National Academy of Sciences has recently introduced (6) the concept of dietary folate equivalents (DFE). DFE are calculated by combining the amount of synthetic folic acid derived from nutrient supplements and fortified foods, multiplied by a conversion factor of 1.7 to adjust for the greater bio-availability of synthetic folic acid, with the amount of folate derived from food sources.

The report of the NIMRAC’s Expert Panel on Folate Fortification noted that during the folate fortification policy-making process no attempt was made to estimate the effects of supplements on folate intakes due to difficulty in estimating folate supplement usage in Australia (1). The population survey monitor household survey provided a practical way to address this need and to analyse certain assumptions made by the NIMRAC panel regarding the knowledge and supplement use of the target population of women at the time of the policy-making process. The present paper reports data for knowledge about folate, and intake of folic acid and vitamin B12 from nutrient supplements, for a range of population subgroups.

Methods

Survey procedures

The sampling and interview procedures used in the Australian Bureau of Statistics’ (ABS) population survey...
monitor (PSM) will be described in a forthcoming paper (17). Data on nutrient supplement intake were obtained from a randomly selected sample of Australian adults from 5422 households in two PSM surveys conducted during August 1995 and February 1996 (8,9). Both surveys took place during the data collection period for the 1995 National Nutrition Survey (10). In each survey the questions about nutrient supplement intake and knowledge regarding folate were asked of a randomly selected member of the household aged 18 years or over.

The number of households surveyed in each PSM survey is considered to be adequate to provide quarterly data for Australia, and annual data for the states and territories (from data obtained over four quarters), at an acceptable level of accuracy and reliability (8). Weighting factors provided by the ABS were used to adjust the sample data to provide population estimates that minimise the effects of non-response bias on the age, sex and area distribution of the sample relative to that of the total population.

Supplement use and knowledge questions

For the purpose of the present survey, nutrient supplements were defined as supplements that contain one or more vitamins or minerals. Interviewees were asked: ‘Yesterday, did you take any vitamin or mineral supplements in tablet, capsule or drop form?’ The same question had been included in the 1995 National Nutrition Survey. Data on knowledge about folate acid were obtained from the responses to two questions. Interviewees were asked: ‘Have you ever heard of folate acid or folate?’ If they answered ‘yes’, they were then asked to select one of the following responses in answer to the question: ‘Do you know why it is important for women of child-bearing age to consume foods or supplements containing folate acid or folate?’, ‘To help them get pregnant’, ‘To help prevent birth defects’, ‘Other reason’, or ‘No or don’t know’.

Determination of nutrient intake from vitamin and mineral supplements requires a detailed knowledge of the ingredient and nutrient composition of specific supplements. In Australia, vitamin and mineral supplements are classified as therapeutic goods and regulated by the Therapeutic Goods Administration (TGA). Most of these products, with a small number of exemptions, must be included in the Australian Register of Therapeutic Goods (ARTG) (11). Products included in the ARTG have an ‘AUST L’ (listed), or an ‘AUST R’ (registered) number that depends, inter alia, on the ingredients as listed on the package. These numbers provide a unique identifier for more than 25,000 dietary supplement products in the ARTG and can be used to determine their ingredient profile (12).

If the person interviewed reported having taken one or more vitamin or mineral supplements during the previous day they were asked, if possible, to provide the supplement container(s) so that the interviewer could record the AUST L or AUST R number of the product(s) on the survey form. Before the introduction of the ARTG in 1993, products purchased overseas and unregistered products did not have an AUST L or AUST R number. For products without an AUST L or AUST R number on the container, the brand name and other relevant product information were recorded. If the container was not available the interviewee was asked to describe the brand and name of the product. Subjects were then asked how many tablets, capsules, drops or spoons of the supplement they had taken yesterday.

Data processing

Release of data obtained through the PSM is governed by the provisions of the Census and Statistics Act (1905). Under these provisions disaggregated data on the frequency counts of specific AUST L and AUST R numbers were not available to the authors. Consequently, the conversion of individual AUST L and AUST R numbers to tabulations of nutrient quantities was conducted by the ABS with advice from the then National Food Authority (NFA), now the Australia New Zealand Food Authority (ANZFA). Negotiations between NFA and the TGA were undertaken to provide the ABS with information on the effective nutrient content of the ingredients in specific products with AUST L and AUST R numbers.

When an AUST L or AUST R number was not available, or the number recorded for a product did not match the ARTG database, an attempt was made by NFA and PSM staff to locate the relevant product in retail stores and, if successful, the nutrient information printed on the label was entered into the survey nutrient database. On occasions when the interviewee reported that they had consumed a ‘vitamin X’ supplement, it was assumed that this was the only nutrient in the supplement and that the amount of vitamin per unit was the same as for a commonly available product of this type in pharmacies in suburban Adelaide.

Many nutrients in supplements are present in several different forms. For example in the case of zinc, as elemental zinc, zinc citrate, zinc oxide and zinc sulphate. Thus conversion factors were needed to translate many of the ingredient weights into a common unit for each nutrient of interest (12). Conversion factors are not required for either folate acid or vitamin B12 as both nutrients are present in supplements only as folic acid or cyanocobalamin respectively.

Prior to data analysis all nutrient quantities in the database were scrutinised by one of the authors (ML). Extreme values, that on the basis of experience were implausible, e.g. milligrams instead of micrograms and vice versa were treated as ‘unit’ coding errors and recoded appropriately.

Data presentation

All percentages presented in the figures, tables and the text of this paper are derived from population-weighted data. Percentages have been calculated for the Australian population (18 years and over) as a whole and for demographic subgroups for which differences in supplement intake have been reported previously in the literature including sex, age, location, education, socioeconomic status in terms of quintiles of the index of relative socioeconomic disadvantage (13) and for intake of vegetables and fruit.

In general analysis has been limited to population subgroups with at least 500 individuals in the survey sample. The 95% confidence interval for a proportion based on 500 persons ranges from about ±3% for proportions close to 15% to about ±4% for proportions close to 30%. In the tables subgroups for which the prevalence differed signiﬁ-
candy ($P < 0.05$) from that for all adults are identified with an asterisk.

**Results**

Knowledge of the importance of folic acid or folate for women of child-bearing age

Table 1 presents descriptive data from the combined August 1995 and February 1996 surveys for knowledge about folate for population subgroups defined according to socio-demographic characteristics. In 1995 and 1996, almost half of Australian adults (44.6%) had not heard of folic acid or folate and only 10.8% knew that it helped to prevent birth defects.

A much higher proportion of men (55.6%) than women had not heard of folate, and for both men and women the proportion of adults who had not heard about folate was highest in the youngest and oldest age groups. Other population subgroups for which the proportion who had not heard of folic acid exceeded 55% included the unemployed (60.7%), those with a trade certificate (58.1%) and adults born outside Australia (57.3%). The proportion that had heard of folate was highest (approximately 67%) in Western Australia and the Australian Capital Territory. Victoria was the only state in which more than 50% of adults had not heard of folate. No significant differences in knowledge about folate were observed with intake of fruit and vegetables (data not shown).

In subgroups in which a higher proportion of adults were aware of folate, the proportion that knew why folate was important for women of child-bearing age was also higher. The proportion of adults who had not heard about folate and did not know about its relationship with NTDs was significantly higher for those who had never married or were divorced, widowed or separated, than for all adults. The proportion aware of the relationship between folic acid and NTDs exceeded 20% only in women aged 18 to 44 years (23.6%) and in residents of Western Australia. In general, the prevalence of knowledge increased with level of education and approached 20% in those with a tertiary degree or diploma.

Among those who had consumed a supplement containing folic acid on the day before the survey (Table 2) less than 20% had not heard of folate and 20% knew about the relationship with NTD. Both proportions were much higher and significantly different from those for the total population. The gender differences in knowledge, however, were similar to those for all adults. That is, approximately twice as many men as women had not heard of folate and more than twice as many women as men were aware of the relationship with NTDs.

Prevalence of folic acid supplement use

The proportion of women who had taken a supplement containing folic acid (10.0%) was twice that for men (5.0%) and for both men and women this proportion increased with age, except for those aged 65 years and over. The proportion that took a supplement containing folic acid was 10% in those employed part-time and generally increased with increasing quintile of the index of relative socioeconomic disadvantage and with education level. For Queensland and Western Australia the proportion that had taken a supplement containing folic acid was higher, and for Tasmania it was significantly below the average for all states.

Contribution of nutrient supplements to folic acid and vitamin B12 intake

In 1995 and 1996, the average intake of folic acid from supplements for Australian adults was 10.3 μg in men, 28.3 μg in women and 29.7 μg in the target group of women aged 18 to 44 years. In contrast, the median intake from supplements for those who consumed a supplement containing folic acid was 200 μg both in men and women and ranged from 20 μg to 15 000 μg.

Data on the median folic acid and vitamin B12 intake of Australian adults who had consumed a supplement containing folic acid and/or vitamin B12 on the day before the survey are presented in Table 3. Of the 626 individuals who had taken a supplement containing either folic acid or vitamin B12 only 48 had consumed a supplement that contained folic acid without B12. This represented less than 1% of the population and only 1.6% of the target group of women aged 18 to 44 years. By contrast 6.7% of the population and 8.8% of the target group had consumed a supplement that contained both folic acid and vitamin B12. The median intake of folic acid from supplements without vitamin B12 was 300 μg per day compared with 200 μg per day from folic acid supplements that also contained vitamin B12.

In all sex and age subgroups the proportion that had consumed a supplement containing vitamin B12 was higher than the proportion that had consumed a supplement containing folic acid. The proportion of women who had consumed a folic acid and/or vitamin B12 supplement was approximately twice that for men, irrespective of whether the supplement contained folic acid, vitamin B12 or both folic acid and vitamin B12. In those who consumed a supplement containing folic acid and vitamin B12 on the day before the survey the median intake of vitamin B12 was 25 μg compared with only 6 μg in those who had taken a supplement that contained only vitamin B12.

**Discussion**

At the time the survey was conducted there had been no national education campaigns to promote awareness of the relationship between folic acid and NTDs. The only substantial education campaign that had been implemented was a state-wide health promotion project for the prevention of NTDs in Western Australia from mid-1992 until March 1995 (14). It was not surprising, therefore, that the proportion of adults who had heard about folate and its relationship with NTDs was higher in Western Australia than in any other state. However, the prevalence of knowledge and supplement use in the present survey was generally lower than reported by surveys conducted in individual states (15–17).

Relative to all other population subgroups a higher proportion of women aged 18 to 44 years (the primary target group for increased folate intake) was aware of folate (73.1%) and of the relationship between folate and birth defects (19.5%). The proportion in the target group who
Table 1. Knowledge about folate and use of folic acid supplements in Australian adults by socio-demographic variables

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Number in sample</th>
<th>Had not heard of folate or folic acid (%)</th>
<th>Helps to prevent birth defects (%)</th>
<th>Other (%)</th>
<th>Do not know (%)</th>
<th>Took folate (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–24</td>
<td>289</td>
<td>69.1*</td>
<td>2.6*</td>
<td>1.7</td>
<td>26.6</td>
<td>2.7</td>
</tr>
<tr>
<td>25–44</td>
<td>974</td>
<td>47.8</td>
<td>8.5*</td>
<td>7.6</td>
<td>36.1</td>
<td>5.1</td>
</tr>
<tr>
<td>45–64</td>
<td>687</td>
<td>56.0*</td>
<td>4.5*</td>
<td>9.3</td>
<td>30.2</td>
<td>6.3</td>
</tr>
<tr>
<td>≥65</td>
<td>399</td>
<td>63.7*</td>
<td>2.8*</td>
<td>3.3</td>
<td>30.2</td>
<td>4.3</td>
</tr>
<tr>
<td>≥18</td>
<td>2349</td>
<td>55.6*</td>
<td>5.7*</td>
<td>6.6</td>
<td>32.2</td>
<td>5.0</td>
</tr>
<tr>
<td><strong>Female</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–24</td>
<td>290</td>
<td>38.8*</td>
<td>7.4*</td>
<td>8.6</td>
<td>45.3</td>
<td>7.6</td>
</tr>
<tr>
<td>25–44</td>
<td>1394</td>
<td>22.9*</td>
<td>23.6*</td>
<td>19.9</td>
<td>33.6</td>
<td>11.4</td>
</tr>
<tr>
<td>45–64</td>
<td>828</td>
<td>32.9*</td>
<td>14.0*</td>
<td>15.3</td>
<td>37.9</td>
<td>11.5</td>
</tr>
<tr>
<td>≥65</td>
<td>561</td>
<td>29.4*</td>
<td>15.7*</td>
<td>14.8</td>
<td>35.5</td>
<td>10.0</td>
</tr>
<tr>
<td>≥18</td>
<td>3073</td>
<td>33.8*</td>
<td>15.7*</td>
<td>14.8</td>
<td>35.5</td>
<td>10.0</td>
</tr>
<tr>
<td><strong>SEIFA quintile</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1166</td>
<td>52.2*</td>
<td>6.4*</td>
<td>10.9</td>
<td>30.5</td>
<td>6.1</td>
</tr>
<tr>
<td>2&gt;932–989</td>
<td>969</td>
<td>48.5*</td>
<td>10.2*</td>
<td>8.4</td>
<td>32.9</td>
<td>6.8</td>
</tr>
<tr>
<td>3&gt;989–1035</td>
<td>1062</td>
<td>43.4</td>
<td>10.6*</td>
<td>11.2</td>
<td>34.8</td>
<td>8.0</td>
</tr>
<tr>
<td>4&gt;1035–1080</td>
<td>985</td>
<td>42.1</td>
<td>13.5*</td>
<td>12.7</td>
<td>31.6</td>
<td>7.9</td>
</tr>
<tr>
<td>5&gt;1080</td>
<td>1240</td>
<td>36.9*</td>
<td>13.2*</td>
<td>10.5</td>
<td>39.4</td>
<td>8.7</td>
</tr>
<tr>
<td><strong>Highest education level</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>School only</td>
<td>2827</td>
<td>53.1*</td>
<td>7.9*</td>
<td>8.4</td>
<td>30.7</td>
<td>6.0</td>
</tr>
<tr>
<td>Trade certificate</td>
<td>564</td>
<td>58.1*</td>
<td>5.0*</td>
<td>4.7</td>
<td>32.1</td>
<td>4.3</td>
</tr>
<tr>
<td>Other certificate</td>
<td>902</td>
<td>33.1*</td>
<td>13.2*</td>
<td>13.7</td>
<td>40.0</td>
<td>10.4</td>
</tr>
<tr>
<td>Degree or diploma</td>
<td>1094</td>
<td>24.3*</td>
<td>19.2*</td>
<td>18.4</td>
<td>38.0</td>
<td>11.1</td>
</tr>
<tr>
<td><strong>Labour force status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Not in labour force</td>
<td>1991</td>
<td>50.3*</td>
<td>9.2*</td>
<td>9.5</td>
<td>30.8</td>
<td>6.4</td>
</tr>
<tr>
<td>Employed full-time</td>
<td>2253</td>
<td>44.9</td>
<td>10.0*</td>
<td>9.3</td>
<td>34.8</td>
<td>7.9</td>
</tr>
<tr>
<td>Employed part-time</td>
<td>900</td>
<td>25.8*</td>
<td>17.4*</td>
<td>14.2</td>
<td>41.9</td>
<td>10.0</td>
</tr>
<tr>
<td>Unemployed</td>
<td>278</td>
<td>60.7*</td>
<td>6.8*</td>
<td>9.9</td>
<td>22.3</td>
<td>4.0</td>
</tr>
<tr>
<td><strong>Birthplace</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Australia</td>
<td>4023</td>
<td>39.8*</td>
<td>11.5*</td>
<td>11.6</td>
<td>37.0</td>
<td>8.0</td>
</tr>
<tr>
<td>Outside Australia</td>
<td>1399</td>
<td>57.3*</td>
<td>8.7*</td>
<td>8.5</td>
<td>25.4</td>
<td>6.2</td>
</tr>
<tr>
<td><strong>Marital status</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Married</td>
<td>3253</td>
<td>41.5*</td>
<td>12.9*</td>
<td>12.5</td>
<td>33.0</td>
<td>7.5</td>
</tr>
<tr>
<td>Widowed or divorced</td>
<td>1100</td>
<td>49.4*</td>
<td>7.9*</td>
<td>10.6</td>
<td>32.1</td>
<td>8.5</td>
</tr>
<tr>
<td>Never married</td>
<td>1069</td>
<td>51.0*</td>
<td>5.8*</td>
<td>5.7</td>
<td>37.5</td>
<td>7.2</td>
</tr>
<tr>
<td><strong>State of residence</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>New South Wales</td>
<td>971</td>
<td>45.2</td>
<td>10.8*</td>
<td>10.2</td>
<td>33.8</td>
<td>7.8</td>
</tr>
<tr>
<td>Victoria</td>
<td>964</td>
<td>53.5*</td>
<td>6.7*</td>
<td>9.1</td>
<td>30.8</td>
<td>6.3</td>
</tr>
<tr>
<td>Queensland</td>
<td>721</td>
<td>39.1*</td>
<td>9.2*</td>
<td>13.9</td>
<td>37.8</td>
<td>9.2</td>
</tr>
<tr>
<td>South Australia</td>
<td>681</td>
<td>39.3*</td>
<td>14.4*</td>
<td>8.9</td>
<td>37.3</td>
<td>7.4</td>
</tr>
<tr>
<td>Western Australia</td>
<td>666</td>
<td>33.3*</td>
<td>20.2*</td>
<td>13.4</td>
<td>33.2</td>
<td>8.7</td>
</tr>
<tr>
<td>Tasmania</td>
<td>502</td>
<td>47.2</td>
<td>8.7*</td>
<td>10.6</td>
<td>33.4</td>
<td>4.3*</td>
</tr>
<tr>
<td>Northern Territory</td>
<td>375</td>
<td>38.0*</td>
<td>15.9*</td>
<td>13.7</td>
<td>32.3</td>
<td>7.9</td>
</tr>
<tr>
<td>Australian Capital Territory</td>
<td>542</td>
<td>32.7*</td>
<td>19.3*</td>
<td>13.6</td>
<td>34.4</td>
<td>5.9</td>
</tr>
<tr>
<td><strong>All adults</strong></td>
<td>5422</td>
<td>44.6</td>
<td>10.8*</td>
<td>10.8</td>
<td>32.9</td>
<td>7.5</td>
</tr>
</tbody>
</table>

* Prevalence different from that for all adults $P < 0.05$.

(a) Weighting factors provided by the Australian Bureau of Statistics are used to adjust the sample data to provide population estimates which minimise the effects of non-response bias on the age-sex-area distribution of the sample relative to that of the total population.

(b) The socioeconomic index for areas (SEIFA) is a measure of socioeconomic status in terms of quintiles of the index of relative socioeconomic disadvantage. The SEIFA index is designed to have an average value of 1000 across all collection districts in Australia and a standard deviation of 100 index points.
was aware of folic acid was comparable with that reported from a survey conducted in Dublin (63.6%) at about the same time (18). However, the proportion in the target group who was aware of the relationship between folic acid and birth defects was substantially smaller than that reported for women aged 25 to 44 years in a survey conducted in New Zealand (56%), two years later (19).

Similarly, the positive associations observed in the present study between knowledge and age (17), socioeconomic status (17,18) and education level (15,18) are consistent with the findings of other studies. They also are consistent with the inverse social class gradient for NTDs (20,21) and a slightly higher reported incidence among younger women (22).

The average intake of folic acid from supplements in the present study was comparable to that of an earlier Australian study in which folic acid supplements on average contributed 2 µg and 22 µg per day to the dietary intake of men and women, respectively (23). Relative to the recommended daily intake of 200 µg for adults and the additional 400 µg recommended by the NHMRC for women of child-bearing age the average intake of folic acid from supplements was small. This is in marked contrast to the average intake of vitamin B12 from supplements (2.6 µg for men and 4.5 µg for women) that exceeded the RDI of 2 µg per day for both men and women. Moreover, nutrient supplements that contained folic acid generally contributed at least the RDI for vitamin B12 in all age and sex subgroups, including the elderly who are particularly vulnerable to the masking of vitamin B12 deficiency by folic supplements.

The average intake of folic acid from supplements was also small when compared with intake from food. Average intake from food was estimated to be 307 µg for men and 233 µg for women in 1995 (19). On average nutrient supplements contributed approximately 3% and 11% of the total folic intake for men and women respectively and only 11% to the total folic intake for women of child-bearing age. Thus the average total intake of folic acid from food and supplements was well below the 1 mg level set by the NHMRC as the upper limit of safety for the intake of individuals (1). Seven participants (0.1%) had taken in excess of 1 mg of folic acid on the previous day but only one of these participants was aged 65 years or over. The findings in the current study of a higher prevalence of folic acid supplement use in women than men, with age, education level and with quintiles of the index of relative social disadvantage, are consistent with the findings of other surveys (22,23) and with findings from this survey for the prevalence of use of all nutrient supplements in a forthcoming paper (7).

Table 2. Knowledge about folic acid in those who had taken a supplement containing folic acid on the day before the survey

<table>
<thead>
<tr>
<th>Subgroup</th>
<th>Number in sample</th>
<th>Percentage of sample</th>
<th>Had not heard of folic acid or folate</th>
<th>Helps to prevent birth defects</th>
<th>Other</th>
<th>Do not know</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–44</td>
<td>49</td>
<td>4.5</td>
<td>23.8</td>
<td>13.8</td>
<td>12.3</td>
<td>50.1</td>
</tr>
<tr>
<td>≥ 45</td>
<td>72</td>
<td>5.7</td>
<td>32.8</td>
<td>8.2*</td>
<td>13.2</td>
<td>45.7</td>
</tr>
<tr>
<td>≥ 18</td>
<td>121</td>
<td>5.0</td>
<td>28.4</td>
<td>10.9*</td>
<td>13.1</td>
<td>47.5</td>
</tr>
<tr>
<td>Female</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>18–44</td>
<td>177</td>
<td>10.4</td>
<td>11.1</td>
<td>31.6*</td>
<td>22.8</td>
<td>34.6</td>
</tr>
<tr>
<td>≥ 45</td>
<td>130</td>
<td>9.5</td>
<td>16.8</td>
<td>18.1</td>
<td>18.4</td>
<td>46.7</td>
</tr>
<tr>
<td>≥ 18</td>
<td>307</td>
<td>10.0</td>
<td>13.2</td>
<td>25.1</td>
<td>20.2</td>
<td>41.4</td>
</tr>
<tr>
<td>All who had taken a folic acid supplement</td>
<td>428</td>
<td>7.5</td>
<td>18.2</td>
<td>20.5</td>
<td>17.9</td>
<td>43.4</td>
</tr>
</tbody>
</table>

* Prevalence different from that for all adults P < 0.05.
(a) Weighting factors provided by the Australian Bureau of Statistics are used to adjust the sample data to provide population estimates which minimise the effects of non-response bias on the age-sex area distribution of the sample relative to that of the total population.

Table 3. Median intake (range) of folic acid and vitamin B12 from supplements for individuals who had taken a supplement containing folic acid and/or vitamin B12 on the day before the survey

<table>
<thead>
<tr>
<th>Group</th>
<th>Age (years)</th>
<th>Number of group</th>
<th>Percent of group</th>
<th>Folic acid (µg)</th>
<th>Vitamin B12 without folic acid</th>
<th>Folic acid and vitamin B12</th>
<th>Vitamin B12 without folic acid</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male</td>
<td>18–44</td>
<td>6</td>
<td>0.5</td>
<td>225</td>
<td>43</td>
<td>4.0</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>18–44</td>
<td>2</td>
<td>0.2</td>
<td>325</td>
<td>70</td>
<td>5.5</td>
<td>200</td>
</tr>
<tr>
<td>Female</td>
<td>18–44</td>
<td>8</td>
<td>0.4</td>
<td>250</td>
<td>113</td>
<td>4.6</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>18–44</td>
<td>27</td>
<td>1.6</td>
<td>300</td>
<td>150</td>
<td>8.8</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>18–44</td>
<td>13</td>
<td>0.8</td>
<td>300</td>
<td>117</td>
<td>8.7</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>18–44</td>
<td>40</td>
<td>1.2</td>
<td>300</td>
<td>267</td>
<td>8.8</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>18–44</td>
<td>48</td>
<td>0.8</td>
<td>300</td>
<td>380</td>
<td>6.7</td>
<td>200</td>
</tr>
<tr>
<td></td>
<td>≥ 18</td>
<td>[60–15000]</td>
<td>[20–1200]</td>
<td>[1–730]</td>
<td>[1–730]</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
The low contribution of supplements containing folic acid to average total intake of folate was due primarily to the low level of supplement use. In the present survey only 10.4% of women aged 18 to 44 years consumed a supplement containing folic acid on the day before the survey. This proportion is substantially lower than that recorded by a national survey in the U.S. which found that 32.2% of the target group consumed supplements containing folic acid (24). The proportion taking a supplement containing only folic acid was much lower and comparable with approximately 2% in the 1995 National Nutrition Survey (10) and 2.7% from a survey conducted in Ireland during the same period (18).

The finding that the overall prevalence of folic acid supplement use was several times greater than that recorded in the 1995 National Nutrition Survey highlights the importance of viewing the actual supplement container in surveys that are designed to collect information about intake of nutrients from supplements. Since the 1995 National Nutrition Survey only asked participants about the intake of a limited range of specific nutrient supplements, respondents who had consumed folic acid as part of a multi-vitamin preparation would not have reported taking a folic acid supplement.

The median contribution of supplements containing folic acid to the folate intake of women who consumed them was 200 μg per day. This figure is consistent with the daily median folic acid intake of 200 μg for women reported in an earlier study of Australian adults (23). In effect this means that prior to the introduction of voluntary fortification of foods with folate women whose diet provided 200 μg or more of folate per day (the average intake) and who consumed a supplement containing folic acid on a daily basis, achieved an intake of around only 400 μg per day (the RDI for pregnancy) and not the 600 to 700 μg proposed by NHMRC (1) as the average target intake for women of child-bearing age.

In order for supplements containing folic acid to be an effective way to achieve the NHMRC recommended folate intake, women of child-bearing age must not only be aware of the relationship between folate and the prevention of NTDs but must also take a supplement on a regular basis. The data from the present survey indicate that the use of supplements containing folic acid increased with increasing knowledge. The positive association between knowledge and use of a supplement containing folic acid has been reported elsewhere (24) and investment in education has been encouraged on the grounds that women are likely to be receptive to increasing folic acid supplement use (24,25).

Information about nutrient intake from supplements is essential in order to derive not only accurate estimates of total dietary intake but also in order to be able to differentiate between the intakes of supplement users and those not taking supplements. This is an important distinction particularly when the nature of a public health issue requires nutrient recommendations to be prepared for specific subgroups as well as the population as a whole.

As discussed in an earlier paper (7), while the PSM surveys provided a practical approach to the estimation of nutrient intake from supplements, there were some limitations in relation to the identification of individual supplements. Specifically, in 40% of instances in 1995 and 1996, it was not possible from the information collected at interview to identify the actual supplement that had been taken. While just over half of these cases were resolved satisfactorily with additional information, in 18% of cases it was still not possible to identify the nutrient profile of the supplement used. Interviewers were aware that the collection of data on supplements containing folate was of particular interest and, therefore, it is likely that the problem of supplement identification was less for supplements containing folate than for supplements in general. The inability to identify some supplements is nevertheless likely to have resulted in an underestimate of the proportion that took a supplement containing folate and of the average contribution of supplements to total folate intake. It is, however, unlikely to account for the lower reported use of folate acid supplements in the present study as compared with state-based surveys (15-17) that is more likely to be due to differences in survey sampling, methodology or timing.

Conclusion

At the time of the gazetted of revised food Standard A9 in 1995, approximately 11% of Australian adults were aware of the relationship between folate and NTDs and a similar proportion of women aged 18 to 44 years had taken a supplement containing folate on the day before the survey. At this time the NHMRC's revised statement on the relationship between dietary folic acid and neural tube defects (26) had been in existence for only two years and few education campaigns had been implemented in Australia to inform individuals about the relationship.

Since 1995 there have been several campaigns to promote knowledge of folate. In addition, voluntary folate fortification of a limited number of food products has been introduced (27) and a pilot folic acid health claims trial has been implemented (28). Both the level of knowledge about folate and the intake of folate from foods and supplements are likely to have changed in the interim. Further surveys are needed to monitor change in knowledge and total folate intake from the diet (including that from fortified foods) and supplements in order to evaluate the effectiveness of the various interventions designed to achieve the NHMRC objective of increasing, the dietary folate intake of women of child-bearing age by an average of 400 μg per day.

References

6. Institute of Medicine. Panel on Folate, other B Vitamins and Choline. Dietary reference intakes: thiamin, riboflavin, niacin, vita-
min B6, folate, vitamin B12, pantothenic acid, biotin and choline.


Appendix 11


Appendix 11


A practical approach to monitoring nutrient supplement intake of Australian adults

Mark A. Lawrence, Ingrid H.E. Rutishauser and Janine L. Lewis

Abstract The adoption, in mid-1995, of the revised food Standard A9, which permits the more liberal addition of nutrients to a range of food products, highlighted the need to obtain information on nutrient intake from supplements to complement the 1995 National Nutrition Survey data on nutrient intake from food. This paper describes the method used to obtain quantitative information on nutrient supplement intake and reports on the prevalence of supplement use in different subgroups of the Australian population. Information on supplement intake was obtained in two Australian Bureau of Statistics Population Survey Monitor surveys in August 1995 and February 1996 using the Therapeutic Goods Administration (TGA) registration numbers to identify individual products. Approximately 18% of men and 29% of women aged 18 years and over reported consuming a nutrient supplement on the day before the survey and these proportions increased to 25% and 35% respectively for consumption during the two weeks before the survey. The prevalence of supplement intake increased with age, education level, socioeconomic status, employment status and with fruit and vegetable intake. The substantial proportion of Australian adults who consume nutrient supplements, and the rapidly changing composition of the Australian food supply in response to changes in food regulation, indicates that there is a need for regular monitoring of nutrient intake from supplements. The use of TGA registration numbers to identify supplements provides a practical way to address this need. (Aust J Nutr Diet 2001;58:98–103)

Key words: nutrient supplements, vitamins, minerals, food regulation, monitoring

Introduction

A fundamental purpose of nutrition monitoring activities is to describe the nutrient intake and sources of nutrients in populations. Such description has relevance for informing public health recommendations, clinical guidelines and food regulation. To fulfil their purpose, monitoring activities need to be conducted on a sufficiently regular basis to detect change in dietary behaviour and the effects of revisions to changes in food standards. The accurate description of the nutrient intake and sources of nutrients in populations requires that monitoring activities account for the contribution of nutrients from both food and supplements. In 1995 when revised food Standard A9, which regulates the addition of vitamins and minerals to general purpose food products on sale in Australia, came into effect (1) the then National Food Authority (NFA), now the Australia New Zealand Food Authority (ANZFA), identified the need to put in place a mechanism to collect baseline nutrient intake to provide a basis for evaluating the impact of the regulatory changes. Previous data from national surveys of Australians' nutrient supplement behaviour (2,3) indicate that a substantial proportion of Australians consume nutrient supplements and that supplement consumption is not uniformly distributed throughout the population, but provide no quantitative data on the contribution of nutrient supplements to the nutrient intake of the Australian population. In addition the National Nutrition Survey (NNS), which was in progress during 1995 and 1996, was designed to provide quantitative data only on nutrient intake from foods and not from nutrient supplements.

In order to document the contribution of nutrient supplements to total dietary intake and to provide a 'baseline' for the monitoring and evaluation of revised food Standard A9, a supplement survey to complement the NNS was needed. As a consequence, the NFA commissioned some questions on nutrient supplement use by adults in two Australian Bureau of Statistics (ABS) Population Survey Monitor (PSM) surveys. The PSM provided a vehicle to obtain nutrient supplement intake data 'contemporary' with the food intake data collected by the 1995 NNS and before the adoption of revised food Standard A9 had influenced the nutrient composition of the food supply. For the purpose of the present paper nutrient supplements are defined as supplements that contain one or more vitamins or minerals.

Determination of nutrient intake from vitamin and mineral supplements requires a detailed knowledge of the ingredient and nutrient composition of specific supplements. In Australia, vitamin and mineral supplements are classified as therapeutic goods and regulated under the auspices of the Therapeutic Goods Administration (TGA). Most of these products, with a small number of exemptions, must be included in the Australian Register of Therapeutic Goods (ARTG) (4). Products included in the ARTG have an 'AUST L' (listed), or an 'AUST R' (registered) number which depends on the ingredients as listed on the package. These numbers provide a unique identifier for more than 25 000 dietary supplement products in the ARTG and can, therefore, be used to determine their ingredient and nutrient profile (5). The availability of the AUST L and AUST R numbers provided the opportunity to collect, for the first time, quantitative as well as qualitative data on nutrient supplements in a representative sample of Australian adults.

The present paper provides a description of the method used in the supplement survey and its limitations in identifying specific supplements. Also, we present the

Mark Lawrence is supported by a Public Health and Research Development Committee Scholarship from the National Health and Medical Research Council.
School of Health Sciences, Faculty of Health and Behavioural Sciences, Deakin University, Victoria
M.A. Lawrence, BSc (Hons), MSc, GradDipNutDiet, GradDip Epidemiology and Biostatistics, NHMRC Scholar
I.H.E. Rutishauser, BSc (Nutrition), MSc (Epidemiology), RPHNutr, Senior Lecturer
Australia New Zealand Food Authority, ACT
J.L. Lewis, BSc, GradDipNutDiet, Principal Nutritionist
Correspondence: M.A. Lawrence, School of Health Sciences, Faculty of Health and Behavioural Sciences, Deakin University, Burwood, Vic 3125. Email: matlawren@deakin.edu.au

98 Australian Journal of Nutrition and Dietetics (2001) 58:2
findings of a descriptive analysis to profile the prevalence of overall supplement use among population subgroups. This analysis did not attempt to identify 'predictive factors' associated with supplement use. Quantitative information on the use of specific supplements, e.g. folic acid and vitamin B12, is provided in a separate paper (6).

Methods

Sampling

In 1995 and 1996 the PSM was conducted by the ABS as an Australia-wide, user-funded, quarterly household-based survey. In addition to the specific data on the commissioned questions, users received data on a set of core socio-demographic variables for the household member interviewed for the survey. In the present survey the questions about nutrient supplement intake and knowledge regarding folate were asked of a randomly selected member of the household aged 18 years or over.

The data in this paper were obtained from a total of 5422 randomly selected households in two surveys conducted during August 1995 and February 1996 (7,8). Both surveys took place during the data collection period for the 1995 NNS (9). The August 1995 survey was the first PSM survey scheduled after the adoption of revised food Standard A9. The questions in the February 1996 survey were commissioned in order to try to capture seasonal variation in nutrient supplement use and to ensure that the sample was large enough to permit reliable comparisons of supplement use in population sub-groups. Fortunately the two PSM surveys used for the supplement survey also included questions on fruit and vegetable intake commissioned as part of an Australian Institute of Health and Welfare project to develop and evaluate indicators for national food and nutrition monitoring (10). As a consequence, the data from the supplement survey could also be analysed in relation to information about fruit and vegetable intake based on responses to questions about the number of serves of fruit and vegetables usually eaten each day.

The PSM covers rural and urban areas across all states and territories of Australia except sparsely settled areas. All usual residents in private households are included in the sampling frame for the PSM but persons living in non-private dwellings are excluded. For the August 1995 survey, 3267 households were visited and completed questionnaires were obtained from 66.2%. In the February 1996 survey completed questionnaires were obtained from 70.4% of the 4625 households visited (Table 1).

The number of households surveyed in each quarterly survey is considered to be adequate to provide quarterly data for Australia, and annual data for the states and territories (from data obtained over four quarters), at an acceptable level of accuracy and reliability (7).

Weighting factors provided by the ABS were used in this paper to adjust the sample data to provide estimates for the Australian population which minimise the effect of age-sex-area variation in non-response in the population sample.

Data collection

The PSM obtains information from adult members of selected households, in face-to-face interviews, conducted by trained interviewers who have extensive experience in conducting household surveys. Prior to the data collection the user-funded questions are pilot tested on a small sample of the population.

At the initial visit, a household form is completed from information provided by an adult member of the household aged 18 years or over. This form contains questions about the basic demographic characteristics of the household and establishes those persons within the household who are within the scope of the survey (i.e. eligible for specific questions).

In order to obtain a personal interview with appropriate respondents, interviewers make appointments to call back as necessary. Every effort is made to contact the occupants of selected dwellings. Interviewers make at least three attempts to call back in rural areas and five in urban areas before a dwelling is classified as 'non-contact'. All interviews are conducted face-to-face either in private or in the presence of other household members according to the wishes of the respondent.

Supplement use

Interviewees were asked: 'Yesterday, did you take any vitamin or mineral supplements in tablet, capsule or drop form?' and 'In the last two weeks have you taken any vitamin or mineral supplements?' The first of these questions had been included in the 1995 NNS and the second in the 1995 National Health Survey (NHS). The purpose of asking the same questions in the PSM was firstly, to establish comparability with these surveys, and secondly to enable comparisons of other data from these surveys to be made for groups with similar levels of supplement use.

If the person interviewed reported having taken one or more vitamin or mineral supplements during the previous day they were asked, if possible, to provide the supplement container(s) so that the interviewer could record the AUST L or AUST R number of the product(s) on the survey form. Before the introduction of the ARTG in 1993, products purchased overseas and unregistered products did not have an AUST L or AUST R number. For products without an AUST L or AUST R number on the container, the brand name and other relevant product information were recorded. If the container was not available the interviewee was asked to describe the brand and name of the product. Subjects were then asked how many

| Table 1. Survey response and sources of sample loss. Values are a (%) |
|-----------------|-----------------|-----------------|
|                 | August 1995     | February 1996   |
| Refusals        | 367 (11.2%)     | 457 (9.9%)      |
| Vacant dwellings| 405 (12.4%)     | 472 (10.2%)     |
| Uncontactable   | 250 (7.7%)      | 340 (7.4%)      |
| Death, illness  | 81 (2.5%)       | 98 (2.1%)       |
| or language     |                 |                 |
| problems        |                 |                 |
| Completed       | 2164 (66.2%)    | 3258 (70.4%)    |
| interviews      |                 |                 |
| Total initial   | 3267            | 4625            |
| sample selected |                 |                 |

Tablets, capsules, drops or spoons of the supplement they had taken yesterday.

Data analysis

All percentages presented in the figures, tables and the text of this paper are population-weighted estimates for the relevant response categories. Estimates have been calculated for the Australian population (18 years and over) as a whole and for demographic subgroups for which differences in supplement intake have previously been reported in the literature (sex, age, location, education, and socioeconomic status in terms of quintiles of the index of relative socioeconomic disadvantage (socioeconomic indexes for areas, SEIFA). The SEIFA index is designed to have an average value of 100 across all collection districts in Australia and a standard deviation of 100 index points [11]. In addition, the prevalence of supplement consumption is reported in relation to the usual frequence of intake of fruit and vegetables.

In general, analysis has been limited to population subgroups with a minimum size of 500 individuals in the survey sample. The 95% confidence intervals for a proportion based on 500 persons ranges from approximately 3% for proportions close to 15% to approximately 4% for proportions close to 30%. In the tables 95% confidence intervals are shown for all estimates.

Results

Prevalence of nutrient supplement use

Data on the proportion of Australian adults who took one or more nutrient supplements during the day before the survey and during the previous two weeks, by season, are presented in Table 2. Overall 23.8% of the adult population had taken at least one nutrient supplement on the day before the survey and 30.0% had taken at least one supplement during the two weeks before the survey. During winter a slightly higher proportion of the adult population took a supplement, both on the day before the survey and in the two weeks before the survey, than in summer but the difference between the seasons did not reach statistical significance.

Combined data from the August 1995 and the February 1996 survey are shown in Tables 3a to 3d. These data indicate that a significantly higher proportion of women than men took one or more supplements both on the day before the survey and during the two weeks before the survey. The percentage of men taking a nutrient supplement did not differ with age, whereas there were age-related differences in women. In young women, aged 18 to 24 years, the prevalence was lower and in older women, aged 45 to 64 years, it was significantly higher and different from the average (Table 3).

Of the 1349 interviewees who reported consuming a supplement during the day before the survey, there were 541 instances (40.0%) when, despite the use of AUSTRALIAN and AUSTRALIAN numbers, additional follow-up was required to identify the nutrient profile of the supplement. In 254 instances (18.8%) it was not possible to identify the nutrient profile of the nutrient supplement reported by the interviewees. Although this problem does not influence the prevalence data because the questions were directly comparable with previous surveys (in which there was no attempt to identify the supplement) it is relevant to the estimation of the contribution of supplements to the total nutrient intake.

The prevalence of supplement consumption increased both with increasing score for an area-based index of relative disadvantage (SEIFA) (Table 4) and with increasing intake of fruit and vegetables (Table 5). In the case of SEIFA, while the trend was for supplement intake to increase with increasing score the only statistically significant difference from the overall prevalence was for the most disadvantaged group, those in quintile 1 of the index of relative disadvantage, who had the lowest prevalence of supplement intake.

The prevalence of supplement intake was least, and significantly different from the average prevalence, both in those who reported the lowest intake of fruit and in those who reported the lowest intake of vegetables (Table 5). Those who usually consumed four or more serves of vegetables each day had a significantly higher than average prevalence of supplement intake but this was not the case for fruit.

Table 3. Percentage of prevalence and 95% confidence interval for a nutrient supplement intake by sex and age

<table>
<thead>
<tr>
<th>Sex and age</th>
<th>Consumed a nutrient supplement yesterday</th>
<th>Consumed a nutrient supplement in the last two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Males</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24 years</td>
<td>209 (20.3 (15.7-24.9)</td>
<td>25.2 (20.2-30.2)</td>
</tr>
<tr>
<td>25-44 years</td>
<td>294 (23.2 (19.0-27.4)</td>
<td>25.2 (22.5-27.9)</td>
</tr>
<tr>
<td>45-64 years</td>
<td>128 (19.6 (16.6-22.6)</td>
<td>24.6 (21.4-27.8)</td>
</tr>
<tr>
<td>65 years and over</td>
<td>114 (18.0 (14.2-21.8)</td>
<td>21.3 (17.3-25.3)</td>
</tr>
<tr>
<td>Males, all ages</td>
<td>2349 (18.2 (16.6-19.8)</td>
<td>24.5 (22.9-26.1)</td>
</tr>
<tr>
<td>Females</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18-24 years</td>
<td>200 (20.3 (15.7-24.9)</td>
<td>25.2 (20.2-30.2)</td>
</tr>
<tr>
<td>25-44 years</td>
<td>1394 (28.3 (25.9-30.7)</td>
<td>37.2 (34.7-39.7)</td>
</tr>
<tr>
<td>45-64 years</td>
<td>828 (34.9 (31.7-38.1)</td>
<td>39.7 (36.4-43.0)</td>
</tr>
<tr>
<td>65 years and over</td>
<td>561 (29.9 (26.1-33.7)</td>
<td>32.0 (28.1-35.9)</td>
</tr>
<tr>
<td>Females, all ages</td>
<td>3073 (29.3 (27.3-31.3)</td>
<td>35.3 (33.7-36.9)</td>
</tr>
</tbody>
</table>

(a) Subgroups for which the prevalence was statistically significantly different from the overall prevalence are shown in bold.
There was no consistent trend for the prevalence of nutrient supplement consumption with level of education. In those who had a tertiary degree or diploma the prevalence was significantly higher than average while the prevalence was lowest in those who had a trade certificate and not in those without any tertiary qualification (Table 6). The proportion taking supplements was significantly lower than average in the unemployed and significantly higher in those employed part-time (Table 7). Individuals born outside Australia had a significantly lower prevalence of supplement intake than those born in Australia (Table 8). No statistically significant differences in the prevalence of supplement intake were observed with marital status or state of residence. The proportion who consumed a nutrient supplement the day before the survey was 23.9% for those who were married or living in a de facto relationship (n = 3223), 26.4% for those who were separated, divorced or widowed (n = 1100), and 22.2% for those who had never been married (n = 1069). The proportion of residents in each state who consumed a nutrient supplement the day before the survey was 27.8% (n = 721) in Queensland, 25.8% (n = 681) in South Australia, 24.5% (n = 666 and 502) in Western Australia and Tasmania respectively, 23.1% (n = 971) in New South Wales, 21.8% (n = 542) in the Australian Capital Territory, 21.5% (n = 964) in Victoria and 20.8% (n = 375) in the Northern Territory.

Discussion

The findings from the present survey indicate that nearly one in four Australian adults consumed a nutrient supple-

Table 4. Percentage of prevalence and 95% confidence interval for nutrient supplement intake by socioeconomic indexes for areas (SEIFA) (11) quintile

<table>
<thead>
<tr>
<th>SEIFA quintile</th>
<th>n</th>
<th>Consumed a nutrient supplement yesterday</th>
<th>Consumed a nutrient supplement in the last two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 (S932)</td>
<td>1166</td>
<td>19.8 (17.5-22.1)</td>
<td>25.0 (22.5-27.5)</td>
</tr>
<tr>
<td>2 (&gt;932-989)</td>
<td>969</td>
<td>20.8 (18.2-23.4)</td>
<td>26.2 (23.4-29.0)</td>
</tr>
<tr>
<td>3 (&gt;989-1035)</td>
<td>1062</td>
<td>25.7 (23.1-28.3)</td>
<td>32.4 (29.6-35.2)</td>
</tr>
<tr>
<td>4 (&gt;1035-1080)</td>
<td>985</td>
<td>26.1 (24.2-28.8)</td>
<td>33.0 (30.1-35.9)</td>
</tr>
<tr>
<td>5 (&gt;1080)</td>
<td>1240</td>
<td>26.3 (24.0-29.0)</td>
<td>33.2 (30.6-35.8)</td>
</tr>
</tbody>
</table>

(a) Subgroups for which the prevalence was statistically significantly different from the overall prevalence are shown in bold.

The prevalence of supplement use among the Australian adult population is similar to that reported in the US (12), but higher than that reported in the UK (13), and the Netherlands (14). It is difficult to make direct comparisons of the prevalence and the pattern of supplement use reported in different studies because the definition both of ‘supplement’ and ‘frequency of use’ varies between studies. Nevertheless the findings of the present survey are consistent with those reported from many other recent studies in the literature. In general the prevalence of nutrient supplement use is found to be higher among women than men (12,14,15) and to increase with age (12,14,15), education level (12,15), socioeconomic status (12,14,15) and employment status (3,16).

The increase in supplement use with increasing consumption of fruit and vegetables is also consistent with the findings from several other studies that individuals who use supplements are more likely to have an adequate nutrient intake, to consume more fruit and vegetables and to follow a healthier lifestyle (3,16-18).

Because we have undertaken only a univariate analysis of the data it is not possible to comment on possible confounders that might explain the significantly higher prevalence of supplement use reported for Australian born participants relative to participants born outside Australia.

The present study, unlike a previous Australian study (2), did not find significant differences in supplement use with marital status. Similarly there were no

Table 5. Percentage of prevalence and 95% confidence interval for nutrient supplement intake by fruit and vegetable intake

<table>
<thead>
<tr>
<th>Number of serves per day</th>
<th>n</th>
<th>Consumed a nutrient supplement yesterday</th>
<th>Consumed a nutrient supplement in the last two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>One or less</td>
<td>1954</td>
<td>19.3 (17.6-21.0)</td>
<td>26.3 (24.3-28.3)</td>
</tr>
<tr>
<td>Two or three</td>
<td>2587</td>
<td>25.4 (23.7-27.1)</td>
<td>31.5 (29.7-33.3)</td>
</tr>
<tr>
<td>Four or more</td>
<td>879</td>
<td>28.8 (25.8-31.8)</td>
<td>33.4 (30.2-36.5)</td>
</tr>
<tr>
<td>No data</td>
<td>2</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

(a) Subgroups for which the prevalence was statistically significantly different from the overall prevalence are shown in bold.

significant differences between states in the present study although the pattern of supplement use was consistent with that in an earlier Australian study (3) which found that the prevalence was higher than the national average in Queensland and lower in the Northern Territory. Evidence for significant variation in supplement use with season, as reported in some overseas studies (14,19) was also not found in the present study although there was a trend for supplement intake to be slightly higher in winter than in summer.

Despite the important contribution that nutrient supplements can make to total dietary intake, most food intake surveys do not account for nutrients from vitamin supplements (5). Surveys that collect data on nutrient supplements are often limited due to qualitative information on

Table 6. Percentage of prevalence and 95% confidence interval for nutrient supplement intake by education level

<table>
<thead>
<tr>
<th>Education level</th>
<th>Consumed a nutrient supplement yesterday</th>
<th>Consumed a nutrient supplement in the last two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>School only</td>
<td>2827</td>
<td>21.5 (20.0–23.0)</td>
</tr>
<tr>
<td>Trade certificate</td>
<td>564</td>
<td>16.5 (13.4–19.6)</td>
</tr>
<tr>
<td>Other certificate</td>
<td>902</td>
<td>29.4 (26.4–32.4)</td>
</tr>
<tr>
<td>Degree or diploma</td>
<td>1094</td>
<td>29.3 (26.6–32.0)</td>
</tr>
<tr>
<td>Other</td>
<td>35</td>
<td>26.6 (25.1–28.1)</td>
</tr>
</tbody>
</table>

(a) Subgroup for which the prevalence was statistically significantly different from the overall prevalence are shown in bold.

(b) —, number in this category was too small to calculate prevalence.

Table 7. Percentage of prevalence and 95% confidence interval for nutrient supplement intake by labour force status

<table>
<thead>
<tr>
<th>Labour force status</th>
<th>Consumed a nutrient supplement yesterday</th>
<th>Consumed a nutrient supplement in the last two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not in labour force</td>
<td>1991</td>
<td>24.2 (22.3–26.1)</td>
</tr>
<tr>
<td>Employed full-time</td>
<td>2253</td>
<td>22.3 (20.6–24.0)</td>
</tr>
<tr>
<td>Employed part-time</td>
<td>900</td>
<td>29.9 (26.9–32.9)</td>
</tr>
<tr>
<td>Unemployed</td>
<td>278</td>
<td>15.8 (11.5–20.1)</td>
</tr>
</tbody>
</table>

(a) Subgroup for which the prevalence was statistically significantly different from the overall prevalence are shown in bold.

Table 8. Percentage of prevalence and 95% confidence interval for nutrient supplement intake by country of birth

<table>
<thead>
<tr>
<th>Birthplace</th>
<th>Consumed a nutrient supplement yesterday</th>
<th>Consumed a nutrient supplement in the last two weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>4023</td>
<td>25.3 (24.0–26.6)</td>
</tr>
<tr>
<td>Outside Australia</td>
<td>1399</td>
<td>19.8 (17.7–21.9)</td>
</tr>
</tbody>
</table>

(a) Subgroup for which the prevalence was statistically significantly different from the overall prevalence are shown in bold.

Decision makers in a food regulation setting are increasingly required to make decisions about many public health interventions, such as food fortification, which involve specific nutrients and other ingredients. They need accurate data to inform decision-making associated with the planning and evaluation of interventions to assess total nutrient intakes against both target levels and safety levels for nutrients. The US Food and Drug Administration has identified information on quantitative frequency of use and amount of nutrient in supplements as a priority (24). Elsewhere it has been noted that the growing data requirements of regulatory agencies for analysis related to the regulation of a rapidly changing food supply are outstripping the ability of conventional national food and nutrition surveys to meet these needs (25).

Innovative methods are required to estimate total daily nutrient intakes from food and supplements (26). We believe that the method described in the present paper provides a practical approach to the estimation of total nutrient intake although it has some limitations in relation to the identification of individual supplements.

In 40.0% of instances it was not possible to identify the specific supplement which had been taken without further information. This happened when the supplement container was not available; when the container was available but the interviewee was not sure which supplement had been consumed; when the container did not display the AUST L or AUST R number; or when the recorded AUST L or AUST R numbers did not match those recorded in the ARTG database. Just over half of these cases of missing information could be resolved with additional information but in approximately 18% of cases it was not possible to identify the nutrient profile of the nutrient supplement reported by the interviewee.

At the time the supplement survey was conducted the AUST L and AUST R system was still relatively new and a substantial number of products in the marketplace had yet to comply with the labelling system. If the survey were to be repeated in 2001 the number of missing AUST L and AUST R numbers would be greatly reduced. In addition, enumerators would be asked to record more detailed information for products without an AUST L or AUST R number to avoid the need for follow-up. In these circumstances the use of AUST L and AUST R numbers to identify supplements in the context of a household survey such as the PSM is likely to provide a relative time-
and cost-efficient approach to collecting data on the amount of nutrient intake contributed by supplements.

Conclusion

The fact that nearly one in four Australian adults consumed at least one nutrient supplement during the day before the supplement survey in 1995 and 1996 highlights the need to collect quantitative data on the contribution of supplements in order to obtain an accurate profile of the total intake of nutrients. In terms of future nutrition monitoring activities it is important to distinguish between the vehicle used for the survey described in the present paper—the PSM—and the method used for obtaining detailed data on supplement use. The use of the PSM surveys in 1995 and 1996 simply made it possible to obtain supplement data at the same time as the NNS using a comparable (household) sampling frame. The value of the PSM for monitoring issues related to food and nutrition policy in a timely fashion has previously been described (9). Asking to see the supplement container to record the AUST L or AUST R number, obtaining quantitative information on supplement use and using the recently developed ARTG database to identify specific supplement components are the critical elements of the method described in this paper. This approach does not rely on the PSM and could be combined with any face-to-face survey collecting food consumption data. The relative newness of the AUST L and AUST R numbers at the time of the present survey resulted in some difficulties with the identification of supplements, but the wider implementation of the AUST L and AUST R numbering system is likely to help overcome many of these difficulties and to enable the collection of reliable quantitative data on supplement intake.

Acknowledgments

The authors wish to acknowledge the generous assistance of the staff at the PSM unit of the ABS in Adelaide who were responsible for coordinating the data collection and providing considerable technical advice for the data analysis. In addition, staff at the TGA assisted the data analysis procedure by providing support with the accessing of the ARTG database.

References

Appendix 12

Lawrence, M., I. Rutishauser and J. Lewis (1999). "An analysis of the introduction of folate-fortified food products into stores in Australia."

An analysis of the introduction of folate-fortified food products into stores in Australia

Mark A. Lawrence, Ingrid H.E. Rutishauser and Janine L. Lewis

Abstract This report presents an analysis of the availability, price and related information about the introduction of folate-fortified food products into Australia. The report is compiled from data collected by a sample of community nutritionists and health workers from 60 stores across Australia over a three-year period from late 1995 through to late 1998. Based on the data collected in this survey, 47 folate-fortified products were available in Australia in late 1998. The labels of most fortified products indicated a folate content of between 25 and 50% of the recommended dietary intake per serve. Among the stores surveyed, there was little difference in the number or price of folate-fortified products available in capital cities between areas with different socioeconomic status; more folate-fortified products were available in stores in capital and regional cities than in rural towns and remote areas; and the price of these products was higher in rural towns and remote areas. These data contribute to the NHMRC’s review of its folate fortification policy and provide baseline information for evaluating the impact of the 1998 decision to allow a health claim for folate-fortified foods. (Aust J Nutr Diet 1999;56:15–21).

Key words: folate fortification, food regulation, food survey.

Introduction

On 14 June 1995, revised Food Standard A9 was gazetted and came into effect (1). This Standard regulates the addition of vitamins and minerals to food products on sale in Australia. Approximately six months later New Zealand adopted similar provisions to Australian Food Standard A9 — Vitamins and Minerals in Amendment 12 to the New Zealand Food Regulations (1984). Food Standard A9 permits certain foods to be fortified with folate acid (pteroyl glutamic acid) on a voluntary basis at up to a claimable level of 50% of the recommended dietary intake (RDI) per reference quantity. This provision was included in Food Standard A9 in response to recommendations prepared by an expert panel of the National Health and Medical Research Council (NHMRC) (2), which were subsequently endorsed at the 117th Session of the Council on 1 and 2 June 1994, that such a permission will help reduce the risk of neural tube defects (NTD) in the Australian population. The NHMRC recommendations were largely based on the findings of epidemiological studies that had reported a negative association between folate supplementation during the peri-conceptional period and the risk of giving birth to a baby with an NTD (3,4).

The NHMRC also recommended that ‘voluntary fortification be reviewed three years after the date of gazettal to determine its effectiveness and whether there is a need for mandatory fortification to be introduced’ (2). One of the initiatives identified by the NHMRC to fulfill this monitoring and evaluation requirement was to: ‘Gauge the effect of fortification by monitoring the number of foods to which folate is added, the level of folate added to specific foods, and the sales of fortified foods’ (2).

In response to the publication of revised Food Standard A9, the then National Food Authority, now called the Australia New Zealand Food Authority (ANZFA), coordinated the planning and implementation of an Australia-wide baseline survey to monitor the availability, price and labelling of food products permitted to be fortified with folate. This survey was subsequently repeated four times over the ensuing three years at approximately eight-monthly intervals.

Time and resource constraints precluded the random sampling of stores in each state and territory. In order to put in place a mechanism to collect baseline data prior to the implementation of the NHMRC’s recommendations the sample was restricted to locations where community nutritionists or health workers were available to conduct the survey.

The primary objectives of the survey were to monitor the availability and cost of folate-fortified food products in stores in Australia during the three years following gazettal of Food Standard A9 and in this way to contribute to the NHMRC’s review of its policy on folate fortification.

Method

Store selection

The selection of stores was based primarily on achieving a broad geographical coverage in all states and territories. A nutritionist from each state and territory (the state-territory coordinator) was identified from an informal state-territory network of nutritionists established by the then Commonwealth Department of Human Services and Health. If a nutritionist was not available through this network, nutritionists or community health workers known to ANZFA staff were contacted. These individuals were responsible for identifying at least two stores in each capital city and at least one store in a regional city, a rural town, and a remote area in their state or territory. These locations were defined as follows:

• capital city, the capital city in each state or territory;
• regional city, population greater than 10,000;
• rural town, population approximately 1000 to 10,000; and

Mark Lawrence is supported by a scholarship from the National Health and Medical Research Council.
School of Health Sciences, Faculty of Health and Behavioural Sciences, Deakin University, Victoria
M.A. Lawrence, BSc (Hons), MSc, GradDipNutDiet, GradDip Epidemiological Science, NHMRC Scholar.
J.H.E. Rutishauser, BSc (Natu), MSc, (Epidemiol.), RPhNutr, Senior Lecturer.
Australia New Zealand Food Authority, Canberra, ACT
J.L. Lewis, BSc, GradDipNutDiet, Principal Nutritionist
Correspondence: M.A. Lawrence, School of Health Sciences, Faculty of Health and Behavioural Sciences, Deakin University, Burwood, Vic 3125

• remote area, population centre of less than 1000 and at least one hour by car to the nearest rural town or two hours to the nearest city.

In each capital city, a store was selected in one low and one high socioeconomic status (SES) area. The indicator of area SES used for this purpose was the Australian Bureau of Statistics (ABS) Index of relative socioeconomic disadvantage. The ABS socioeconomic indexes for areas (SEIFA) are derived from a set of census variables, representing socioeconomic conditions in defined geographic areas. The Australian average score is 1000. For the purposes of this survey a low SES area was defined as an area with an index number of less than 1000, and a high SES area was an area with an index number greater than 1000.

Sixty stores were involved in the survey, although not all of these stores were involved in each survey during the survey period (the number of stores involved in each survey is listed in Table 1). A map of Australia indicating the approximate location of the stores involved in the survey is shown in Figure 1.

Woolworths (Safeway in Victoria) was selected randomly as the supermarket chain for data collection in each location. If it was not practical to collect data from a Woolworths store, then a Coles store was chosen and if a Coles store was not available, store selection was left to the discretion of the local enumerator.

With the exception of the Australian Capital Territory, Tasmania and Victoria, for which enumerators were only available for capital city stores, all stores and territories were represented by stores in each type of location. Stores in rural and remote areas were specifically included, despite low population density, because the prevalence of NTD has been reported as being higher (6) and blood folate levels lower (7) among Aboriginal and Torres Strait Islander communities living in these areas.

Data collection

Schedule

The baseline survey was conducted from late 1995 to early 1996 in the period between the release of the folate fortification policy and before any available food products were fortified with folate. The survey was then repeated four times at approximately eight-monthly intervals. During this period there was regular communication between ANZFA staff and enumerators, regarding the progress of the surveys and future amendments, either by correspondence or via the state coordinator and when possible by articles briefly describing the purpose of the study in professional newsletters.

Product selection

Products included in the baseline survey were from those categories listed in the table to Clause 3 of Food Standard A9. It was not practical to list every brand for each food category included in the table. Instead, the most popular brands for each food category were included on the survey form and space was provided to allow the enumerator to record additional product(s) fortified with folate if necessary. The selection of the most popular brands was based both on advice from food manufacturers regarding market share and on direct observation of the shelf space devoted to relevant food products in several large supermarkets.

Other foods that were sources of naturally occurring folate, e.g. fruit and vegetables, were also included in the baseline survey. A comments section was included on each survey form to enable enumerators to provide any additional relevant information. For example, to record whether information about the folate content of particular fruits and vegetables was provided at the point of sale. Feedback from enumerators and correspondence with food manufacturers enabled product coverage to be reduced for the subsequent surveys.

Data on price were collected both for fortified products and for a number of ‘control’ products not fortified with folate but similar in dietary purpose and nutrient composition, such as ‘home brand’ products manufactured and marketed as equivalents to regular brands. These products were included to enable price variations associated with cost of living increases to be monitored during the survey period.

Data recording

The primary objective of the survey was to record the major folate-fortified food products available in stores in

<table>
<thead>
<tr>
<th>Table 1. Number of folate-fortified food products(a) available in Australia 1995 to 1998</th>
</tr>
</thead>
<tbody>
<tr>
<td>-------------------------------</td>
</tr>
<tr>
<td>Number of stores</td>
</tr>
<tr>
<td>Bread</td>
</tr>
<tr>
<td>Pasta</td>
</tr>
<tr>
<td>Breakfast cereal</td>
</tr>
<tr>
<td>Snack products(b)</td>
</tr>
<tr>
<td>Meal replacements(c)</td>
</tr>
<tr>
<td>Fruit and vegetable juice</td>
</tr>
<tr>
<td>Supplementary food products(d)</td>
</tr>
</tbody>
</table>

(a) Includes products claiming to be good sources of naturally occurring folate.
(b) Snack products have a level of folate at least 10% RDI as a result of the carryover from their equivalent breakfast cereal formulation (Williams P., Kellogg (Aust) Pty Ltd, Sydney, 1996, personal communication).
(c) Meal replacements, Food Standard A9.
(d) Supplementary food products, Food Standard A9—folate-fortified milk products.

16 Australian Journal of Nutrition and Dietetics (1999) 56:1
Australia. For the purpose of the survey a product was defined as folate-fortified if:

- it made a nutrient claim to this effect on its label; or,
- the nutrition information panel stated that the product provided at least 10% of the RDI for folate per serve. The nutrition information panel lists the amount of total folates in terms of µg/100 g product as well as percentage of reference RDI per serve. The reference RDI for total folate is 200 µg/day. These amounts represent total folate content comprising naturally occurring folates, which are generally folic acid derivatives with differing numbers of conjugated glutamate residues; or naturally occurring folates plus any added synthetic folic acid (pteroyl glutamic acid) up to the maximum claim permitted by Food Standard A9. The labelling regulations do not make allowance for the different biological activities of the various forms of folates, or if,
- folate was listed in the ingredient list.

All folate-fortified products, except for infant food products fortified with folate under the provisions of Food Standard R6, were included regardless of their legal standing in relation to the provisions of the Food Standards Code. Products available in different packet sizes or in different flavours were treated as a single product for the purpose of this survey. Those products with the same name but available in different forms, e.g. breakfast cereal and breakfast bars, were recorded as distinct products.

Enumerators were instructed to record only the regular price of a product even if the product was 'on special' at the time of the survey. Space was provided on the survey form to record the details of any folate content claims for a listed product. Enumerators recorded information onto the survey forms while in the store except for some remote stores for which enumerators had to rely on telephone interviews with store managers. Instructions were provided to all enumerators in written form. The instructions emphasised the need to record the 'usual' price of the product, to check that the product was not simply temporarily out of stock; and to record data from the same store and for the same packet size for each product throughout the survey. All enumerators were provided with a letter of introduction to store managers to explain the purpose of the survey. The use of the letter was left to the discretion of individual enumerators.

Data entry

Prior to data entry all survey forms were scrutinised by one of the authors and ANZFA staff for completeness and conformity with the recording procedure. Data on product availability and nutrition information were also checked with relevant manufacturers. Data that appeared incorrect or incomplete were checked with enumerators and discarded if they could not be verified.

Data analysis

Folate-fortified food products available in Australia during the survey period were classified in accordance with food categories outlined in the Food Standards Code. The total number of these products was calculated overall and for each food category. A product was recorded as present regardless of the actual packet size available. However, for calculations associated with price analysis, only standard packet sizes were used to conduct comparisons. The analysis of the influence of fortification on the price of selected leading brand folate-fortified products was conducted in three stages. First, two leading brands of breakfast cereal fortified with folate were selected and matched with a similar unfortified product. Second, the mean price of the selected fortified and control foods was calculated at the baseline survey (December 1995 to February 1996) and the final survey (May to September 1998). Finally, the influence of folate fortification on the price of the selected food products was then assessed by using the change in price for the control products to assess the additional cost of fortification for the fortified products. This analysis was repeated for a bread product. As no bread available at baseline was subsequently fortified with folate during the survey period, a white bread product was selected as the baseline equivalent for a white bread product that was fortified with folate and introduced into the market during the survey period. These two bread products were similar in appearance and price.

Paired Student's t-tests and ANOVA were used to test for significant differences between the means.

The mean price of the leading breakfast cereal brand for the three major breakfast cereal manufacturers and for a leading bread was calculated for each location from the grouped data for location type from all the states and territories. Data were used from only those stores that had the product available at both baseline and in 1998.

Results

Number of folate-fortified food products available

Data on the number of folate-fortified food products recorded during the survey period are summarised in Table 1. The first folate-fortified food product was recorded approximately 12 months after the gazettal of revised Food Standard A9. The introduction of the remaining products occurred progressively over the next two years. In the three-year period following the gazettal of revised Food Standard A9, a total of 47 folate-fortified
Folate fortified food

Food products became available. Twenty-eight of the products were breakfast cereals, six meal replacement products, five breads, three supplementary food products, three snack products, one brand of pasta, and one brand of fruit juice. During the course of the survey period two additional bread products were developed and promoted as being a good source of naturally-occurring folate. Products that were fortified with folate were not also available in an unfortified form. There were no claims about folate observed for fruits and vegetables.

Level of fortification with folate

The advertised levels of folate in fortified food products are presented in Table 2, expressed as micrograms of folate per 100 g and as a percentage of the RDI for folate per serve. The majority of food products fortified with folate claimed to provide between 25 and 50% of the RDI per serve. One product claimed 67% of the RDI per serve and another 500% of the RDI per serve. Under the provisions of Food Standard A9 foods fortified with folate are not permitted to claim more than 50% of the RDI per serve, however this prohibition does not apply to unfortified foods. For example, the manufacturer of the breakfast cereal product claiming 500% of the RDI for folate per serve advised the authors that this amount of folate was derived from natural plant extracts used as ingredients in the product’s manufacture. Most products in the breakfast cereal category also exhibited a nutrition message on their label. The nutrition messages varied from references to the relationship between folate and red blood cells to the importance of folate for women during their child-bearing years. Nutrition messages were rarely used on the labels of products from other food categories.

The influence of fortification on the price of folate-fortified products

The price of selected food products during the survey is presented in Table 3. The data indicate that during the survey period the average price of all products in the table increased but the increase was statistically significant only for wheat biscuit cereal A (8 cents), cornflake cereal A (18 cents), a white bread and its ‘matched pair’ (39 cents) and generic white bread (23 cents). A comparison of the mean increase between the fortified and unfortified bread products indicates that the increase in the price of the fortified product was statistically significantly different and higher than for the unfortified control product (P < 0.001). However, this result must be interpreted with caution. As previously discussed, unlike the breakfast cereal category, there were no bread products at baseline that were observed as being fortified during the survey period. Although the two white bread products are similar in appearance and were selected as a matched pair, the fortified product was introduced as a new product during the survey period and cannot be assumed to be an exact equivalent of the non-fortified product. It may be more relevant to consider the practical significance of the absolute price rises within the selected food categories that ranged from three to 18 cents for the breakfast cereals and 23 to 39 cents for the breads. Moreover, between the food categories the increase in the price of the bread products was greater in absolute and percentage terms than that for breakfast cereals.

Table 3 also provides data comparing the price difference between products at baseline and at May to September 1998. The data indicate that for each of the paired products the price difference increased after fortification. However, this increase was statistically significant for the bread products only.

Average number of folate-fortified food products by location

The average number of folate-fortified food products available in different locations during the survey period is presented in Table 4. The average number of fortified products available increased over the course of the survey period in all locations. The actual number of fortified products available at individual stores, however, varied widely within each location. The data also indicate that after the baseline survey, the average number of folate-fortified food products was always less in rural towns and stores in remote areas than in other locations. By the time of the fourth and fifth survey when the number of fortified products had increased, the mean number of folate-fortified food products differed significantly between store locations (P < 0.05), the mean number being lowest for remote stores and highest for capital cities.

Table 2. Advertised levels of folate in fortified products(a)

<table>
<thead>
<tr>
<th>Type of product</th>
<th>Reference quantity</th>
<th>Number of products</th>
<th>Folate per 100 g (µg)</th>
<th>% folate RDI per serve</th>
</tr>
</thead>
<tbody>
<tr>
<td>Breads</td>
<td>50 g</td>
<td>6</td>
<td>66-115</td>
<td>25-40</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>200</td>
<td>67</td>
</tr>
<tr>
<td>Pasta (dry)</td>
<td>Amount equivalent to 35 g of uncooked dried pasta</td>
<td>1</td>
<td>40</td>
<td>50</td>
</tr>
<tr>
<td>Breakfast cereals</td>
<td>‘A normal serving’</td>
<td>27</td>
<td>111-333</td>
<td>25-50</td>
</tr>
<tr>
<td></td>
<td></td>
<td>1</td>
<td>2500</td>
<td>500</td>
</tr>
<tr>
<td>Snack foods</td>
<td>‘A normal serving’</td>
<td>3</td>
<td>4-150</td>
<td>33-50</td>
</tr>
<tr>
<td>Meal replacements</td>
<td>Amount recommended to replace one meal</td>
<td>6</td>
<td>30</td>
<td>-</td>
</tr>
<tr>
<td>Fruit juice</td>
<td>200 mL</td>
<td>1</td>
<td>20</td>
<td>25</td>
</tr>
<tr>
<td>Supplementary food products</td>
<td>200 mL</td>
<td>2</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(a) Includes products labelled as good sources of naturally occurring folate.

(b) These products contain at least 10% of the folate RDI per serve, because they are manufactured from fortified ingredients. Such foods are not permitted to declare vitamin or mineral content if more than 10% of the product’s weight is derived from added sugar and/or fats. Reference to the ingredient list shows which particular ingredients were fortified.
Table 3. The influence of fortification on the price of selected leading brand folate-fortified food products (mean = SD)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>750 g wheat biscuit A (30)</td>
<td>$2.95 ± 0.17</td>
<td>$3.04 ± 0.22</td>
<td>$0.09 ± 0.11***</td>
<td>$0.02 ± 0.21</td>
<td>$0.03 ± 0.29</td>
</tr>
<tr>
<td>750 g wheat biscuit B (30)</td>
<td>$2.98 ± 0.28</td>
<td>$3.01 ± 0.35</td>
<td>$0.03 ± 0.38</td>
<td>$0.02 ± 0.21</td>
<td>$0.03 ± 0.29</td>
</tr>
<tr>
<td>550 g cornflake cereal A (21)</td>
<td>$2.52 ± 0.27</td>
<td>$3.69 ± 0.29</td>
<td>$0.18 ± 0.19***</td>
<td>$0.53 ± 0.12</td>
<td>$0.63 ± 0.22</td>
</tr>
<tr>
<td>500 g cornflake cereal B (21)</td>
<td>$2.98 ± 0.25</td>
<td>$3.06 ± 0.27</td>
<td>$0.08 ± 0.12</td>
<td>$0.48 ± 0.06</td>
<td>$0.64 ± 0.12***</td>
</tr>
<tr>
<td>700 g white bread matched pair (16)</td>
<td>$1.97 ± 0.09</td>
<td>$2.36 ± 0.11</td>
<td>$0.39 ± 0.06***</td>
<td>$0.48 ± 0.06</td>
<td>$0.64 ± 0.12***</td>
</tr>
<tr>
<td>680 g generic white bread (16)</td>
<td>$1.49 ± 0.08</td>
<td>$1.72 ± 0.07</td>
<td>$0.23 ± 0.10***</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

*** P < 0.001

(a) Fortified product.

Table 4. Mean [and range] of the number of folate-fortified food products[^a] by store location (number of observations)

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Rural town (10)</td>
<td>0 (7)</td>
<td>1 [0–3] (7)</td>
<td>10 [6–19] (6)</td>
<td>13 [10–22] (9)</td>
<td>22 [18–28] (7)</td>
</tr>
<tr>
<td>Remote area (16)</td>
<td>0 (8)</td>
<td>1 [0–2] (8)</td>
<td>3 [0–11] (9)</td>
<td>7 [11–11] (9)</td>
<td>10 [3–18] (8)</td>
</tr>
</tbody>
</table>

[^a]: Includes products labelled as good sources of naturally occurring folate.
[^b]: Data were not collected from all stores during each survey.

In capital cities there was no detectable trend in the mean number of folate-fortified products in stores located in areas of high and low SES.

In late 1996, except for one rural store and three remote stores, all stores had available at least one folate-fortified food product.

The influence of location on the price of folate-fortified products

The mean price of select leading brands of folate-fortified food products at different locations at the final survey (May to September 1998) is given in Table 5. The data indicate that there were no apparent price differences between capital and regional cities for any of the products. However, with the exception of the folate-fortified white bread, the mean price was higher in rural towns and remote areas than in the cities. The number of observations was too small to test this trend for statistical significance across all locations except for wheat biscuit cereal A. For this product the trend in mean price was significant (P < 0.05), being lowest for capital and regional city stores and highest for remote stores. In contrast the mean price of cornflake cereal A did not differ significantly between cities and rural towns.

Discussion

Product availability, nutrition information and price

Implementation of the NHMRC's recommendation on folate fortification has been modest and uneven. During the survey period 47 folate-fortified food products and two products specially prepared as good sources of naturally occurring folate were introduced into the monitored stores. Sixty per cent of the folate-fortified products were breakfast cereals (28 products). Whereas nine of the 10 most popular breakfast cereals were among the brands fortified with folate in this category, only about 30% of the target group (i.e. women of child-bearing age) report consuming breakfast cereal on a given day (8). In contrast, food products which are consumed by a higher proportion of the target population such as breads and rolls, fruit juice and vegetable juice included a much smaller number of fortified products. The other food products fortified with folate, would not be expected to be consumed by a large proportion of the target population (meal replacements) or were restricted to a small proportion of the available brands in these respective food categories (snack products, pasta, and supplementary food products).

If fortification had been carried out more broadly across the food categories, for example had included more brands of fruit juice and bread as well as breakfast cereals, it would have been more effective since the target population is more likely to consume one or two servings of fruit juice and bread and a serve of breakfast cereal rather than three servings of breakfast cereal during the course of a day. Both the breakfast cereals and the limited number of breads that were fortified tended to be among the more expensive brands within these food categories. This is an important consideration given the reported higher prevalence of NTDs among lower SES population groups (9).
manufacturers to qualify for the 'good source' nutrient claim permitted at a nutrient level of at least 25% of the RDI per serve. Whereas many manufacturers chose to fortify their products to the maximum claimable level of 50% of the RDI per serve it is possible that additional folate beyond this level may have been added since the Food Standards Code does not specify an upper limit for folate fortification levels.

Some breakfast cereal manufacturers adopted different approaches to the NHMRC recommendations. Some chose to restrict their folate fortification implementation to just one cereal in their breakfast cereal range. These cereals were chosen as they were each marketed to the target group (10,11). While another manufacturer, Kellogg (Australia) Pty Ltd, stated in a letter dated 14 November 1996 that it chose to fortify most of its brands with folic acid on the basis that "...we could improve folate intake among a larger number of people and not only women of childbearing age" (McMahon A, Kellogg (Australia) Pty Ltd, Sydney, 1996, personal communication).

There is limited evidence from this study that fortification with folate increased the price of selected products relative to unfortified similar products. However, these price increases were only statistically significant for the selected fortified bread product relative to an unfortified bread product.

**Availability and price of folate-fortified food products by type of store location**

Fewer folate-fortified products were available in stores in remote areas and those products that were available tended to be more expensive. Differences in availability and price, however, were not evident between different SES areas in capital cities. With the exception of one rural and three remote stores, the time of first availability of a folate-fortified food product was recorded within 18 months of the gazettal of Food Standard A9, i.e. by the end of 1996. The delay in the availability of folate-fortified versions of existing products in these four stores was probably due to the longer time period to turn over old stock.

The differences in availability and cost associated with store location observed during the survey period are consistent with those reported elsewhere in relation to the relative disadvantage of remote communities to affordable food and a quality food supply, especially for fruits and vegetables (12).

Some qualifications need to be taken into account in comparing the availability and relative price of folate-fortified food products among stores. The number of fortified products available in a store provides only a crude indicator of the implementation of the NHMRC policy.

The level of consumption of specific products by the target group and whether fortification of products extends across several staple food categories or is restricted predominately to one food category are important factors in determining the success of the intervention. It is difficult to draw firm conclusions in relation to the price of folate-fortified food products, based on comparisons among stores. The comparison of the price of leading brands of folate-fortified products, as summarised in Table 5, only provides a crude indication of the overall profile of affordability of such products among stores. It may be that the price of fortified products relative to other store products is a more significant influence on the purchase of these products by the population served by the store than is absolute price in relation to other stores. In stores where folate-fortified food products were more expensive, unfortified products also tended to be more expensive.

Although the survey was designed to document and to quantify, rather than to explain the reasons for differences between stores, comments made by enumerators during the data collection process help to explain some of the observed differences. The price of products can be influenced by a variety of local conditions. For example at Mimi's, a remote store in South Australia, the survey enumerator commented in relation to the price of a chocolate flavoured cereal that the "store keeper indicated that the community had decided to mark up the price to discourage consumption, as this product was high in sugar and children tended to favour it over other varieties". Similarly, product availability was affected at two other remote stores by exceptional circumstances. At One Arm Point, in Western Australia, little stock was available in the store during the second survey because the supply barge had not arrived for several months, while at Bourke, in New South Wales, the store burnt down between the second and third survey periods.

**Limitations**

Some limitations associated with the data collection and analysis must also be taken into account in the interpretation of the findings of this survey. These limitations are related to the resource and time constraints placed upon the original survey design and implementation. Specifically, it cannot be assumed that the survey is representative of all stores across Australia as the rationale for store selection was based on the practical availability of an enumerator. Nevertheless, these data provide valuable information on the impact of the NHMRC's recommendation on voluntary folate fortification.

Since food manufacturers' intentions in relation to the fortification of specific food products with folate could

<table>
<thead>
<tr>
<th>Store location (number of stores)</th>
<th>Wheat biscuit cereal A 750 g</th>
<th>Cornflake cereal A 550 g</th>
<th>Wheat flake cereal 425 g</th>
<th>White bread 700 g</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capital city, high SES (10)</td>
<td>$3.05 ± 0.22 (8)</td>
<td>$3.67 ± 0.16 (8)</td>
<td>$3.19 ± 0.32 (5)</td>
<td>$2.35 ± 0.12 (6)</td>
</tr>
<tr>
<td>Capital city, low SES (8)</td>
<td>$3.01 ± 0.25 (8)</td>
<td>$3.66 ± 0.15 (7)</td>
<td>$3.32 ± 0.27 (5)</td>
<td>$2.27 ± 0.22 (6)</td>
</tr>
<tr>
<td>Regional city (16)</td>
<td>$2.97 ± 0.17 (11)</td>
<td>$3.61 ± 0.14 (10)</td>
<td>$3.26 ± 0.20 (3)</td>
<td>$2.32 ± 0.11 (9)</td>
</tr>
<tr>
<td>Rural town (10)</td>
<td>$3.31 ± 0.40 (7)</td>
<td>$3.77 ± 0.35 (6)</td>
<td>$4.02 ± 0.47 (2)</td>
<td>$2.32 ± 0.1 (1)</td>
</tr>
<tr>
<td>Remote area (16)</td>
<td>$4.18 ± 0.76 (7)</td>
<td>$4.09 ± 0.83 (3)</td>
<td>na(a)</td>
<td>na(a)</td>
</tr>
</tbody>
</table>

(a) na. products not available.
not be anticipated in the design of the survey form, the accuracy and completeness of the recorded data is largely dependent upon the enumerators' awareness of the availability of new folate-fortified products and this may have resulted in minor variation in the comprehensiveness of the data recorded at different stores.

Conclusion

The data from this survey provide valuable information about the availability, price and use of nutrient claims and nutrition messages on folate-fortified food products across Australia. They indicate that the response by food manufacturers to the NHMRC's folate fortification policy has resulted in only a modest availability of folate-fortified food products in stores across Australia. The policy may need to be revised to encourage greater implementation by food manufacturers (13). These revisions could include:

- permission for the food manufacturer to use an explicit health claim;
- mandating folate fortification as part of the review process; and
- programs to improve the availability and affordability both of folate-fortified food products and foods that are natural sources of folate in remote areas (13).

A pilot for health claim messages on food products, the first of these options has already been endorsed. An amendment to the Food Standards Code and an interim code of practice for the communication of the health benefits of food products have been established specifically for a pilot for health claims relating to folic and NTDs (14). A health claim might help to inform individuals in the target group of the relationship between folic and reduced risk of NTDs and provide an incentive for food manufacturers to fortify their products with folic. The data from this survey provide valuable baseline information for the pilot folic health claim initiative.

Mandating folate fortification would ensure maximum implementation of the policy recommendations and coverage of the target population. In addition, it has the advantage that all products are fortified, not just those that are more expensive. However, mandating folate fortification would remove any opportunity for a consumer to choose an unfortified staple food product. Voluntary fortification recommendations enable certain manufacturers the opportunity to provide a choice to consumers. While there may be a need to increase the number of folate-fortified food products in the marketplace in order to achieve the folic intake target of the NHMRC policy, the policy document also noted the need to avoid an excessive folic intake among the population (2). Potential safety concerns have been raised in relation to excessive folic intake (15,16). There is also the ethical consideration that the benefits and risks (slight though they may be) do not apply to the same people. Young men with a large overall food intake are more likely to obtain an excess of folic than women of child-bearing age who may receive the intended benefit. Given the controversial nature of this intervention both locally and internationally (only the United States has mandated folic fortification) mandatory fortification may be better considered after the results of further evaluation of this intervention, including the influence of the permission to use a health claim, have become available.

Initiatives are also required to improve the availability and affordability of folate-fortified food products in stores in remote areas. Such initiatives are particularly important given the disadvantages faced by communities in remote areas in accessing affordable, good quality fruit and vegetables.

It is intended that this information will contribute towards both the NHMRC's monitoring recommendations and to food and nutrition policy activities in those local areas involved in the survey. It is important that this monitoring be maintained. The next stage of monitoring will enable the influence of the pilot folic health claim to be assessed. More fundamentally, monitoring the policy's implementation will provide valuable information for the broader evaluation of the NHMRC's folate fortification recommendations as a case study of the implementation and development of public health nutrition policy.

Acknowledgments

The authors wish to acknowledge all the nutritionists and health workers across Australia who voluntarily offered their time and expertise in collecting the store data. The assistance of Catherine Deeps (nutritionist) and Kelly Croucher (administration) at ANZFA is also acknowledged.

References