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# Monitoring the health impacts of mandatory folic acid and iodine fortification







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**2016**

Australian Institute of Health and Welfare  
Canberra

Cat. no. PHE 208

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ISBN 978-1-74249-940-6 (PDF)

ISBN 978-1-74249-941-3 (Print)

#### **Suggested citation**

Australian Institute of Health and Welfare 2016. Monitoring the health impacts of mandatory folic acid and iodine fortification. Cat. no. PHE 208. Canberra: AIHW.

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Published by the Australian Institute of Health and Welfare

This publication is printed in accordance with ISO 14001 (Environmental Management Systems) and ISO 9001 (Quality Management Systems). The paper is sourced from sustainably managed certified forests.



**Please note that there is the potential for minor revisions of data in this report. Please check the online version at <[www.aihw.gov.au](http://www.aihw.gov.au)> for any amendments.**

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# Acknowledgments

This report was authored by Peta Craig, Ann Hunt and James Pearce from the Australian Institute of Health and Welfare, with support and assistance from Louise York, Tim Beard, Arianne Schlumpp, Ruby Brooks, Lisa McGlynn and Lynelle Moon.

The Institute would like to particularly acknowledge those who contributed data for the report, namely Food Standards Australia New Zealand, the New Zealand Ministry for Primary Industries, and Lisa Hilder from the National Perinatal Epidemiology and Statistics Unit at the University of New South Wales.

This work was commissioned and funded by the Australian Health Ministers' Advisory Council (AHMAC). The project was overseen by a Food Regulation Standing Committee/AHMAC Working Group and the Department of Health.

# Abbreviations

2002 Children's Survey	New Zealand Children's Nutrition Survey
2007 Children's Survey	Australian National Children's Nutrition and Physical Activity Survey
AATSIHS	Australian Aboriginal and Torres Strait Islander Health Survey
ABS	Australian Bureau of Statistics
ACT	Australian Capital Territory
AHMAC	Australian Health Ministers' Advisory Council
AHS	Australian Health Survey
AIHW	Australian Institute of Health and Welfare
ASGS	Australian Statistical Geography Standard
CDAH	Child Determinants of Adult Health
CI	confidence interval
(the) Code	Australian and New Zealand Food Standards Code
DIAMOND	Dietary Modelling of Nutritional Data
DFE	dietary folate equivalent
EAR	estimated average requirement
FSANZ	Food Standards Australia New Zealand
Ministerial Council	Australia and New Zealand Food Regulation Ministerial Council
MPI	New Zealand Ministry for Primary Industries
MUIC	median urinary iodine concentration
NATSIHMS	National Aboriginal and Torres Strait Islander Health Measures Survey
NATSIHS	National Aboriginal and Torres Strait Islander Health Survey
NATSINPAS	National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Study
NHMS	National Health Measures Survey
NHS	National Health Survey
NNPAS	National Nutrition and Physical Activity Survey

NNS	National Nutrition Survey
NRV	nutrient reference value
NSW	New South Wales
NT	Northern Territory
NTD	neural tube defect
Qld	Queensland
SA	South Australia
SEIFA	Socio-Economic Indexes for Areas
SES	socioeconomic status
Tas	Tasmania
UIE	urinary iodine excretion
UL	upper level of intake
WA	Western Australia
WHO	World Health Organization
Vic	Victoria

# Symbols

%	per cent
g	gram
kg	kilogram
L	litre
mg	milligram
mL	millilitre
ng	nanogram
nmol	nanomole
μg	microgram

# Summary

At the request of the then Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council), Food Standards Australia New Zealand developed mandatory fortification requirements for folic acid and iodine to address two important public health issues: to reduce the prevalence of neural tube defects (NTDs) (serious birth defects) in Australia, and to deal with the re-emergence of iodine deficiency in both Australia and New Zealand. These mandatory requirements were accepted in 2007 and became effective as part of Standard 2.1.1 *Cereals and cereal products* in the Australia New Zealand Food Standards Code (the Code) from September–October 2009.

In agreeing to the Code changes, the Ministerial Council asked that a comprehensive and independent review be initiated 2 years after their implementation, and that the Food Regulation Standing Committee and the Australian Health Ministers' Advisory Council oversee the review process. The three-stage review comprises an assessment of:

1. food industry compliance and impacts on enforcement agencies
2. population health effects of mandatory folic acid and iodine fortification
3. the effectiveness of the mandatory folic acid and iodine fortification initiatives.

This report is the second stage of the review, focusing on the population health effects of mandatory folic acid and iodine fortification. It assesses changes in nutrient intake, nutrient status and health effects before September 2009 (pre-mandatory fortification) and after September 2009 (post-mandatory fortification), where data sources permit.

## Key findings

These mandatory requirements have resulted in increases in the level of folic acid and iodine in the food supply, and subsequent increases in nutrient intakes and nutrient status.

Post-mandatory folic acid fortification in Australia, there was a statistically significant 14.4% decrease in the rate of NTDs in the total study population (the total study population included New South Wales, Queensland, Western Australia, South Australia and the Northern Territory; data were not available or of sufficient quality from Victoria, the Australian Capital Territory and Tasmania) (10.2 to 8.7 per 10,000 conceptions that resulted in a birth). Omitting New South Wales residents (where data on NTDs are less complete), there was a non-significant 12.5% decrease in NTDs (12.8 to 11.2 per 10,000 conceptions that resulted in a birth). The reduction in NTD rates in these populations is in keeping with that predicted during the development of the mandatory fortification requirement.

The decrease in NTDs was most substantial for Aboriginal and Torres Strait Islander women and teenagers. There was a 74.2% decrease in the rate of NTDs among Indigenous women in the total study population (from 19.6 to 5.1 per 10,000 conceptions that resulted in a birth) and an 80.2% decrease among Indigenous women in the population omitting New South Wales residents (from 22.8 to 4.5 per 10,000 conceptions that resulted in a birth). These results were statistically significant.

There was a 54.8% decrease in the rate of NTDs among teenagers in the total study population (from 14.9 to 6.7 per 10,000 conceptions that resulted in a birth) and a 62.6% decrease among teenagers in the population omitting New South Wales residents (from 18.6 to 7.0 per 10,000 conceptions that resulted in a birth). These results were statistically significant.

Sensitivity analysis was undertaken using data that omitted New South Wales residents from the total study population to assess the potential bias of missing data from the state. The analysis showed that including New South Wales data provided a much larger population and improved the study power. The level of NTD ascertainment (detection) in New South Wales has been shown to be generally consistent over time, allowing the use of these data to assess changes in NTD rates.

These results should be considered in the context of the short study period post-fortification and the relative rarity of NTDs, both of which contribute to variability in NTD rates. Australian NTD rates need ongoing monitoring to confirm whether these reductions will be sustained.

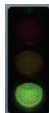
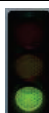
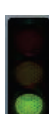
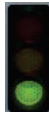
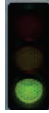
Post-mandatory iodine fortification in Australia, the population was consuming sufficient iodine to address the recent re-emergence of mild iodine deficiency at a population level. Median urinary iodine concentration (MUIC) – a measure of iodine status – for the general population was 131 µg/L, within the range of adequacy (100 to 199 µg/L). Children aged 5–8 had the highest MUIC (175 µg/L) and women aged 16–44 had a lower MUIC (121 µg/L). Intakes for pregnant women aged 16–44 (116 µg/L) were still inadequate to meet their increased requirements during pregnancy and breastfeeding.

Post-mandatory iodine fortification in New Zealand, there was a modest improvement in iodine intakes; however, some groups were still at risk of mild iodine deficiency. The MUIC for adults aged 18–64 was 73 µg/L and for women aged 18–44 was 68 µg/L, indicative of mild iodine deficiency. The MUIC for children aged 8–10 was 113 µg/L, which was within the range of iodine adequacy, but thyroid hormone levels suggest marginal risk of inadequacy.

# Overview

This overview outlines the population health effects of mandatory folic acid and iodine fortification. Based on the five key monitoring questions (column 1 in tables O1–O3 that follow and in Box 1.1), pre- and post-mandatory fortification data were analysed to assess the impact of the policy change, which also considered the expected outcome (see ‘Further details’ column where applicable). A ‘green’ rating indicates the desired outcome was achieved for a key question; ‘amber’ indicates partial achievement; and ‘red’, no achievement. ‘Not applicable’ is shown where data did not support an overall assessment or a rating was not appropriate.

**Table O1: Key mandatory folic acid fortification outcomes in Australia**

Key monitoring question and measurement	Pre-mandatory fortification	Post-mandatory fortification	Further details	Outcome
Has the level of folic acid in our food supply increased? <i>Mean folic acid level of bread</i>	20–29 µg/100 g	134–200 µg/100 g	When developing the mandatory fortification requirement, the post-fortification estimate was 120 µg/100 g in bread.	
Are the food industries adequately complying with the mandatory fortification standards?	Not applicable	Mills and baking businesses have systems in place to ensure compliance.		
Have folic acid intakes of women of child-bearing age increased? <i>Mean folic acid intakes in women aged 16–44</i>	102 µg/day	247 µg/day (145 µg/day increase; 142%)	When developing the mandatory fortification requirement, the post-fortification predicted increase was 100 µg/day.	
Has the folate status of women of child-bearing age improved? <i>Mean red blood cell and serum folate</i>	Serum folate data are available for limited assessment.  No adequate red blood cell folate baseline data are available.	<u>Red blood cell folate</u> All women aged 16–44: 1,647 nmol/L Pregnant women aged 16–44: 1,958 nmol/L Breastfeeding women aged 16–44: 1,775 nmol/L	Mean serum folate levels post-fortification were higher than at baseline; however, results must be interpreted with caution because different methodologies were used (see Section 2.4).	Not applicable
Has the incidence of neural tube defects (NTDs) decreased? <i>NTD incidence per 10,000 conceptions that resulted in a birth</i>	<u>Total study population</u> All women: 10.2 Indigenous women: 19.6 Teenagers: 14.9 <u>Population omitting NSW residents<sup>(a)</sup></u> All women: 12.8 Indigenous women: 22.8 Teenagers: 18.6	<u>Total study population</u> All women: 8.7 (14.4% decrease) Indigenous women: 5.1 (74.2% decrease) Teenagers: 6.7 (54.8% decrease) <u>Population omitting NSW residents<sup>(a)</sup></u> All women: 11.2 (12.5% decrease) Indigenous women: 4.5 (80.2% decrease) Teenagers: 7.0 (62.6% decrease)	When developing the mandatory fortification requirement, the post-fortification predicted average decrease in NTDs was 14%.  Ongoing monitoring of NTDs is required to confirm whether these reductions will be sustained.	
Does mandatory folic acid fortification result in adverse health effects for the population? <i>Proportion of the population with folic acid intakes above the upper level of intake (UL)</i>  <i>Cancer and all-cause mortality</i>	Women aged 16–44: 0% Persons aged 19 and over: 0% Children aged 4–8: 3% Children aged 2–3: 5%	Women aged 16–44: 0% Persons aged 19 and over: <1% Children aged 4–8: 15% Children aged 2–3: 21%  No increase in cancer or all-cause mortality can be directly associated with increase in folic acid intakes in adults.	Minimal change in adults exceeding the UL. A higher proportion of children aged 2–16 exceeded the UL but is not considered a health risk. The UL incorporates a fivefold safety margin and is based on an end point for high intakes in older adults.	Not applicable  

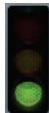


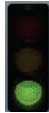


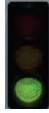
(a) Sensitivity analysis was undertaken using data that omitted New South Wales residents from the total study population to assess the potential bias of missing data from the state. Inclusion of New South Wales provided a much larger population and improved the study power.



**Table O2: Key mandatory iodine fortification outcomes in Australia**

Key monitoring question and measurement	Pre-mandatory fortification	Post-mandatory fortification	Further details	Outcome
Has the level of iodine in our food supply increased? <i>Mean iodine level of bread</i>	<2 µg/100 g	53–70 µg/100 g	When developing the mandatory fortification requirement, the post-fortification estimate was 46 µg/100 g.	
Are the food industries adequately complying with the mandatory fortification standards?	Not applicable	Salt manufacturers and bakers have systems in place to ensure compliance.		
Have iodine intakes in the population increased, particularly in women of child-bearing age and young children? <i>Mean iodine intakes</i> <i>Proportion of the population with iodine intakes below the estimated average requirement (EAR)</i>	Women aged 16–44: 98 µg/day Children aged 2–3: 127 µg/day Women aged 16–44 (non-pregnant EAR): 60% Women aged 16–44 (pregnancy EAR): 95% Women aged 16–44 (lactating EAR): 100% Children aged 2–3: 9%	Women aged 16–44: 149 µg/day (51 µg/day increase; 52%) Children aged 2–3: 164 µg/day (37 µg/day increase; 29%) Women aged 16–44 (non-pregnant EAR): 9% Women aged 16–44 (pregnancy EAR): 65% Women aged 16–44 (lactating EAR): 85% Children aged 2–3: <1%	When developing the mandatory fortification requirement, the post-fortification predicted increase was 46 µg/day among women aged 16–44 and 38 µg/day among children aged 2–3. Iodine intakes sufficient for the general population. Iodine supplementation for pregnant and breastfeeding women continues to be necessary (as expected when developing the mandatory fortification requirement).	
Has the iodine status of the population improved, particularly in women of child-bearing age and young children? <i>Median urinary iodine concentration (MUIC)</i>	Children aged 8–10: 96 µg/L	Children aged 5–8: 175 µg/L All women aged 16–44: 121 µg/L Pregnant women aged 16–44: 116 µg/L Breastfeeding women aged 16–44: 103 µg/L	Pre- and post-mandatory fortification data for children suggest an increase in MUIC. MUIC for all women aged 16–44 and children aged 5–8 indicative of iodine adequacy. Note, the MUIC for pregnant and breastfeeding women aged 16–44 is indicative of insufficient iodine intake post-fortification.	
Has the iodine status of the population improved? <i>Iodine status</i>	Refer to information on nutrient status.			
Does mandatory iodine fortification result in adverse health effects for the population? <i>Proportion of the population with iodine intakes above the upper level of intake (UL)</i>	Women aged 16–44: 0% Persons aged 17 and over: 0% Children aged 4–8: 0% Children aged 2–3: 7%	Women aged 16–44: 0% Persons aged 17 and over: 0% Children aged 4–8: <1% Children aged 2–3: 20%	Minimal change in adults exceeding the UL. A higher proportion of children aged 2–3 exceeded the UL but is not considered a health risk. The UL for children is based on an end point for high intakes in adults. The proportion of young children exceeding the UL also decreases with age with <1% exceeding the UL after age 4.	Not applicable

**Table O3: Key mandatory iodine fortification outcomes in New Zealand**

Key monitoring question and measurement	Pre-mandatory fortification	Post-mandatory fortification	Further details	Outcome
Has the level of iodine in our food supply increased? <i>Mean/median iodine level of bread</i>	<2 µg/100 g (mean)	28–49 µg/100 g (median)	When developing the mandatory fortification requirement, the post-fortification estimate was 46 µg/100 g.	
Are the food industries adequately complying with the mandatory fortification standards?	Not applicable	Salt manufacturers and bakers have systems in place to ensure compliance.		
Have iodine intakes in the population increased, particularly in women of child-bearing age and young children? <i>Mean iodine intakes</i>	Women aged 16–44: 99 µg/day Children aged 5–14: 45 µg/day	Women aged 18–44: 108 µg/day Children aged 5–14: 93 µg/day (48 µg/day increase)	Iodine intakes for women were higher than at baseline; however, results must be interpreted with caution because different methodologies were used (see Section 4.3). When developing the fortification requirement, the post-fortification predicted increase was 73 µg/day among women of child-bearing age. Iodine intakes continue to be insufficient.	 Women of child-bearing age  Children aged 5–14
<i>Proportion of the population with iodine intakes below the estimated average requirement</i>	Women aged 16–44: 68% Children aged 5–14: 95%	Women aged 18–44: 39% Children aged 5–14: 21%	Iodine supplementation for pregnant and breastfeeding women continues to be necessary (as expected when developing the fortification requirement).	
Has the iodine status of the population improved, particularly in women of child-bearing age and young children? <i>Median urinary iodine concentration (MUIC)</i>	Women aged 18–44: 48 µg/L Children aged 8–10: 68 µg/L	Women aged 18–44: 68 µg/L Children aged 8–10: 113 µg/L	MUIC for women aged 18–44 is indicative of mild iodine deficiency. MUIC for children aged 8–10 is indicative of iodine adequacy.	 Women of child-bearing age  Children aged 8–10
Has the iodine status of the population improved? <i>Iodine status</i>	Refer to information on nutrient status.			
Does mandatory iodine fortification result in adverse health effects for the population? <i>Proportion of the population with iodine intakes above the upper level of intake (UL)</i>	Adults: 0% Children aged 5–14: <1%	Adults: Not applicable Children aged 5–14: <1%	No assessment of intakes against the UL was performed for adults post-fortification. As intakes are lower than expected, adults aged 18–64 are not expected to be above the UL.	Not applicable

# 1 Introduction

This report is a review of the population effects of mandatory folic acid and iodine fortification after their implementation in 2009. It assesses changes in food composition, nutrient intake, nutrient status and health effects pre- and post-mandatory fortification.

In 2004, the then Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) requested that Food Standards Australia New Zealand (FSANZ) consider mandatory folic acid fortification to help reduce the incidence of neural tube defects (NTDs) (serious birth defects), and mandatory iodine fortification to address the re-emergence of iodine deficiency in the population.

After extensive consultation, two mandatory fortification requirements were accepted in 2007 and became effective as part of Standard 2.1.1 *Cereals and cereal products* in the Australia New Zealand Food Standards Code (the Code) from September–October 2009. The Standard requires the addition of folic acid to wheat flour for making bread in Australia and iodine (via iodised salt) to bread in both Australia and New Zealand (excluding bread represented as ‘organic’ in both countries).

In agreeing to the Code changes, the Ministerial Council stipulated that the Standard be monitored and reviewed to assess the effectiveness and safety of, and continuing need for, these public health interventions. The three stages of the independent review include:

1. food industry compliance and impacts on enforcement agencies
2. population health effects of mandatory folic acid and iodine fortification
3. the effectiveness of mandatory folic acid and iodine fortification.

This report is the second stage of the review and is based on the mandatory food fortification monitoring framework and associated key monitoring questions, as detailed in Box 1.1. The framework was accepted in 2007 by the Australian Health Ministers’ Advisory Council (AHMAC), as recommended by the then Australian Population Health Development Principal Committee after development by the Food Regulation Standing Committee (see Appendix A for an overview of the governmental committees).

The framework is based on an ‘outcomes hierarchy’ outlining the process, impact and outcome questions to be considered. This approach is based on a step-wise progression from the first action (the policy change) to the policy objective (a reduction in NTDs and iodine deficiency). Each step represents a measurable achievement necessary to attain the next step and the ultimate outcome (see Appendix B for a diagrammatic representation of the outcomes hierarchy).

### **Box 1.1: Key monitoring questions addressed in this report**

#### **1. Food composition and food industry compliance\***

*Has the level of folic acid and iodine in our food supply increased?*

*Are the food industries adequately complying with the mandatory fortification standards?*

#### **2. Nutrient intake**

*Have folic acid intakes in women of child-bearing age increased?*

*Have iodine intakes in the population increased, particularly in women of child-bearing age and young children?*

#### **3. Nutrient status**

*Has the folate status of women of child-bearing age improved?*

*Has the iodine status of the population improved, particularly in women of child-bearing age and young children?*

#### **4. Health benefits**

*Has the incidence of neural tube defects decreased?*

*Has the prevalence of iodine deficiency decreased?*

#### **5. Adverse health effects**

*Does mandatory folic acid and iodine fortification result in adverse health effects for the population?*

\*The assessment of food industry compliance was the focus of the first stage of the independent review and so is not covered extensively in this report.

## **1.1 Folic acid**

There is convincing evidence that folic acid is protective against NTDs (NHMRC & NZMoH 2006) (see Box 1.2 for a description of the types of NTDs). Since 1993, various strategies have been put in place in Australia to encourage women of child-bearing age to increase their dietary folic acid/folate intake, including:

- promotion of folic acid supplements and diets containing foods naturally rich in folate
- voluntary fortification of foods with folic acid and promotion of these foods
- approval of a folate-NTD health claim for folate-rich foods meeting specified nutrition criteria.

Between the 1990s and 2000s, reported NTD rates in some states declined by between 10–30% (Victorian Perinatal Data Collection Unit 2005). However, reductions were inconsistent across all ethnic and socioeconomic groups (AIHW: Macaldowie & Hilder 2011). Aboriginal women were twice as likely as non-Aboriginal women to have a baby with an NTD, and the decline in NTDs was mainly confined to the non-Aboriginal population (Bower et al. 2004).

Many women of child-bearing age were still having inadequate folic acid intakes, largely due to:

- the considerable number of unplanned pregnancies
- lack of knowledge regarding the benefits of folic acid

- knowledge not always equating to behaviour change
- barriers to supplement use, including cost, access and compliance issues.

## Mandatory folic acid fortification

Mandatory folic acid fortification was introduced in Australia to further increase folic acid intakes in women of child-bearing age (16–44 years) and thereby further reduce the incidence of NTDs in the population (FSANZ 2006b).

Bread was selected as the food vehicle for this mandatory requirement because it was widely consumed by the target population (women aged 16–44). From September 2009, folic acid had to be added to all wheat flour for making bread in Australia, except for all flour and bread represented as ‘organic’.

Standard 2.1.1 *Cereals and cereal products* of the Code requires the addition of 2–3 milligrams (mg) of folic acid per kilogram (kg) of wheat flour for making bread in Australia. This mandatory requirement does not apply in New Zealand.

Fortification at this level was expected to result in an average value of 120 micrograms (µg) of folic acid per 100 grams (g) of bread in Australia (about three slices) and to increase mean folic acid intake by a further 100 µg among women aged 16–44 (to 208 µg/day). This increase in intake was estimated to further reduce the number of NTD-affected pregnancies by 14–49 per year (an average decrease of 14%), when combined with existing voluntary folic acid permissions and current levels of supplement use (FSANZ 2006b).

### Box 1.2: Types of neural tube defects

#### Anencephaly

Total or partial absence of the upper part of the brain, the bones of the top of the skull, and the covering skin. There may be disorganisation or damage to the remaining brain tissue.

#### Encephalocele

Exposure of part of the brain or the tissues through an opening in the skin and skull bones.

#### Isolated neural tube defects

Neural tube defects with either no coexisting congenital anomalies (birth defects) or with coexisting anomalies directed related to the neural tube defect.

#### Non-isolated neural tube defects

Neural tube defects with coexisting congenital anomalies not directly related to the neural tube defect. Isolated or non-isolated neural tube defects are thought to originate from separate causes. It is generally thought sufficient folate (folic acid) will reduce isolated neural tube defects but have little effect on non-isolated neural tube defects.

#### Spina bifida

Exposure of the spinal cord, nerves of the tissue that covers them through an opening in the skin and one or more of the backbones (the spinal column). The exposed nerves and spinal cord may be disorganised or damaged.

*Source:* Adapted from Hilder (2016).

## 1.2 Iodine

Iodine is required for the synthesis of thyroid hormones, which play a key role in regulating metabolism and influence fetal and childhood physical and cognitive development (WHO 2007). Therefore, adequate iodine nutrition is particularly important for pregnant women and young children.

Historically, New Zealand and some parts of Australia, notably Tasmania, had low iodine intakes partly due to low soil iodine levels. Over the last decade, several studies had shown a re-emergence of iodine deficiency in parts of Australia and New Zealand. National studies in both countries further confirmed that both populations were mildly deficient (Li et al. 2008; Parnell et al. 2003). The reasons for the re-emergence of iodine deficiency are not fully understood but may be related to:

- decreases in iodised salt consumption
- lower iodine levels in milk, resulting from the dairy industry ceasing to use iodine-based sanitisers
- variations in iodine levels in drinking water.

### Mandatory iodine fortification

Mandatory iodine fortification was introduced in Australia and New Zealand to improve the iodine status of the population, particularly young children, women of child-bearing age (16–44 years) and breastfeeding women (FSANZ 2008a). Additional iodine was to be provided to reduce the risk of physical and mental impairment in children, and thyroid disease across all age groups.

Bread was again selected as the food vehicle for this mandatory requirement because of its wide consumption within the population, including the target groups. From September 2009 in New Zealand and from October 2009 in Australia, Standard 2.1.1 of the Code required the use of iodised salt instead of non-iodised salt in bread, except for in bread represented as 'organic'.

The level of salt iodisation required is between 25–65 mg of iodine per 1 kg of salt, the same level as the current voluntary permission for iodised salt. Fortification at this level was expected to result in an average of 46 µg iodine per 100 g of bread (from iodised salt and other ingredients) and to increase intakes by 46 µg and 73 µg among women of child-bearing age in Australia and New Zealand, respectively, and 38 µg per day among children aged 2–3 in Australia. It was also expected to reduce the prevalence of inadequate iodine intake from 43% of the population to 5% in Australia (FSANZ 2008a, 2008c).

## 1.3 Baseline data for monitoring mandatory fortification

The AHMAC commissioned the Australian Institute Health and Welfare (AIHW) to prepare relevant baseline data for monitoring mandatory folic acid and iodine fortification. In June 2011, the AIHW completed the necessary work to establish a monitoring program through the delivery of the following reports:

- *Mandatory folic acid and iodine fortification in Australia and New Zealand: baseline report for monitoring* (the Baseline Report) (AIHW 2011a)

- *Mandatory folic acid and iodine fortification in Australia and New Zealand: supplement to the baseline report for monitoring* (the Baseline Supplement Report) (AIHW 2011b).

These reports provided baseline data for monitoring mandatory folic acid and iodine fortification and helped to inform this second stage of the review (the population health effects of mandatory fortification).

## 1.4 Nutrient reference values for folic acid and iodine intakes

Nutrient reference values (NRVs) are nutritional guidelines used to assess the adequacy and safety of intake for various nutrients, based on currently available scientific knowledge. In this review, the following NRVs were used to assess folate (folic acid) and iodine intakes:

- *estimated average requirement* (EAR) – a daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group. The EAR is used to estimate the prevalence of inadequate intakes within a population
- *upper level of intake* (UL) – the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases (NHMRC & NZMoH 2006).

### Folate

The specific NRVs for folate relate to the different forms found in food; namely, dietary folate equivalents (DFEs) and folic acid (Box 1.3). The folate NRV for estimating nutritional adequacy (the EAR) refers to DFEs and not folic acid. In contrast, the NRV for assessing the UL for folate is based on folic acid only and not DFEs. The UL is based on neurological effects seen with Vitamin B<sub>12</sub> deficiency that may be observed in older adults with high intakes of folic acid (NHMRC & NZMoH 2006). The EAR and UL for folate for different subpopulations are included in appendix tables C1 and C2, respectively (Appendix C).

Although no adverse effects have been observed with the amounts of DFEs normally consumed in foods or fortified foods, there is evidence of adverse effects associated with high supplemental intakes of folic acid (NHMRC & NZMoH 2006). This report considers both folic acid and DFE intakes in order to assess both nutritional adequacy and safety.

### **Box 1.3: Folate, folic acid and dietary folate equivalents—what’s the difference?**

**Folate**—a B group vitamin needed for healthy growth and development, including of the nervous system. Naturally occurring folate is found in a wide variety of foods, such as green leafy vegetables, cereals, fruits and grains.

**Folic acid**—the synthetic form of folate used in supplements or added to food. Since the 1960s, there has been mounting evidence that increasing folic acid intake in early pregnancy is associated with a decreased prevalence of neural tube defects. The current folic acid recommendation to help prevent neural tube defects is:

Women capable of, or planning, pregnancies should consume additional folic acid as a supplement or in the form of fortified foods at a level of 400 µg/day folic acid for at least one month before and three months after conception, in addition to consuming food folate from a varied diet (NHMRC & NZMoH 2006:99).

**Dietary folate equivalents**—a measure that accounts for the difference in bioavailability between the different forms of folates. The bioavailability of folates in food is about 50–60%, whereas folic acid in fortified foods or supplements is about 85% when taken with meals, and 100% when taken on an empty stomach. Dietary folate equivalents are used as the basis to assess the adequacy of a population’s folate intake.

1 µg of dietary folate equivalent = 1 µg food folate  
= 0.5 µg folic acid on an empty stomach  
= 0.6 µg folic acid with meals or as fortified foods.

## **Iodine**

Iodine intakes were compared with the EAR for iodine for each population subgroup. Women of child-bearing age were assessed separately due to their specific requirements during pregnancy and breastfeeding. The UL for iodine is based on elevated thyroid stimulating hormone concentrations, which is an adaptive response to increased iodine intakes that is reversible, with the UL for children and adolescents extrapolated from the adult recommendation on a body weight basis (NHMRC & NZMoH 2006). The EAR and UL for iodine for different subpopulations are included in Table C3 (Appendix C).

## **Review of nutrient reference values**

At the time of publication, the Department of Health, in conjunction with the New Zealand Ministry of Health, was reviewing the NRVs to ensure they remained relevant, appropriate and useful. The initial focus was on sodium, iodine and fluoride. There are no time frames on the availability of the new NRVs; therefore, the current NRVs are used in this review.

## **1.5 Biomedical reference values for folic acid and iodine status**

### **Folate**

Measures of folate status include assessing folate in serum and red blood cells. Serum folate levels reflect recent dietary folate intake, whereas red blood cell folate levels are less sensitive to dietary fluctuations intakes and reflect folate stores.



The mean or median value of serum and red blood cell folate can be used to assess changes in folate status over time. The current international recommendation is that, while both serum and red blood cell folate concentrations are useful for monitoring changes in folate status, red blood cell folate is preferred, given there is less biological variation and because a threshold has been established for NTD risk. The microbiological assay is recommended to measure folate concentrations (WHO 2015).

The World Health Organization (WHO) specifies that, at the population level, red blood cell folate concentrations should be above 400 nanograms per millilitre (ng/mL) (906 nanomoles per litre [nmol/L]) in women of reproductive age to achieve the greatest reduction of NTDs. This recommendation is based on the microbiological assay for the analysis of folate (WHO 2015).

## Iodine

Urinary iodine excretion (UIE) provides an indication of recent iodine intake. The WHO, in collaboration with the United Nations Children's Fund and the International Council for Control of Iodine Deficiency Disorders, provides guidelines for assessing iodine deficiency disorders, and approaches for monitoring their elimination using median urinary iodine concentration (MUIC). For measuring population iodine status, the recommended MUIC for iodine adequacy is 100–199 µg/L (WHO 2007).

The criteria for assessing iodine nutrition in school-aged children and for pregnant women are outlined in tables C4 and C5 (Appendix C). As well as these criteria, the WHO also recommends that no more than 50% of a studied population be below 100 µg/L (mild deficiency), and no more than 20% be below 50 µg/L (moderate deficiency). The criteria for assessing iodine nutrition in adults are currently under review (Box 1.4).

An MUIC of more than 300 µg/L represents excessive iodine intake, and could pose a risk of adverse health consequences (iodine-induced hyperthyroidism, autoimmune thyroid diseases). For populations of pregnant women, an MUIC of more than or equal to 500 µg/L indicates excessive iodine intake (that is, in excess of the amount required to prevent and control iodine deficiency) (WHO 2007). There are no recommendations provided for young children or lactating women.

### Box 1.4: Assessing iodine nutrition in adults

The World Health Organization criteria for assessing population iodine status have been derived from the median urinary iodine concentration for school children, who have an average daily urine volume of 1.0 L. As there are no validated cut-offs for adults, the World Health Organization cut-offs are often applied to adults. However, adults often have a larger daily urine volume, assumed to be 1.5 L. This larger urine volume can dilute iodine concentrations and result in lower median urinary iodine concentrations. Therefore, caution is needed when assessing the iodine status of an adult population using the World Health Organization cut-offs. Further studies are currently being undertaken to validate the cut-offs for median urinary iodine concentration in adults (Zimmermann & Andersson 2012).

Iodine status can also be measured through blood constituents, including thyroxine and thyroglobulin. Iodine deficiency reduces the ability of the body to produce thyroxine, resulting in lower circulating levels in deficient populations. Reference ranges for thyroxine have been established for populations with normal thyroid function; for children aged 6–10, the range is between 75–154 nmol/L (Zurakowski et al. 1999).

Thyroglobulin is a thyroid protein that is a precursor in the synthesis of thyroid hormones. Iodine deficiency triggers increased serum thyroglobulin levels. Thyroglobulin levels reflect iodine nutrition over a period of months or years, compared with MUIC which assesses more immediate iodine intake (WHO 2007). Serum thyroglobulin is normally below 10 µg/L in individuals with normal thyroid function. Higher thyroglobulin levels indicate increased risk of iodine deficiency (Zimmermann 2008).

## 1.6 Data sources used in this report

The data for monitoring mandatory folic acid and iodine fortification in Australia and New Zealand are summarised in tables 1.1–1.3. The tables include details on each data source and how the data were used to answer the key monitoring questions, which includes the baseline data used for comparison (where applicable) (Box 1.1). The usefulness of each data source for national monitoring is noted, and further details provided in Chapter 5.

One main data source is used for each monitoring question, with the focus on representative national data. However, additional data sources have been included to complement the primary data source where required.

In relation to the baseline data source, there were some changes to the data reported in *Mandatory folic acid and iodine fortification in Australia and New Zealand: baseline report for monitoring* (AIHW 2011a). These changes are:

- revised estimates of folic acid and iodine intake in Australia, as reported by FSANZ, to accommodate enhanced methods; however, the results were of a similar magnitude
- more comprehensive data on NTD incidence pre-fortification, as reported by Hilder (2016).

Additional subnational surveys were previously used to supplement the baseline findings estimates; however, these were not included as part of this review, due to funding availability.

**Table 1.1: Post-fortification data for monitoring mandatory folic acid fortification in Australia**

Key monitoring question and measurement	Data source	Notes
Has the level of folic acid in our food supply increased? <i>Mean folic acid level of bread</i>	Food Standards Australia New Zealand (FSANZ) bread analytical surveys	<ul style="list-style-type: none"> <li>Two-phase national survey was undertaken in 2010 and 2012.</li> <li>Data were assessed against the predicted increase in folic acid in bread when developing the mandatory fortification requirement.</li> </ul>
Are the food industries adequately complying with the mandatory fortification standards?	Catalyst Ltd review	<ul style="list-style-type: none"> <li>Catalyst Ltd reviewed compliance with, and enforcement impacts of, the mandatory fortification of bread with folic acid.</li> <li>Findings were based on feedback from 6 Australian millers and 8 bakers, representing over 95% of the bread market.</li> </ul>
Have folic acid intakes of women of child-bearing age increased? <i>Mean folic acid intakes in women aged 16–44</i>	FSANZ 2014 dietary intake assessment Supporting information from the Australian Bureau of Statistics (ABS) 2011–12 National Nutrition and Physical Activity Survey	<ul style="list-style-type: none"> <li>FSANZ combined up-to-date data on the level of folic acid in bread (from the bread analytical surveys) with food consumption data from the 1995 National Nutrition Survey and the 2007 Australian National Children’s Nutrition and Physical Activity Survey.</li> <li>The most recent data from the ABS survey was not available at the time of the FSANZ analysis. Bread consumption appears to have decreased slightly since 1995 but is unlikely to have major impacts on folic acid intakes.</li> <li>Data were assessed against the predicted increase when developing the mandatory fortification requirement.</li> </ul>
Has the folate status of women of child-bearing age improved? <i>Mean red blood cell and serum folate</i>	ABS 2011–12 National Health Measures Survey (NHMS) ABS 2011–13 National Aboriginal and Torres Strait Islander Health Measures Survey (NATSIHMS)	<ul style="list-style-type: none"> <li>The ABS 2011–12 NHMS and 2011–13 NATSIHMS measured serum and red blood cell folate levels using the chemiluminescence immunoassay method.</li> <li>The cut-off for risk of neural tube defects is based on the microbiological folate method of analysis and is not appropriate to apply to the ABS data. As such, only mean serum and red blood cell folate levels are presented here.</li> <li>Pre-fortification data from the Child Determinants of Adult Health (CDAH) Study were compared with the 2011–12 NHMS data to outline possible changes post-mandatory fortification. The potential for participation bias in the CDAH Study limited the reliability of this comparison.</li> </ul>
Has the incidence of neural tube defects (NTDs) decreased? <i>NTD incidence per 10,000 conceptions that resulted in a birth</i>	<i>Neural tube defects in Australia, 2007–2011</i> (Hilder 2016)	<ul style="list-style-type: none"> <li>NTD data were available from New South Wales, Queensland, Western Australia, South Australia and the Northern Territory. This provides the most comprehensive NTD data available to date.</li> <li>New South Wales data lacked complete ascertainment and so separate analyses have been provided.</li> <li>The omission of Victorian, Tasmanian and Australian Capital Territory data means results may not be fully representative of the Australian population.</li> <li>Data were assessed against the predicted decrease when developing the mandatory fortification requirement.</li> </ul>
Does mandatory folic acid fortification result in adverse health effects for the population? <i>Proportion of the population with folic acid intakes above the upper level of intake</i>  <i>Cancer and all-cause mortality</i>	FSANZ 2014 dietary intake assessment  Systematic review by Mackerras et al. (2013)	<ul style="list-style-type: none"> <li>See ‘Notes’ on FSANZ 2014 dietary intake assessment for ‘Have folic acid intakes of women of child-bearing age increased?’</li> <li>The systematic review and meta-analysis examined the effects of folic acid on selected cancer outcomes in humans and all-cause mortality.</li> </ul>

**Table 1.2: Post-fortification data for monitoring mandatory iodine fortification in Australia**

Key monitoring question and measurement	Data source	Notes
Has the level of iodine in our food supply increased? <i>Mean iodine level of bread</i>	Food Standards Australia New Zealand (FSANZ) bread analytical surveys	<ul style="list-style-type: none"> <li>• Three-phase survey was undertaken in 2010, 2012 and 2013.</li> <li>• Data were assessed against the predicted increase in iodine in bread when developing the mandatory fortification requirement.</li> </ul>
Are the food industries adequately complying with the mandatory fortification standards?	Catalyst Ltd review	<ul style="list-style-type: none"> <li>• Catalyst Ltd reviewed compliance with, and enforcement impacts of, the mandatory fortification of bread with iodine.</li> <li>• Findings were based on feedback from 2 Australian salt manufacturers and 8 bakers, representing the major market providers.</li> </ul>
Have iodine intakes in the population increased, particularly in women of child-bearing age and young children? <i>Mean iodine intakes</i> <i>Proportion of the population with iodine intakes below the estimated average requirement</i>	FSANZ 2014 dietary intake assessment Supporting information from the Australian Bureau of Statistics (ABS) 2011–12 National Nutrition and Physical Activity Survey	<ul style="list-style-type: none"> <li>• FSANZ combined up-to-date data on the level of iodine in bread (from the bread analytical surveys) with food consumption data from the 1995 National Nutrition Survey and the 2007 Australian Children’s Nutrition and Physical Activity Survey.</li> <li>• The most recent data from the ABS survey were not available at the time of the FSANZ analysis. Bread consumption appears to have decreased slightly but is unlikely to have major impacts on folic acid intakes.</li> <li>• As well, the accurate measurement of iodine intake was problematic because the contribution of iodised salt used at the table and in cooking is difficult to quantify. Two models were used to account for discretionary salt use.</li> <li>• Data were assessed against the predicted increase/decrease when developing the mandatory fortification requirement.</li> </ul>
Has the iodine status of the population improved, particularly in women of child-bearing age and young children? <i>Median urinary iodine concentration (MUIC)</i>	ABS 2011–12 National Health Measures Survey ABS 2011–13 National Aboriginal and Torres Strait Islander Health Measures Survey	<ul style="list-style-type: none"> <li>• National MUIC data were available for respondents aged 5 and over.</li> <li>• Data were assessed against the World Health Organization cut-offs for iodine status and pre-mandatory fortification data from the National Iodine Nutrition Study.</li> </ul>
Has the iodine status of the population improved? <i>Iodine status</i>	Refer to information on nutrient status.	
Does mandatory iodine fortification result in adverse health effects for the population? <i>Proportion of the population with iodine intakes above the upper level of intake</i>	FSANZ 2014 dietary intake assessment	<ul style="list-style-type: none"> <li>• See ‘Notes’ on FSANZ 2014 dietary intake assessment for ‘Have iodine intakes in the population increased, particularly in women of child-bearing age and young children?’ .</li> </ul>

**Table 1.3: Post-fortification data for monitoring mandatory iodine fortification in New Zealand**

Key monitoring question and measurement	Data source	Notes
Has the level of iodine in our food supply increased? <i>Mean iodine level of bread</i>	New Zealand Ministry for Primary Industries (MPI) bread analytical surveys	<ul style="list-style-type: none"> <li>Two national surveys were undertaken in 2010 and 2012.</li> <li>Data were assessed against the increase in iodine in bread predicted when developing the mandatory fortification requirement.</li> </ul>
Are the food industries adequately complying with the mandatory fortification standards?	Catalyst Ltd review	<ul style="list-style-type: none"> <li>Catalyst Ltd reviewed compliance with, and enforcement impacts of, the mandatory fortification of bread with iodine.</li> <li>Findings were based on feedback from 1 New Zealand major salt manufacturer and 7 bakers.</li> </ul>
Have iodine intakes in the population increased, particularly in women of child-bearing age and young children? <i>Mean iodine intakes</i> <i>Proportion of the population with iodine intakes below the estimated average requirement</i>	MPI data	<ul style="list-style-type: none"> <li>For adults, data were from 301 randomly sampled people from Dunedin and Wellington in 2012; 24-hour urinary iodine excretion data were used to estimate iodine intakes. <ul style="list-style-type: none"> <li>Data may not be representative of the population due to the sample size. Different methodologies used to measure iodine intakes (24-hour excretion versus food intakes) may make it difficult to compare with pre-fortification estimates.</li> <li>Results from the 2014–15 New Zealand Health Survey, expected by mid-2016 for the population aged 15 and over, will be an important adjunct to existing New Zealand data on iodine intake.</li> </ul> </li> <li>For children, MPI combined up-to-date data on the level of iodine in bread (from the bread analytical surveys) with food consumption data from the 2002 Children’s Nutrition Survey. <ul style="list-style-type: none"> <li>The accurate measurement of iodine intake is problematic due to the contribution of discretionary iodised salt use. Three models were used to account for this.</li> </ul> </li> <li>Data were assessed against the predicted increase/decrease when developing the mandatory fortification requirement.</li> </ul>
Has the iodine status of the population improved, particularly in women of child-bearing age and young children? <i>Median urinary iodine concentration (MUIC)</i>	MPI data for adults Study by Skeaff & Lonsdale-Cooper (2013) for children	<ul style="list-style-type: none"> <li>MUIC data for adults were based on the same sample of 301 randomly sampled people from Dunedin and Wellington in 2012 (as for iodine intake). <ul style="list-style-type: none"> <li>The sample size means these data may not be representative of the population. Results from the 2014–15 New Zealand Health Survey will be an important adjunct to the existing data on iodine status.</li> </ul> </li> <li>MUIC data for children were from the study by Skeaff &amp; Lonsdale-Cooper (2013) who randomly selected 147 children aged 8–10 from 2 New Zealand cities. <ul style="list-style-type: none"> <li>The sample size means these data may not be representative of the population. The 2014–15 New Zealand Health Survey does not include people aged under 15 and so will not assist in providing further information on iodine status in children.</li> </ul> </li> <li>Data were assessed against the World Health Organization cut-offs for iodine status and compared with data from the 2008–09 New Zealand Adult Nutrition Survey. Differences in urinary volumes between adults and children may result in an underestimate of iodine adequacy in adults.</li> </ul>
Has the iodine status of the population improved? <i>Iodine status</i>	Refer to information on nutrient status.	
Does mandatory iodine fortification result in adverse health effects for the population? <i>Proportion of the population with iodine intakes above the upper level of intake</i>	MPI data	<ul style="list-style-type: none"> <li>See ‘Notes’ on MPI data for ‘Have iodine intakes in the population increased, particularly in women of child-bearing age and young children?’</li> </ul>

## 1.7 Structure of this report

Besides this introductory chapter, this report contains the following chapters:

- Chapter 2 – Mandatory folic acid fortification in Australia, which assesses changes post-implementation of mandatory folic acid fortification in Australia
- Chapter 3 – Mandatory iodine fortification in Australia, which assesses changes post-implementation of mandatory iodine fortification in Australia
- Chapter 4 – Mandatory iodine fortification in New Zealand, which assesses changes post-implementation of mandatory iodine fortification in New Zealand
- Chapter 5 – Discussion, which discusses the key findings, limitations and further steps for monitoring.

Each chapter is structured around the main components of the mandatory food fortification monitoring framework and associated key monitoring questions (see Box 1.1).

Supplementary tables of the data underlying the figures in this report are available at <http://www.aihw.gov.au/publication-detail/?id=6012955435>.

## 2 Mandatory folic acid fortification in Australia

### 2.1 Food composition

**Key monitoring question:** *Has the level of folic acid in our food supply increased?*

**Data sources:** 2010 and 2012 FSANZ bread analytical surveys.

**Key findings:**

Post-mandatory fortification:

- The mean level of folic acid in commonly consumed bread ranged from 134–200 µg per 100 g.
- These levels were substantially higher than the 20–29 µg/100 g bread at baseline and exceeded the 120 µg/100 g bread predicted when developing the mandatory fortification requirement.

#### Bread analytical surveys

As a part of ongoing monitoring activities, FSANZ conducted several surveys of bread and bread products, as part of the Implementation Subcommittee on Food Regulation National Coordinated Food Survey Plan, to determine the levels of folic acid and iodine in commonly consumed breads available in Australia. The folic acid component of the survey was conducted in two phases, first in 2010 and again in 2012 (FSANZ 2015b).

Phase 1 of the survey, conducted in 2010, took 100 samples of bread and bread products from major supermarkets and bread shops from capital cities in all Australian states and territories. Samples were grouped into 7 bread types (white, wholemeal, multigrain and seeds, flat, English muffins, organic and gluten free), with most samples coming from the 3 most commonly consumed bread types (white, wholemeal and multigrain).

Phase 2, conducted in 2012, sampled 96 breads selected from the 3 most commonly consumed bread types from all Australian states and territories. As well as the commercial breads sampled, FSANZ prepared 4 samples of white, wholemeal and multigrain bread made with unfortified wheat flour for analysis as blank samples. The blank samples were used to assess the background amount of folic acid detected using unfortified wheat flour with this analytical testing procedure.

Folic acid values from Phases 1 and 2 for the most commonly consumed bread types were incorporated into the Australian food composition database compiled by FSANZ and used for modelling folic acid and DFE intakes (see Section 2.2).

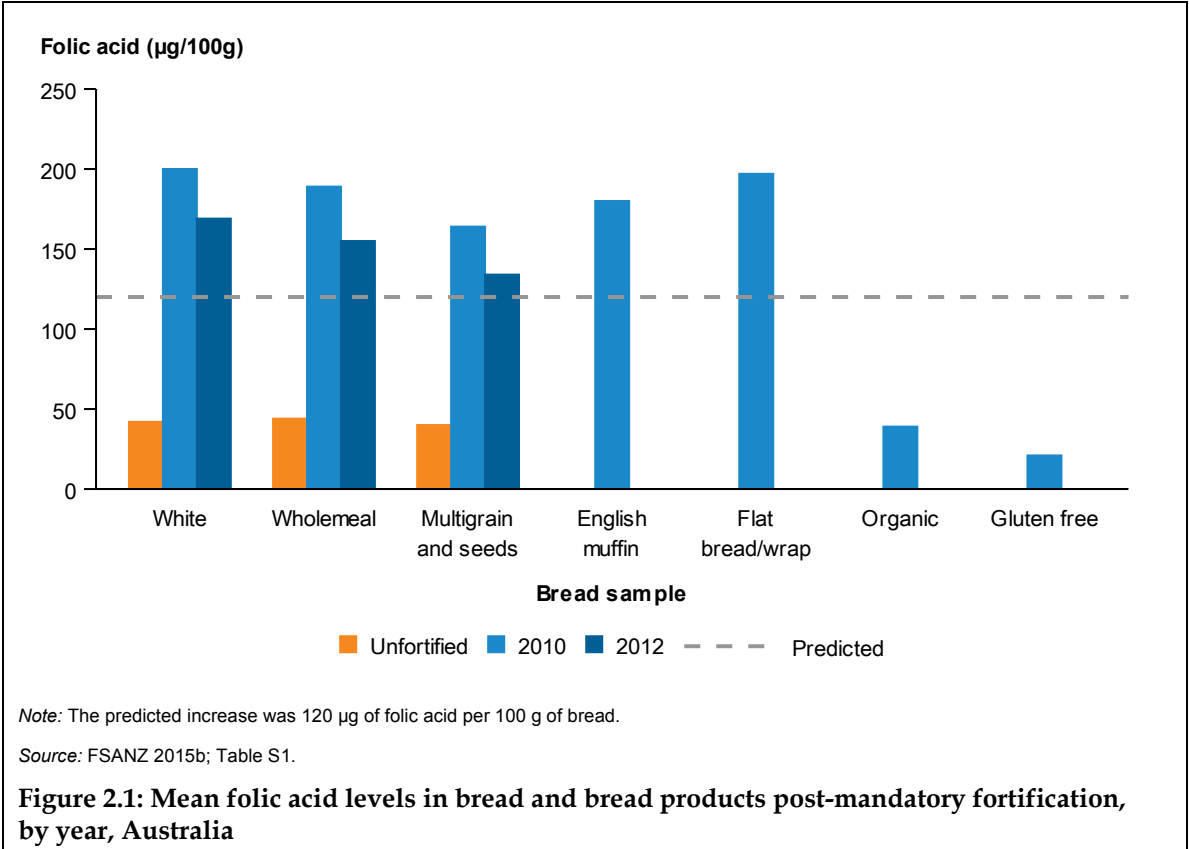
#### Results

Of the most commonly consumed bread groups, mean folic acid levels ranged from 134–200 µg per 100 g of bread across the survey periods (Figure 2.1). This level exceeded the estimate of 120 µg/100 g of bread initially predicted when developing the mandatory fortification requirement (FSANZ 2007) and is substantially higher than the 20–29 µg/100 g of bread at baseline (FSANZ 2006b).

All sampled bread and bread products mandated to contain folic acid were shown to have folic acid levels that indicate the use of folic acid fortified wheat flour. Organic and gluten-free breads were not expected to contain fortified wheat flour and results show mean folic acid at levels expected for unfortified products.

Phase 1 samples contained higher folic acid, on average, than Phase 2 samples. Across both phases, there was a trend for white bread to contain the highest folic acid levels, followed by wholemeal, and then multigrain and seeds. The differences between surveys and bread types are not considered an issue. Possible reasons for differences in the analysed levels of folic acid include:

- the proportion of folic acid fortified flour used in a bread recipe
- the influence of various constituents, such as wholegrain flour or seed-containing dough, displacing folic acid containing flour in a recipe
- possible folic acid degradation during the dough proving stage of bread production
- water loss from the dough during baking
- heat degradation of folic acid during the baking process (FSANZ 2015b).





## 2.2 Food industry compliance

**Key monitoring question:** *Are the food industries adequately complying with the mandatory fortification standards?*

**Data source:** 2015 Catalyst Ltd review.

**Key finding:**

- Post-mandatory fortification, Australian milling and baking businesses have systems in place to ensure compliance with the mandatory folic acid fortification requirement.

### Compliance and enforcement review

For Stage 1 of the mandatory fortification review, Catalyst Ltd was commissioned to review compliance with, and enforcement impacts of, the mandatory fortification of bread with folic acid and iodine (Catalyst Ltd 2015). The main food industries impacted by mandatory folic acid fortification requirements are flour millers and bread producers. This review was based on feedback from 6 Australian millers and 8 Australian bakers, representing over 95% of the bread market.

### Results

All mills reported having quality assurance programs and systems in place to ensure compliance with the mandatory folic acid requirement. Folic acid levels were verified using a combination of measures, including engineering practices (such as the automatic folic acid feeder processes and variance alarms), auditing practices and testing protocols. All mills had external third party audits of their systems.

All baking companies reported having quality management systems in place specifying the flour requirements. Suppliers had contractual requirements to meet product specifications. Some companies required a certificate of analysis and others also tested folic acid levels in products. Bread and baked goods manufacturers supplying products to supermarkets reported being subject to third party external auditing. Respondents not subject to external auditing reported having internal auditing practices in place.

Based on millers' protocols for the amounts of flour milled and folic acid added, Catalyst estimates an increase of 2.5–2.7 tonnes of folic acid per annum in the Australian food supply since 2009, as a result of mandatory folic acid fortification.

## 2.3 Nutrient intake

**Key monitoring question:** *Have folic acid intakes in women of child-bearing age increased?*

**Data sources:**

- FSANZ's 2014 dietary intake assessment.
- Supporting information from the Australian Bureau of Statistics (ABS) 2011–12 National Nutrition and Physical Activity Survey (NNPAS).

**Key findings:**

Post-mandatory fortification:

- All population groups increased their estimated mean folic acid intake.
- Estimated mean folic acid intake for women aged 16–44 increased by 145 µg/day (102 µg to 247 µg/day; a 142% increase), which is greater than the predicted increase of 100 µg/day.
- Aboriginal and Torres Strait Islander people had higher estimated mean folic acid intakes than the general Australian population.
- The contribution of regular breads and rolls to estimated folic acid intake more than doubled for women of child-bearing age and adults aged 19 and over. Regular breads and rolls became the largest contributor to estimated folic acid intakes for children aged 2–16.
- Yeast and other extracts and breakfast cereals continued to be important sources of folic acid.
- Despite low levels of general knowledge about mandatory folic acid fortification, reported consumption of fortified bread products remains high in the population.

### Dietary folic acid/folate intake

FSANZ conducted a dietary intake assessment to estimate folic acid intakes for the Australian population after the implementation of mandatory folic acid fortification (FSANZ 2015b). This assessment determined adequacy of folic acid intake for the target population (women of child-bearing age).

FSANZ also calculated the population's intake of DFEs, which considers intake of folates that occur naturally in foods and synthetic folic acid through fortification. Assessment of DFEs is recommended for planning and evaluating the adequacy of the population's folate intake and can be used to demonstrate the effect of mandatory folic acid fortification on folate intake across the population.

FSANZ used its customised Dietary Modelling of Nutritional Data (DIAMOND) program for the analysis (see Appendix D). The weighted mean folic acid level in all breads sampled during the two phases of the FSANZ bread surveys were incorporated into its food composition database to provide current data on folic acid levels in the food supply (see Section 2.1). These revised food composition data, together with food consumption data from the 1995 National Nutrition Survey (NNS) and the 2007 Australian National Children's Nutrition and Physical Activity Survey (2007 Children's Survey), were used to estimate folic acid and DFE intakes.

FSANZ used these nutrition surveys to estimate baseline folic acid intakes and predict future intakes when developing the mandatory fortification requirement. Combined with updated

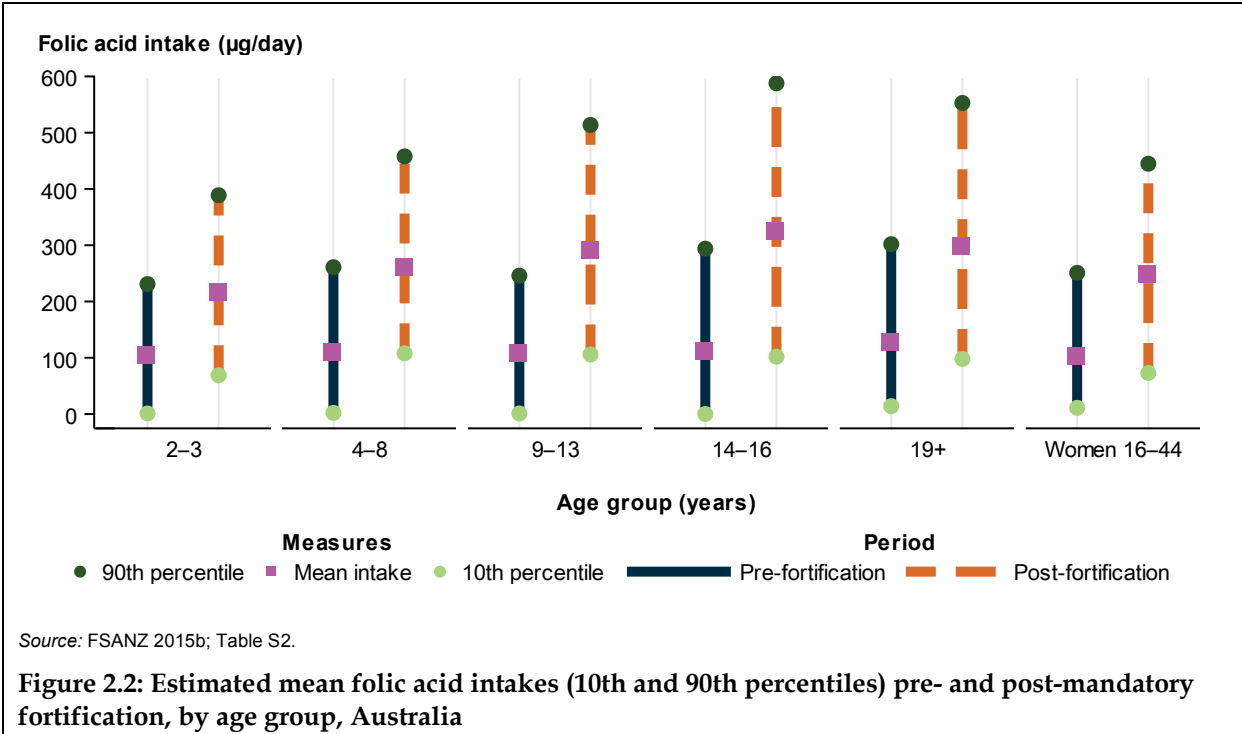
folic acid data (from the 2010 and 2012 bread surveys), this provided the best available methodology for comparing the impact of mandatory folic acid fortification with pre-fortification levels. Although more recent food consumption data are available from the ABS 2011–12 NNPAS, these data were not available for analysis in DIAMOND and so could not be used in the FSANZ dietary assessment.

FSANZ incorporated data from the 2007 Children’s Survey on supplement use for children aged 2–16 to model two different folic acid and DFE consumption scenarios to see what impact, if any, supplement intakes have on total nutrient intake. No data on supplement use were available for adult respondents in the 1995 NNS. Mean folic acid data were based on the average of 2 days’ food consumption data, and estimated 10th and 90th percentile population intakes were presented to demonstrate high and low consumers of folic acid (see Appendix D for details of dietary intake methodology).

**Results**

**Change in folic acid intake**

Estimated mean folic acid intake increased across all population groups post-mandatory folic acid fortification in September 2009 (Figure 2.2). Mean folic acid intake for women aged 16–44 increased by 145 µg/day, from 102 to 247 µg/day (a 142% increase), greater than the predicted increase of 100 µg/day. Changes also occurred for children aged 2–16 and adults aged 19 and over, with intakes increasing by 156% and 134%, respectively (108 to 277 µg/day and 127 to 297 µg/day). The 10th and 90th percentiles of estimated folic acid intakes across the population groups increased markedly following fortification.

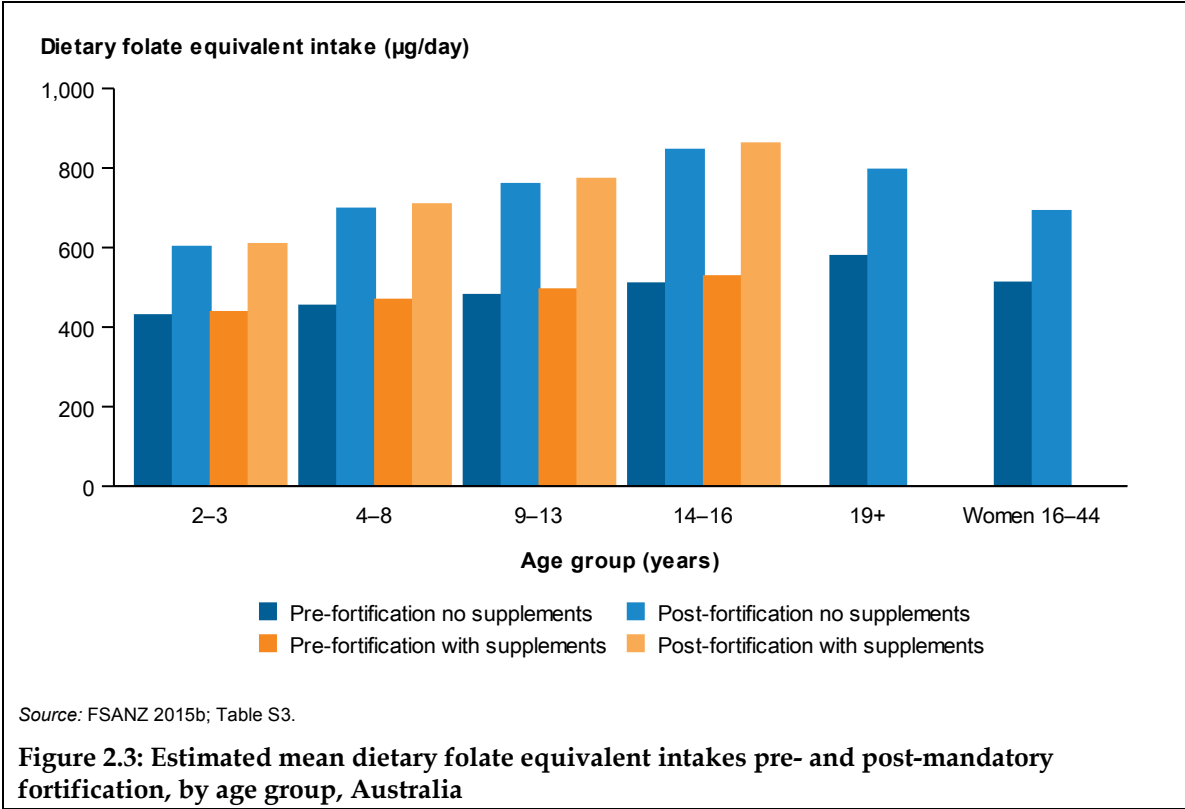


**Change in DFE intake**

Estimated DFE intake increased across all groups following implementation of mandatory fortification (Figure 2.3). For the target population (women aged 16–44), mean DFE intake increased by 35%, from 512 to 692 µg/day. A similar increase (37%) occurred for adults aged

19 and over; however, larger increases (56%) were seen for children aged 2–16, where DFE intake increased from 472 to 737 µg/day.

When considering supplement use in children aged 2–16, estimated DFE intake increased by 14 µg/day pre-fortification and 13 µg/day post-fortification (2% and 3% increase, respectively). The small impact of supplement use on DFE intake estimates is likely due to the low level of reported supplement use in the 2007 Children’s Survey (12% of children).

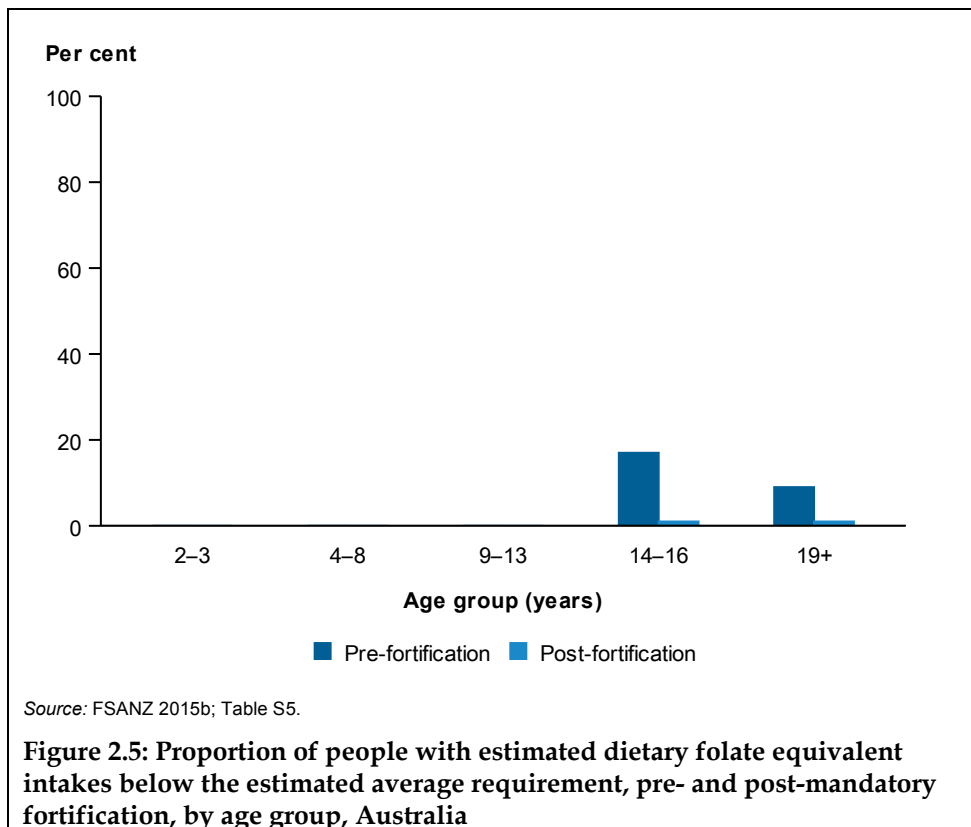
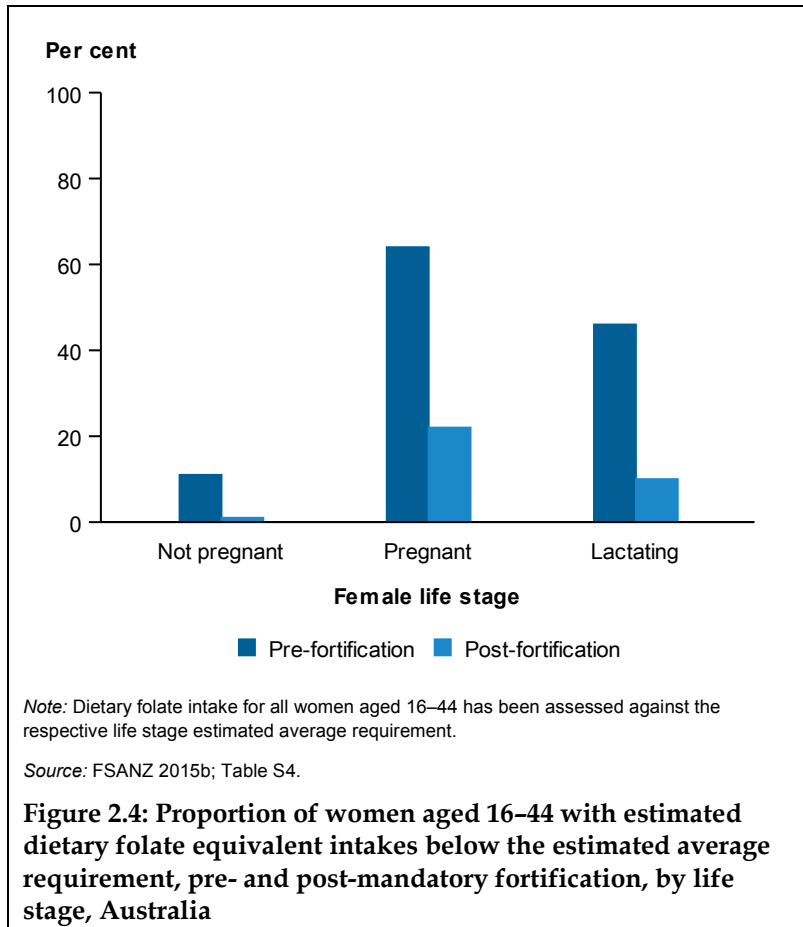


**Adequacy of folate intake**

Post-mandatory fortification estimates show a substantial decrease in the proportion of the population with inadequate DFE intakes (below the EAR for DFEs). The EAR for women is defined by the requirements for special life stages. The EAR for non-pregnant women is 320 µg/day but increases to 520 µg/day for pregnant women and 450 µg/day for breastfeeding women, to account for the increased requirements during these periods.

Before mandatory fortification, 11% of all women aged 16–44 had estimated DFE intakes below the EAR for non-pregnant women; 64% were below the EAR for pregnant women, and 46% were below the EAR for breastfeeding women. Improved intakes post-fortification reduced the prevalence of insufficient intake, and estimates showed that all but 1% of women aged 16–44 met the EAR for non-pregnant women. However, 22% and 10% of women aged 16–44 were still below the EAR for pregnancy and breastfeeding, respectively (Figure 2.4).

Pre-mandatory fortification, most children met or exceeded the DFE EAR for their age range. For children aged 14–16 pre-mandatory fortification, 17% had estimated intakes below the EAR and this fell to less than 1% post-mandatory fortification. For adults aged 19 and over, pre-mandatory fortification, 9% had intakes below the EAR and this fell to 1% post-mandatory fortification (Figure 2.5).

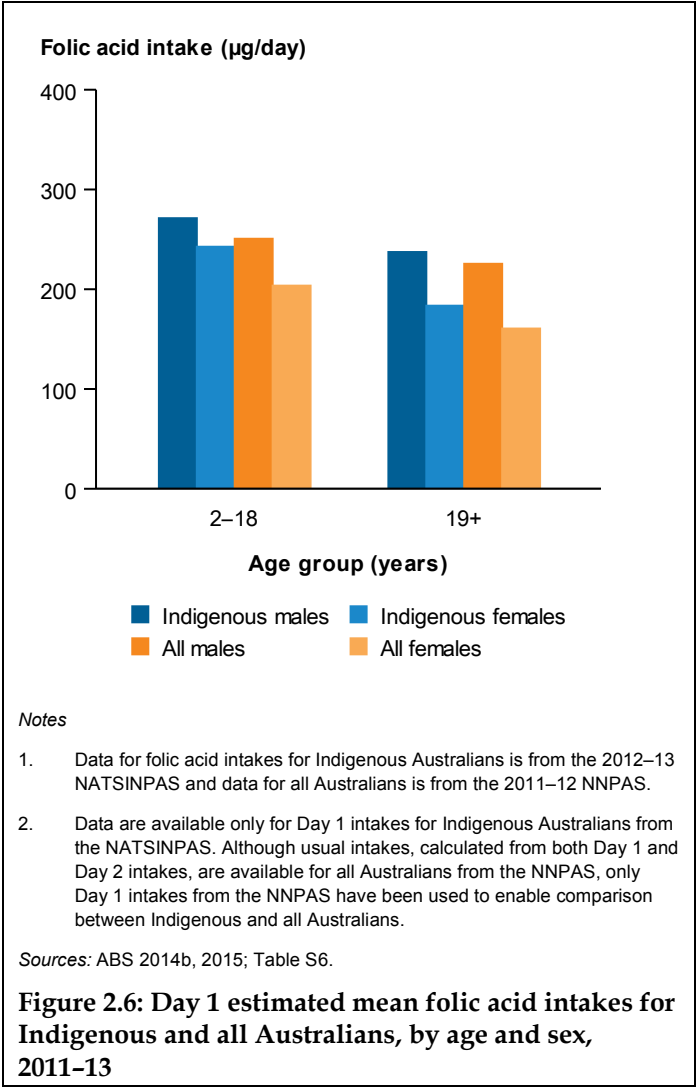


**Folic acid and DFE intake for Aboriginal and Torres Strait Islander people**

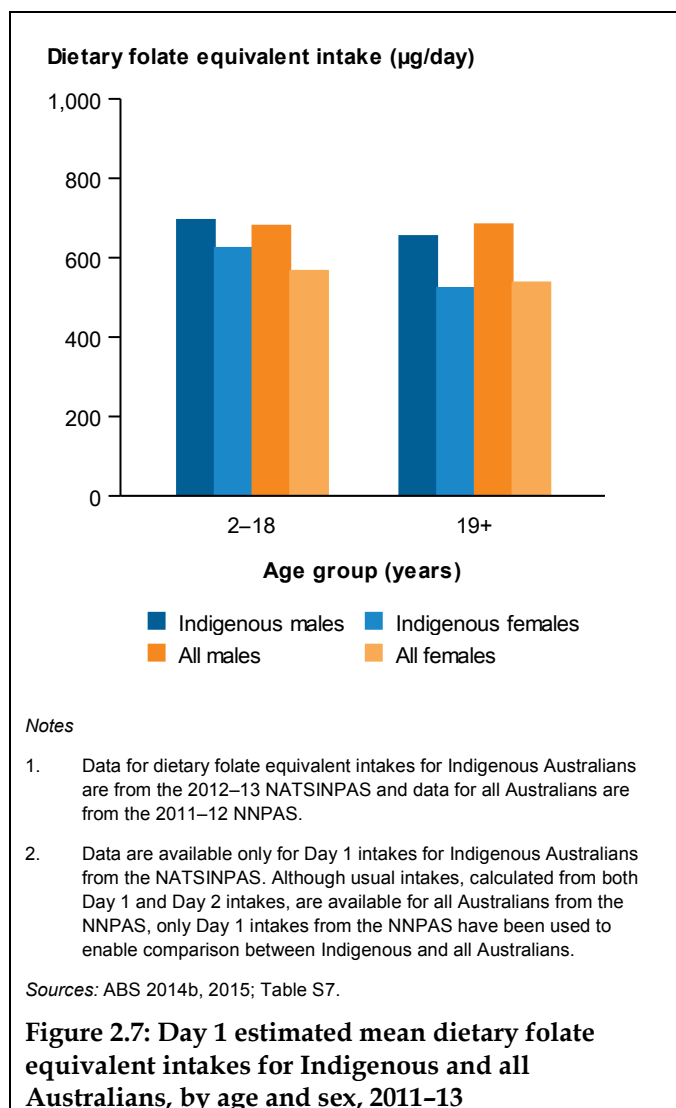
During the development of the mandatory fortification requirement, Aboriginal and Torres Strait Islander women of child-bearing age were identified as a target subgroup, given that previous efforts to reduce NTDs in this population had been unsuccessful. However, specific nutrient intake data for this group were unavailable at the time (FSANZ 2006a). Summary data from the 2012–13 ABS National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey (NATSINPAS) provide an indication of folic acid and DFE intake for Indigenous Australians. Data for the comparator group (all Australians) comes from the 2011–12 NNPAS (1-day intakes).

Since 2000, flour fortified with iron, thiamine and folic acid (Jackaroo Flour) has been supplied to stores in remote communities in North Queensland and the Northern Territory. Therefore, the nutrient profile used to estimate folic acid intakes for people living in remote areas in the NATSINPAS was modified to reflect this fortification.

Indigenous Australians had higher estimated mean folic acid intake than all Australians, for both adults and children (Figure 2.6). Across both population groups and all age groups, there was a trend for males to have higher folic acid intakes than females. Australian men aged 19 and over had an estimated mean folic acid intake of 226 µg/day compared with 161 µg/day for women. For Indigenous Australians aged 19 and over, men consumed 237 µg/day compared with 184 µg/day for women.



While estimated DFE intakes for Indigenous Australian children aged 2–18 were higher than those for all Australian children, this trend was not observed for the population aged 19 and over (Figure 2.7).



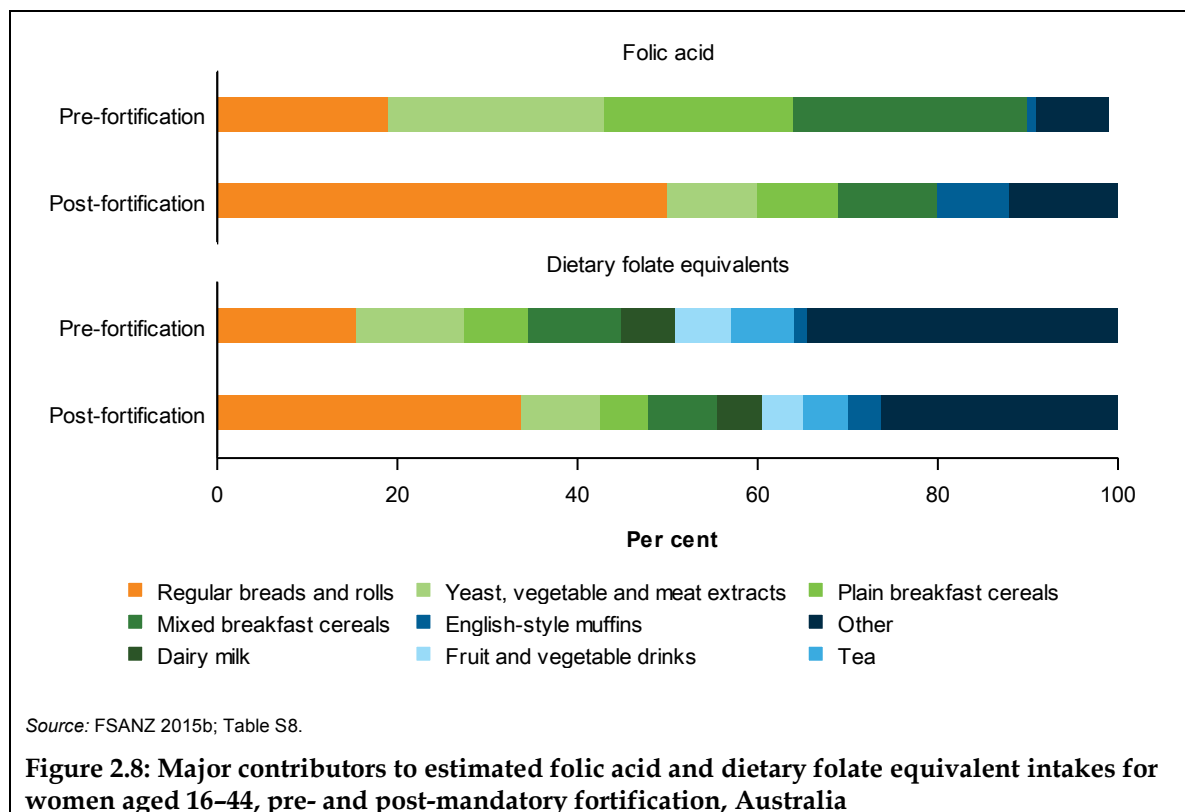
## Food contributors to folic acid intake

The FSANZ dietary intake assessment was used to investigate the foods contributing to folic acid and DFE intake pre- and post-mandatory fortification.

## Results

### Women of child-bearing age (target population)

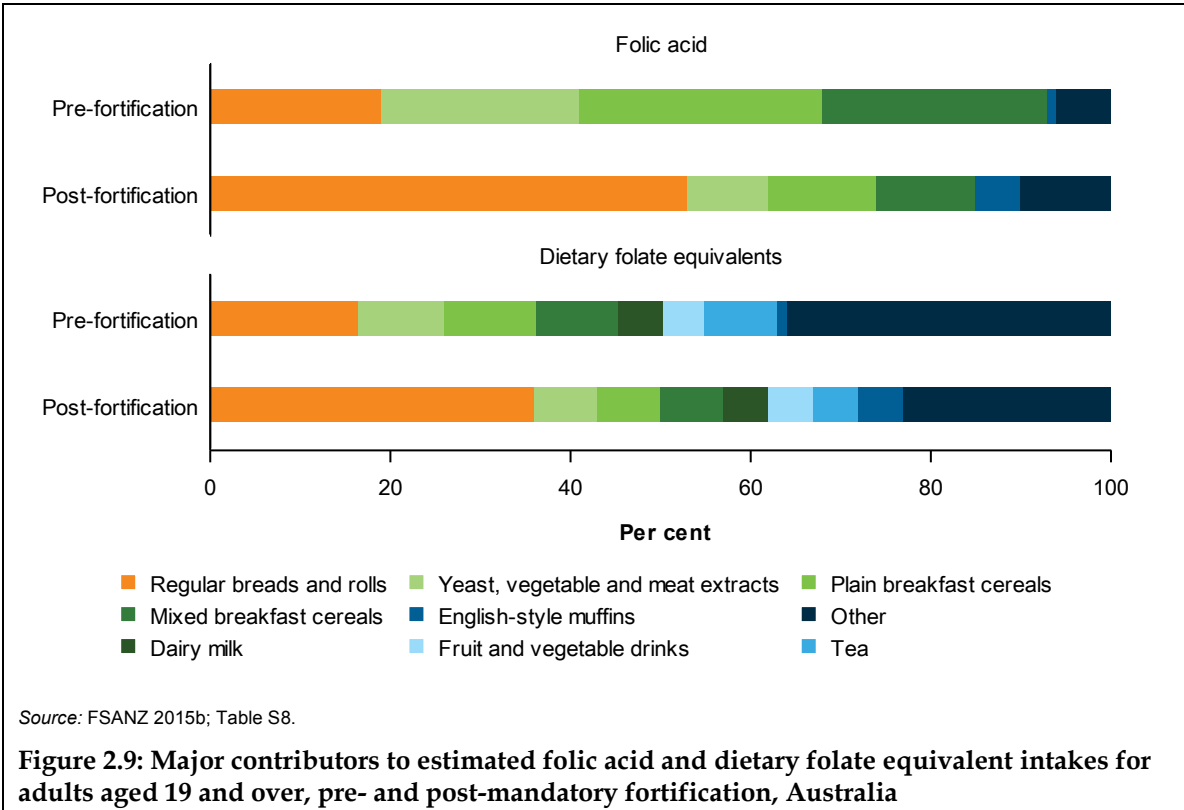
Pre-mandatory fortification, regular breads and rolls, breakfast cereals and yeast and other extracts were the primary contributors to estimated folic acid and DFE intake for women aged 16–44 (Figure 2.8). Post-fortification, the contribution from regular breads and rolls more than doubled for both folic acid and DFEs, from 19% to 50% and from 15% to 34%, respectively, with subsequent decreases in the percentage contributions from other foods. However, breakfast cereals and yeast and other extracts continue to be important sources of folic acid post-fortification.



### Adults and children (non-target population)

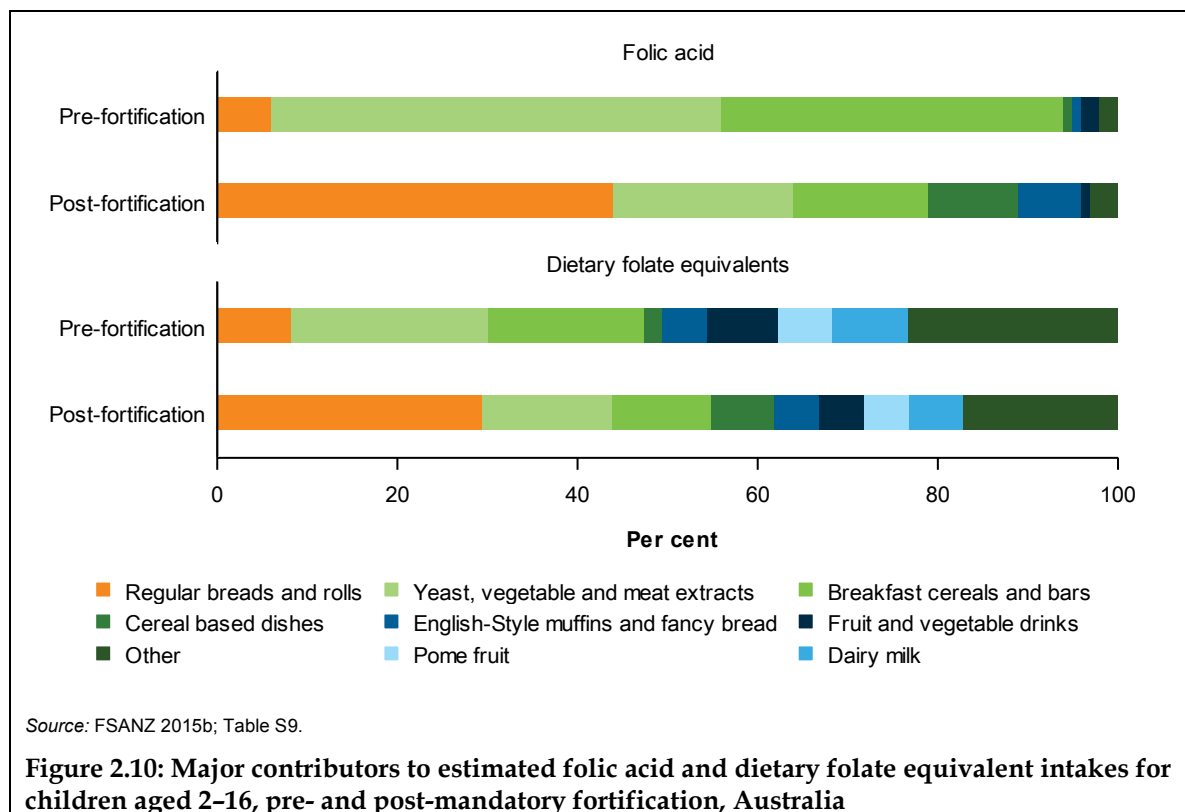
Similar results to those found for the target group were found for the remaining adult population (Figure 2.9). Regular breads and rolls as a contributor to estimated folic acid and DFE intakes increased for all adults post-mandatory fortification. For the population aged 19 and over, the proportion of regular breads and rolls as a contributor to folic acid and DFE intakes increased from 19% to 53% and from 16% to 36%, respectively. Post-mandatory fortification, the three food groups contributing most to folic acid and DFE intakes for adults were regular breads and rolls, yeast and other extracts, and breakfast cereals.





Before mandatory folic acid fortification, yeast and other extracts was the major contributing food group to estimated folic acid intake for children aged 2-16, making up almost half of folic acid intake (Figure 2.10).

Post-fortification, the contribution from regular breads and rolls to folic acid and DFE intakes increased from 6% to 44% and from 8% to 29%, respectively. Yeast and other extracts, and breakfast cereals continued to be important food contributors for children post-fortification. Dairy milk and fruit and vegetable drinks also continued to be small but important contributors for younger people.



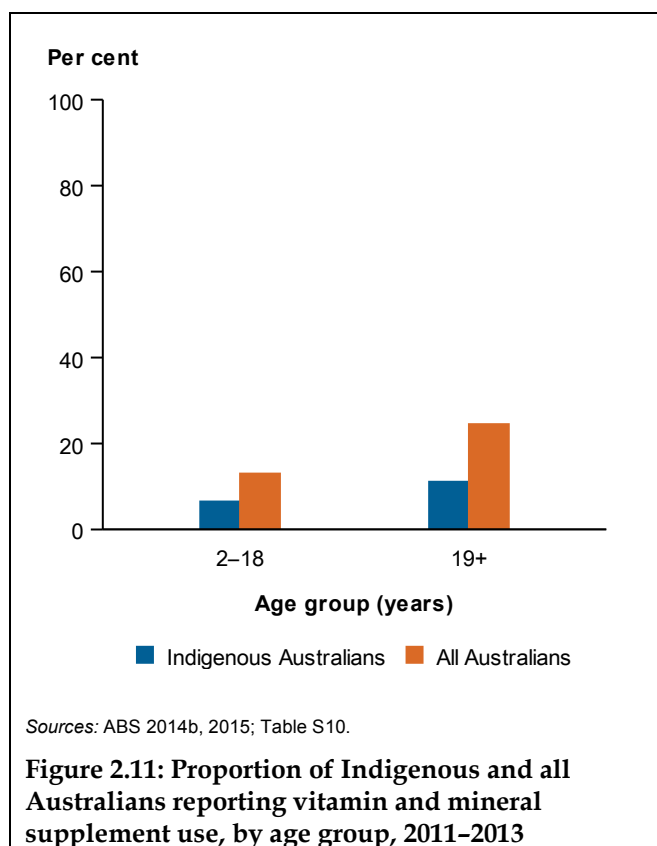
### Comparison with recent food consumption data

As noted, while recent food consumption data are available from the 2011-12 NNPAS, these data have not been incorporated into DIAMOND and so could not be used in the FSANZ dietary assessment.

While it is generally recognised that people’s consumption of staple foods does not change markedly over time (Cox & Anderson 2004), some changes in bread consumption (‘regular breads and rolls’) were found between the 1995 NNS and 2007 Children’s Survey, and the 2011-12 NNPAS. For children aged 2-16, the proportion of bread consumers and mean consumption of bread was similar between surveys. However, for adults aged 19 and over and women aged 16-44, the proportion of people consuming bread and the mean consumption of bread were lower between surveys. About 20 g less bread was consumed per day in the 2011-12 NNPAS compared with the 1995 NNS, with one slice of bread equivalent to about 30 g (FSANZ 2015b).

### Dietary supplement use

Vitamin and mineral supplement use was recorded for participants in the 2011-12 NNPAS and 2012-13 NATSINPAS. These surveys showed that supplement use increased with age. In the all-Australian population, both adults and children reported supplement use about double that of Indigenous Australians (Figure 2.11). For all Australians aged 19 and over, a quarter (25%) took a vitamin or mineral supplement, compared with 11% of Indigenous Australians. For children aged 2-18, 13% reported taking a supplement, compared with 7% of Indigenous Australians. While less than 1% of women aged 18-50 reported taking a specific folic acid supplement, folic acid may have been part of an overall multivitamin supplement.



## Consumers' awareness of, attitudes towards and behaviours in respect to food fortification

In 2013, FSANZ published the results of its population consumer survey investigating the awareness of, attitudes towards and behaviours of Australian and New Zealander consumers in respect to food fortification.

The target population for the survey was people aged 16 and over, living in households with landline telephones between June-July 2011. For the Australian component, 800 complete interviews were conducted, with 40% of the respondents being men, and 18% being women of child-bearing age (16-44 years) (FSANZ 2013).

### Results

Awareness of mandatory bread fortification in Australia was low. Around a quarter of all Australians surveyed (24%) and of women of child-bearing age (25%) were able to identify bread as being mandatorily fortified. When asked what vitamins or minerals were mandated for use in bread, less than a third (32%) correctly identified folic acid.

Women were more likely to provide a specific and correct response on the intended benefits of folic acid fortification than men (43% compared with 24%), with 38% of women aged 16-44 giving a specific and correct response.

Awareness of the current mandatory fortification standards, and knowledge of the associated fortified foods and benefits of the specific added nutrients was low for both the whole sample population and women aged 16-44. Despite low levels of general knowledge about fortification, reported consumption of fortified bread products was high.

Most consumers reported eating a type of bread that would be fortified with folic acid (89%), with 83% of women aged 16–44 reporting that they consumed bread fortified with folic acid. More women reported that they do not normally consume bread (8%) than men (2%).

## 2.4 Nutrient status

**Key monitoring question:** *Has the folate status of women of child-bearing age improved?*

**Data sources:**

- ABS 2011–12 National Health Measures Survey (NHMS).
- ABS 2011–13 National Aboriginal and Torres Strait Islander Health Measures Survey (NATSIHMS).

**Key findings:**

Post-mandatory fortification:

- Mean red blood cell folate level for women aged 16–44 was 1,647 nmol/L. Women aged 16–44 reporting as pregnant or breastfeeding had higher levels than all women aged 16–44 (1,958 nmol/L and 1,775 nmol/L, respectively).
- There were only small differences in mean serum and red blood cell folate levels based on level of disadvantage (levels were slightly higher in areas with the lowest level of disadvantage).
- Mean serum folate levels for Aboriginal and Torres Strait people was lower than for the general population across all age groups (by 14–24%).
- Mean serum folate levels in the NHMS were higher than those reported at baseline for women in the child-bearing age group. However, because of uncertainty in the ability to directly compare studies, these results must be interpreted with caution.

### Biomedical assessment of folate

The 2011–12 NHMS assessed serum and red blood cell folate levels (see Appendix D for further details on this survey). Data were available for the target population (women aged 16–44) as well as for those who reported being pregnant or breastfeeding at the time of the survey (ABS 2013b).

In the 2011–12 NHMS, blood samples were analysed for folate using the chemiluminescence immunoassay method (a method to determine the concentration of samples according to the intensity of the luminescence that the chemical reaction emits). As the cut-off for NTD risk is based on the microbiological method of analysis, it is not appropriate to apply this cut-off to the 2011–12 NHMS data (WHO 2015) (see Section 5.2 for more details). Instead, only mean serum and red blood cell folate levels are presented here.

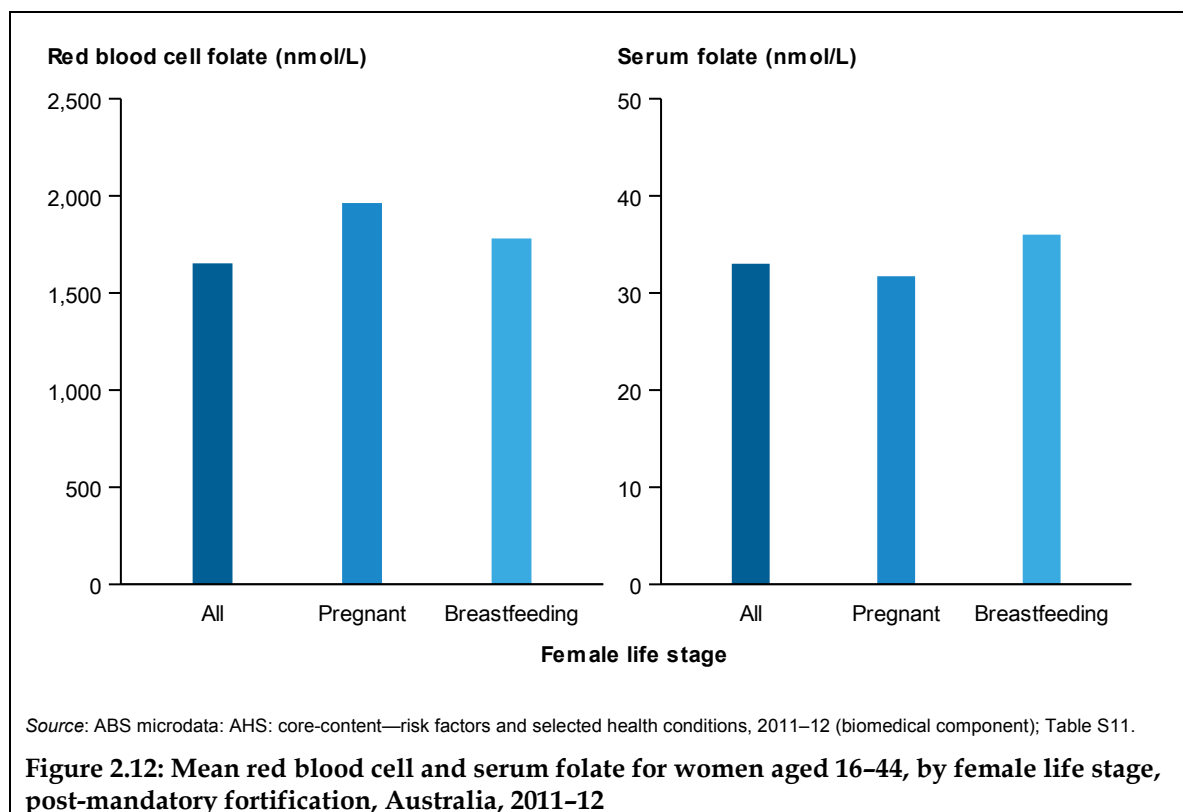
To outline possible changes post-fortification, data are provided on serum folate levels from the Child Determinants of Adult Health (CDAH) Study (pre-fortification) and the 2011–12 NHMS (post-fortification). Data are also provided from a large public hospital pathology laboratory that allows an internal comparison of red blood cell and serum folate levels using the same methodology pre- and post-fortification.

## Results from the National Health Measures Survey

### Folate status for the target population (women aged 16–44)

Based on data from the 2011–12 NHMS, the mean red blood cell folate level for all women aged 16–44 was 1,647 nmol/L (Figure 2.12). Women aged 16–44 reporting as pregnant had a higher mean red blood cell folate level compared with all women aged 16–44 (1,958 nmol/L), as did breastfeeding women (1,775 nmol/L).

The mean serum folate level for all women aged 16–44 was 33 nmol/L. Pregnant women had a slightly lower mean serum folate level (32 nmol/L), while breastfeeding women had the highest level (36 nmol/L).



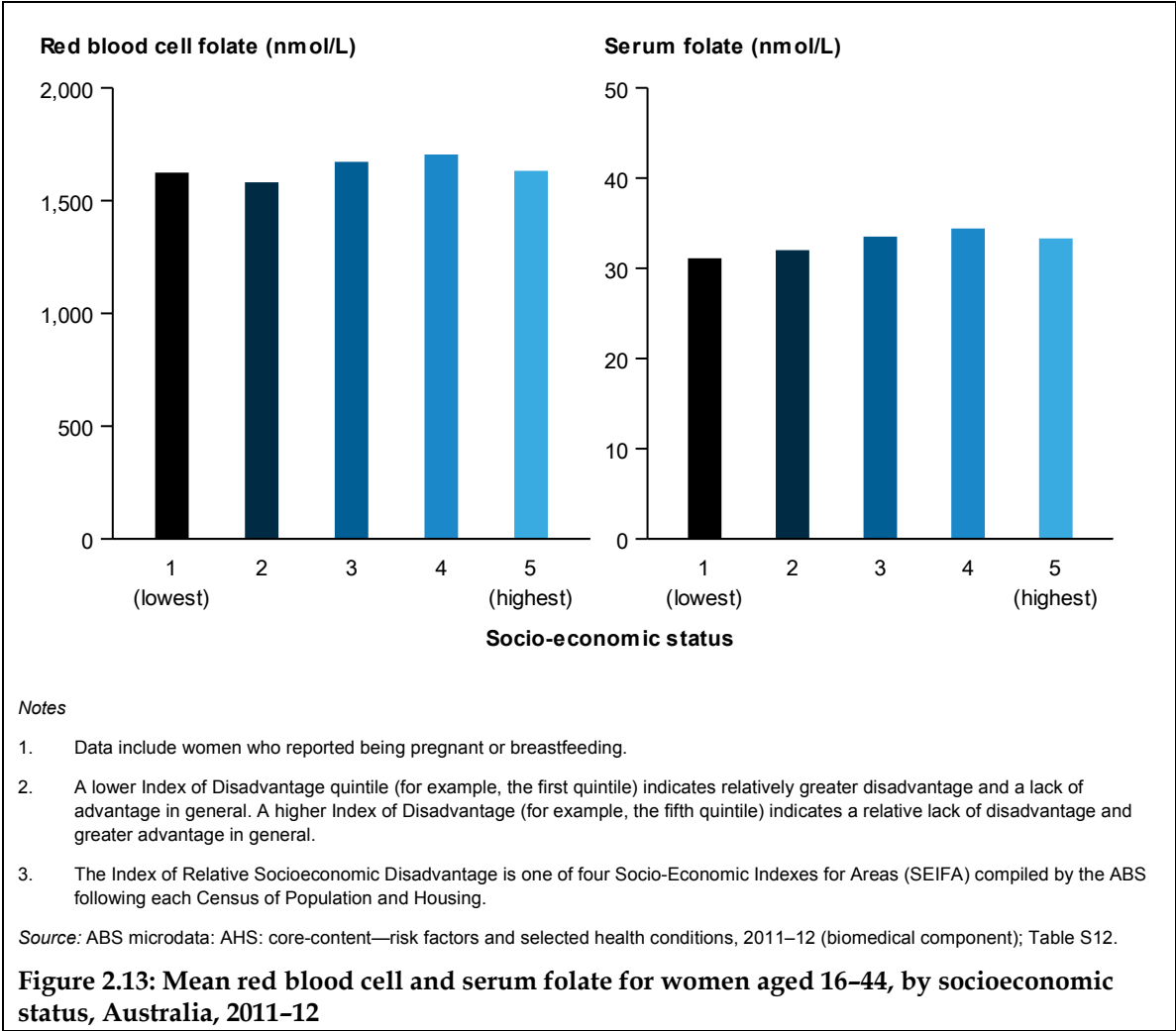
### Folate status by demographic characteristics

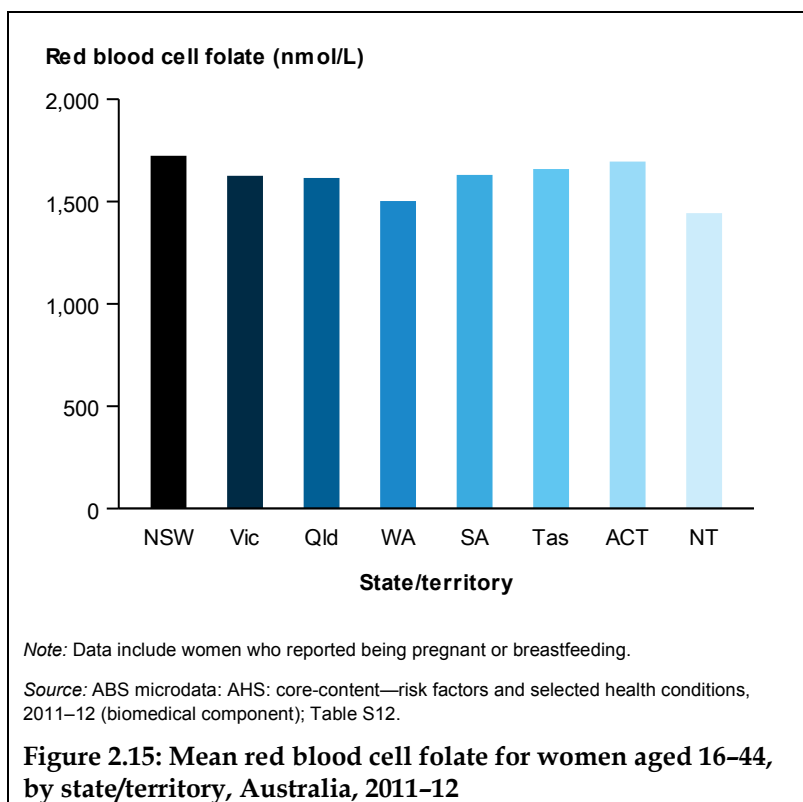
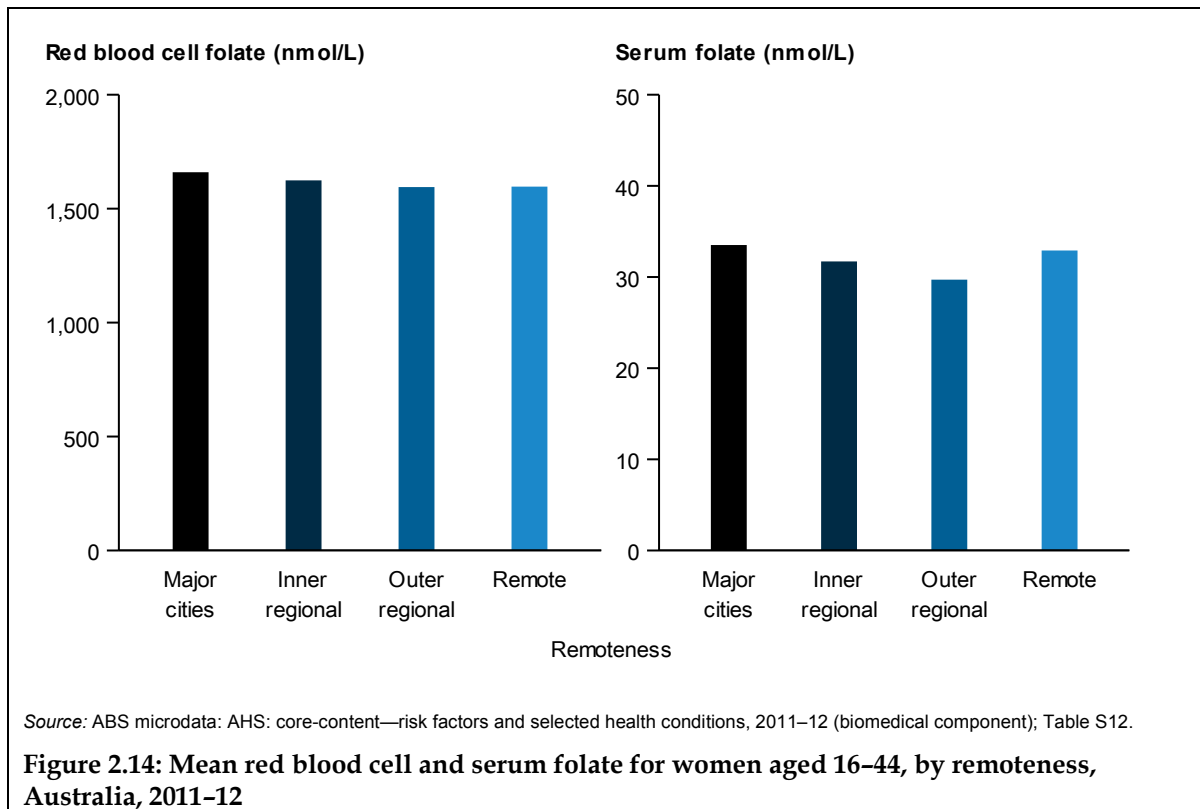
When considering levels of disadvantage, no consistent trend was observed across quintiles of socioeconomic status (SES) for either serum or red blood cell folate for women aged 16–44 (Figure 2.13). Overall, those with the lowest SES were found to have lower red blood cell and serum folate status than those with the highest SES, but differences were small (1,620 nmol/L and 1,628 nmol/L and 31 nmol/L and 33 nmol/L, respectively).

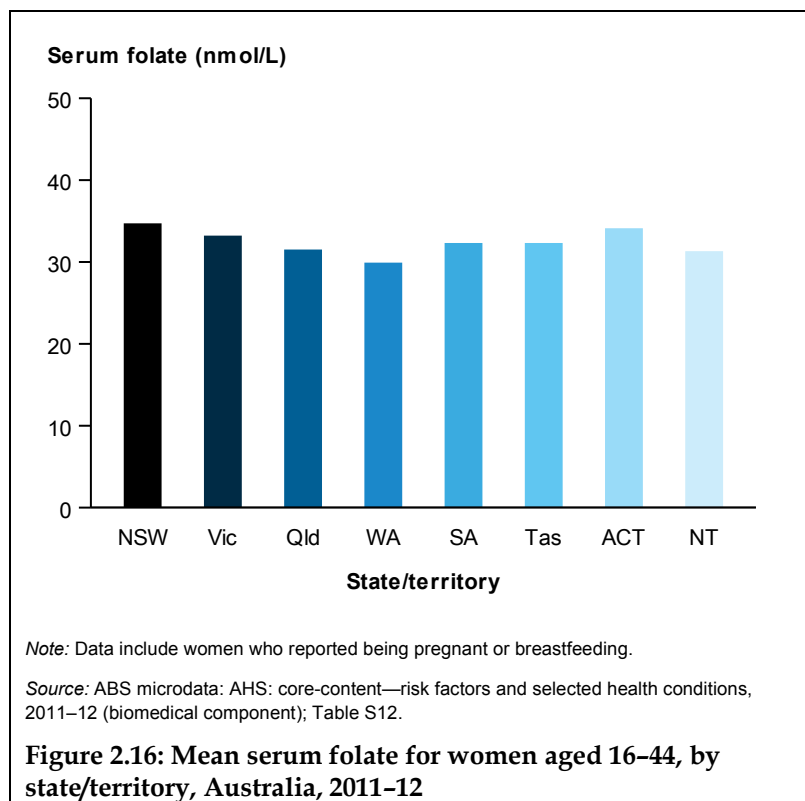
In terms of remoteness of residence, red blood cell and serum folate status for women aged 16–44 was highest for those living in *Major cities* (1,655 nmol/L and 33 nmol/L, respectively) (Figure 2.14). Red blood cell folate was lowest for those living in *Outer regional* and *Remote* areas (1,590 nmol/L and 1,592 nmol/L, respectively) and those living in *Outer regional* areas were found to have the lowest serum folate (30 nmol/L). The serum folate status for those living in *Remote* areas was similar to those living in *Major cities* (33 nmol/L).

New South Wales, the Australian Capital Territory and Victoria were the three jurisdictions with the highest mean serum folate for women aged 16–44; Queensland, the Northern Territory and Western Australia were the lowest (figures 2.15 and 2.16). Similar results were

found for red blood cell folate, with the bottom three jurisdictions being the same for both tests. The top three jurisdictions differed slightly, with New South Wales, South Australia and Tasmania having the highest red blood cell folate levels.





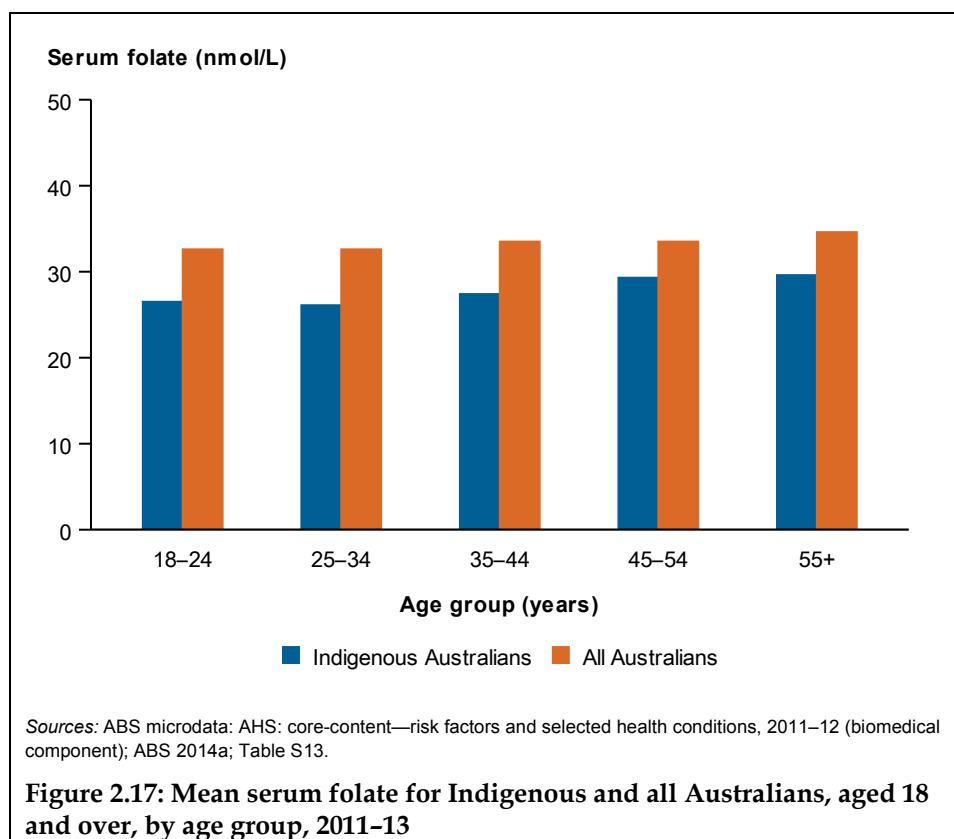


### Folate status for Aboriginal and Torres Strait Islander people

At the time of drafting this report, summary data on folate status from the 2011–13 NATSIHMS were available only for males and females combined, as individual record files were yet to be released by the ABS. Hence, it was not possible to assess differences in folate status for the female population alone.

The available data showed that mean serum folate for Indigenous Australians was lower than for the general population across all age groups (by 14–24%) (Figure 2.17). Mean serum folate levels increased with age in both population groups, and the gap between Indigenous and all Australians was smallest for those aged over 45.





### Child Determinants of Adult Health Study

The CDAH Study is a national cohort study of people who initially participated in the 1985 Australian Schools Health and Fitness Survey. As part of the CDAH Study, blood samples from 996 non-pregnant women aged 26–36, collected between 2004 and 2006, were analysed to determine serum folate levels using a chemiluminescent microparticle folate binding protein assay on an Abbott Architect Analyser (Gall et al. 2012).

Pre-mandatory fortification, the mean serum folate level for women aged 26–36 in the CDAH Study was 27 nmol/L (AIHW analysis of CDAH data). Post-mandatory fortification, mean serum folate for women aged 25–34 in the 2011–12 NHMS was 33 nmol/L. While these data indicate a possible increase in mean serum folate status following mandatory folic acid fortification, results must be interpreted with caution. This is due to differences in folate analysis methodologies and potential participation bias in the CDAH Study (see Section 5.1 for details).

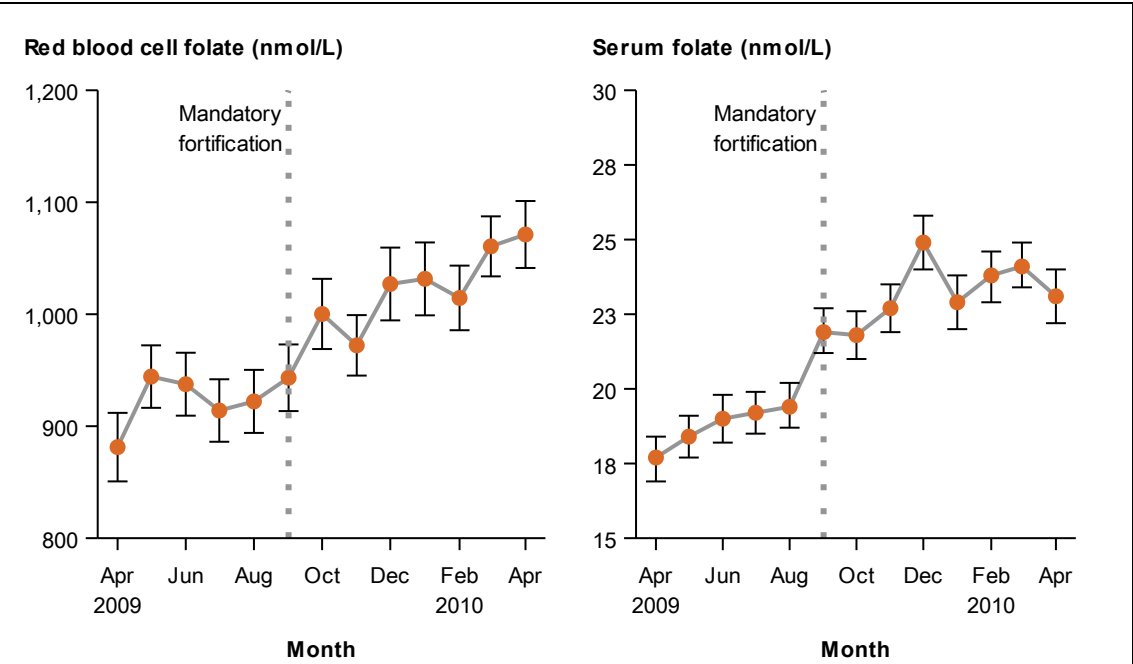
### Laboratory analysis

Brown et al. 2011 offer some insight into the changes to folate status for select populations in Australia pre- and post-fortification. However, this population group may not be representative of the Australian population since blood samples were taken to investigate a possible folate deficiency.

Data were available on 20,592 serum and red blood cell folate assay results collected between April 2007 and April 2010 from a wide variety of inpatients and outpatients. These data were analysed at the Royal Prince Alfred Hospital in Sydney (Figure 2.18).

Brown et al. found a 77% and 85% decrease post-mandatory fortification in the prevalence of low serum levels (from 9.3% to 2.1%) and red blood cell folate levels (from 3.4% to 0.5%),

respectively, measured against the reference range of the assay used. These results showed an improvement in folate status in the period following mandatory fortification. The total number of women with low folate was low across all time periods, but a decrease was observed post-mandatory fortification for all women, and for women aged 15–50.



Source: Brown et al. 2011; Table S14.

**Figure 2.18: Mean red blood cell and serum folate, by month, April 2009 to April 2010, Australia**

## 2.5 Health benefits

**Key monitoring question:** *Has the incidence of neural tube defects decreased?*

**Data source:** National Perinatal Epidemiology and Statistics Unit's report *Neural tube defects in Australia, 2007–2011* (Hilder 2016).

**Key findings:**

Post-mandatory fortification:

- NTD rates decreased by 14.4% in the total study population (significant), and 12.5% in the population omitting NSW residents (non-significant). These decreases are in line with the estimated reduction.
- Among Indigenous women, NTD rates decreased by 74.2% in the total study population, and by 80.2% in the population omitting NSW residents (both significant).
- Among teenagers, NTD rates decreased by 54.8% in the total study population, and by 62.6% in the population omitting NSW residents (both significant).
- NTD birth prevalence decreased by 10.9% in 2011, compared with rates in 2007–2008 (5.5 versus 4.9 per 10,000 total births, respectively).

### Rates of neural tube defects

In 2014, the Department of Health commissioned the National Perinatal Epidemiology and Statistics Unit to undertake a review of NTD rates pre- and post-mandatory fortification (Hilder 2016). Data were sourced from New South Wales, Queensland, Western Australia, South Australia, Northern Territory and Tasmania between 2007–2011.

This study by Hilder benefited from the inclusion of all available NTD data in Australia from 2007 to 2011. For the first time, data were available from Queensland and the Northern Territory. Data from Victoria were not available for the whole study period. This is a key limitation with this research, due to the substantial maternal population in Victoria and missing data for women from other states who terminate their pregnancy in Victoria. The Australian Capital Territory does not have a congenital anomaly data collection and so could not be included. In addition, Tasmania includes only live births in its congenital anomaly register and not terminations of pregnancy.

A report will be provided for Victoria separately for the 2007–09 period when data are available. For a full list of data sources and data collection methods see Hilder (2016).

Some caution is therefore needed when interpreting the results presented here as they may not be fully representative of the entire Australian population (see Section 5.1 for further details) and due to the small numbers for specific subgroups. In addition, the relative rarity of NTDs and the short study period post-fortification need to be considered in terms of their contribution to the variability in NTD rates.

### Neural tube defect population measures

Data from the NTD-affected babies were used to inform two population measures of NTDs:

1. NTD rate – the number of babies with an NTD among pregnancies that ended as a birth or a termination for a congenital anomaly regardless of pregnancy gestation, divided by the population of total births (live births and still births) in a specified

time and place. The data from Tasmania were excluded from the calculation of NTD rates as only live births are included in its data collection

New South Wales data were known to be less complete because of under-ascertainment (under-detection) and the level of missing values in the data obtained for NTDs. Therefore, a sensitivity analysis was performed including and excluding NTD-affected babies from New South Wales (294, 32.9% of total) to assess possible bias from missing data that could skew the results of the comparison over time. Both sets of data are presented.

See Appendix D for further details on jurisdictional data quality.

The two population groups used in the analysis of NTD rates were therefore:

- (i) total study population, comprising New South Wales, Queensland, Western Australia, South Australia and the Northern Territory
- (ii) population omitting New South Wales residents, comprising Queensland, Western Australia, South Australia and the Northern Territory.

2. Birth prevalence of NTDs – the proportion of all babies born who have an NTD. Total differences in NTD rates pre- and post-fortification were calculated and further analysed by:

- isolated and non-isolated NTDs
- different NTD types: anencephaly, spina bifida and encephalocele
- specific age groups
- Indigenous compared with non-Indigenous
- Data to calculate neural tube defect rates.

Although mandatory folic acid fortification became fully effective from September 2009, many flour millers and bakers began fortification before this date. To reduce the potential confounding effect of transitioning to this mandatory requirement, the Hilder (2016) study separated data into the following three periods:

- pre-mandatory fortification period – conceptions occurring during the period from October 2006 to December 2008 (27 months), except for Queensland data which started later (from April 2007 to December 2008)
- transition period – conceptions occurring during the period from January 2009 to September 2009 (9 months)
- post-mandatory fortification period – the period from October 2009 to 2011 (18 months).

In the total study population, data were available for 894 NTD-affected babies conceived during the period of the study for the three types of NTDs (see Box 1.1 for details of NTD types). Of the 894 NTD-affected babies, 459 were conceived during the pre-fortification period, 153 during the transition period and 282 during the post-fortification period. When the 294 NTD-affected babies resident in New South Wales were omitted, 297 were conceived during the pre-fortification period, 105 during the transition period and 198 during the post-fortification period.

## Results

The analysis shows that rates omitting New South Wales residents are better absolute measures of NTD risk, but have wider confidence intervals (CIs). Including data from New South Wales with its known under-ascertainment resulted in lower absolute NTD rates; however, as the level of under-ascertainment appears, on average, to be constant over time

(Hilder 2016), this does not affect the proportional difference between rates from different time periods (see Appendix D for further details). In summary, inclusion of New South Wales provided a much larger population and improved the study power.

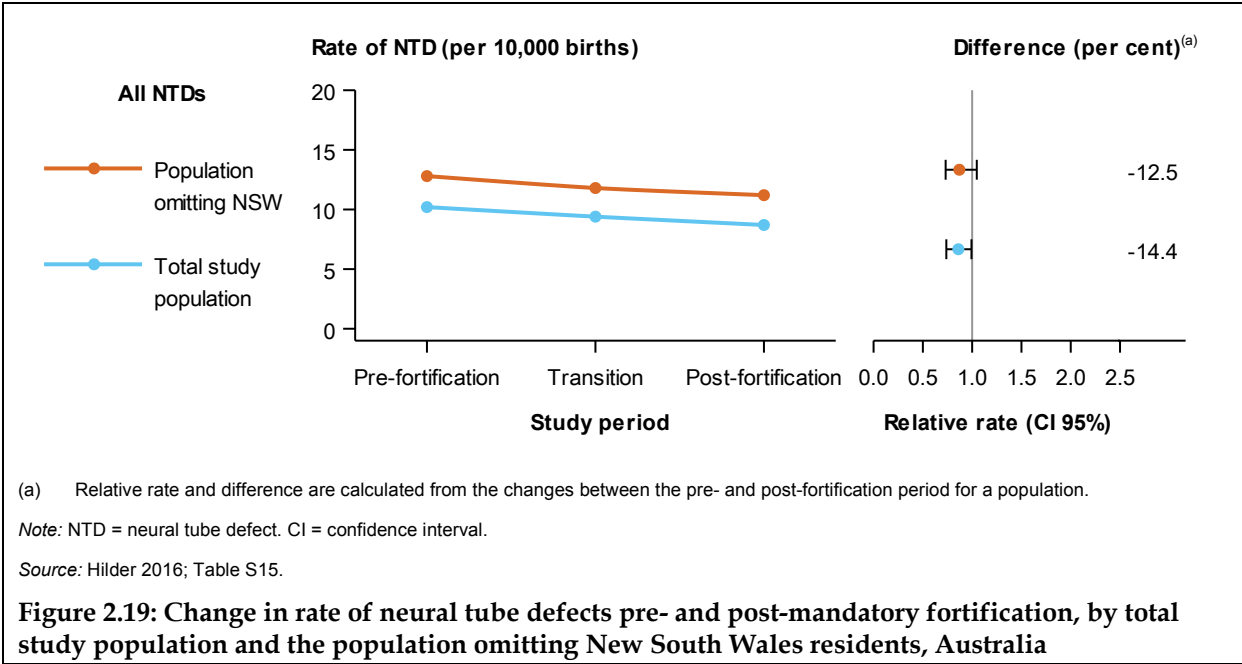
**NTD rates for 2007–2011**

During the development of the mandatory fortification requirement, estimates were made of a decrease of 14–49 NTD-affected pregnancies per year, which represents a 4% to 16% reduction in NTD-affected pregnancies, with an average decrease of 14% (FSANZ 2006b).

Hilder (2016) showed a statistically significant 14.4% decrease in the rate of NTDs from pre-fortification to the post-fortification period (Figure 2.19) in the total study population and a non-statistically significant 12.5% decrease in the rate of NTDs in the population omitting New South Wales residents. This moderate reduction in overall NTD rates masks the much larger reductions seen in babies of teenage mothers and Aboriginal or Torres Strait Islander mothers (see ‘NTD rates by maternal Indigenous status’ for further details).

The NTD relative rate in the total study population was 0.86, with a 95% CI from 0.738 to 0.993. A relative rate below unity (that is, 1.00) indicates a protective effect and is statistically significant if the 95% CI does not cross unity. These results indicate a true difference between the pre- and post-mandatory fortification periods across all babies conceived in the study period, and were at the upper level of the predicted reduction from original estimates (4% to 16%). The decrease in the NTD rate in the population omitting New South Wales residents was of a similar order to that in the total study population, but did not reach statistical significance.

NTD rates calculated with the omission of data from New South Wales show a higher rate of NTDs for each of the study periods (12.8, 11.8 and 11.2 per 10,000 conceptions that resulted in a birth), which are better measures of absolute NTD risk than NTD rates calculated with data from New South Wales (10.2, 9.4 and 8.7 per 10,000 conceptions that resulted in a birth).



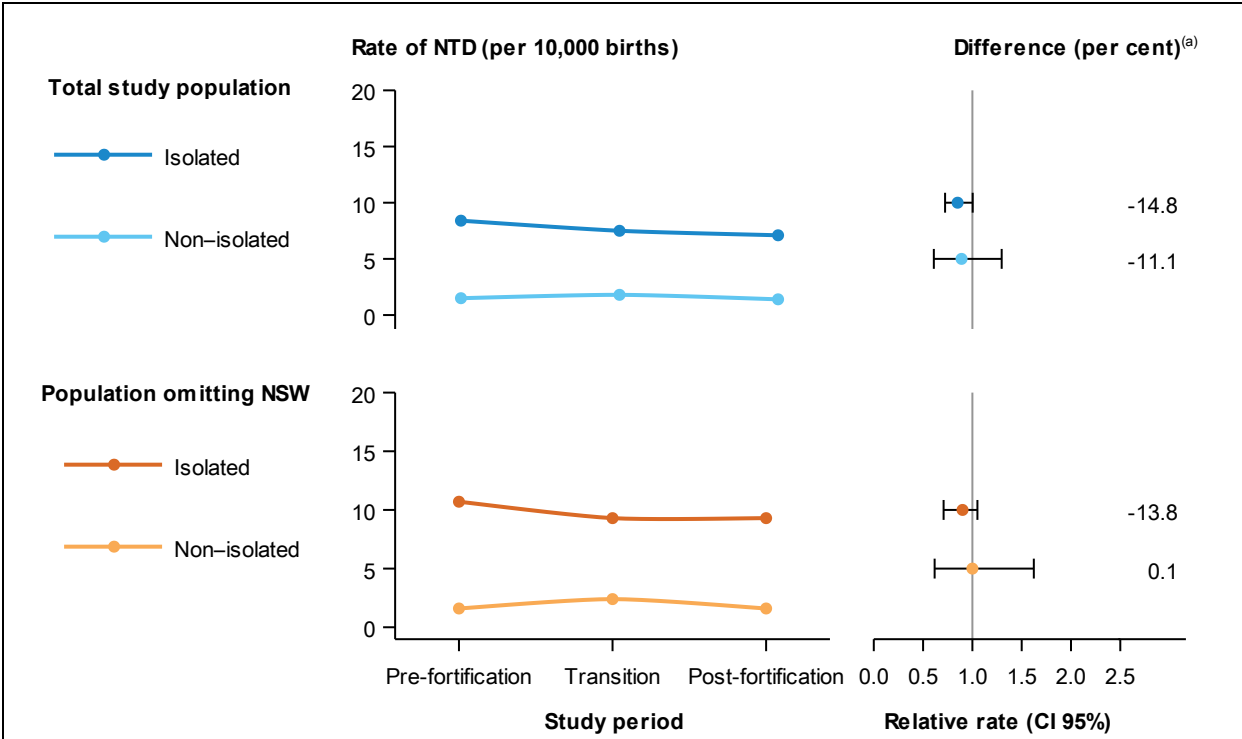
**NTD rates by isolated and non-isolated neural tube defects**

Isolated NTDs have been considered to be more closely associated with folate insufficiency than with other causes of NTDs; therefore, analysis was undertaken to differentiate isolated and non-isolated NTDs (see Appendix D for further details).

In both the total study population and the population omitting NSW residents, isolated NTD rates decreased across the three study periods (by 14.8% and 13.8%, respectively, from pre- to post-fortification, with these reductions just below statistical significance) (Figure 2.20). The percentage difference in the NTD rate for isolated NTDs in these two populations was similar to the decline in overall NTD rates.

In both study populations, rates of non-isolated NTDs first increased between the pre-fortification and transition period and then decreased post-fortification (Figure 2.20).

Note that isolated and non-isolated NTDs may be subject to misclassification because detection of coexisting anomalies varies according to the duration of pregnancy.



(a) Relative rate and difference are calculated from the changes between the pre- and post-fortification period for a population.

Note: NTD = neural tube defect. CI = confidence interval.

Source: Hilder 2016; Table S16.

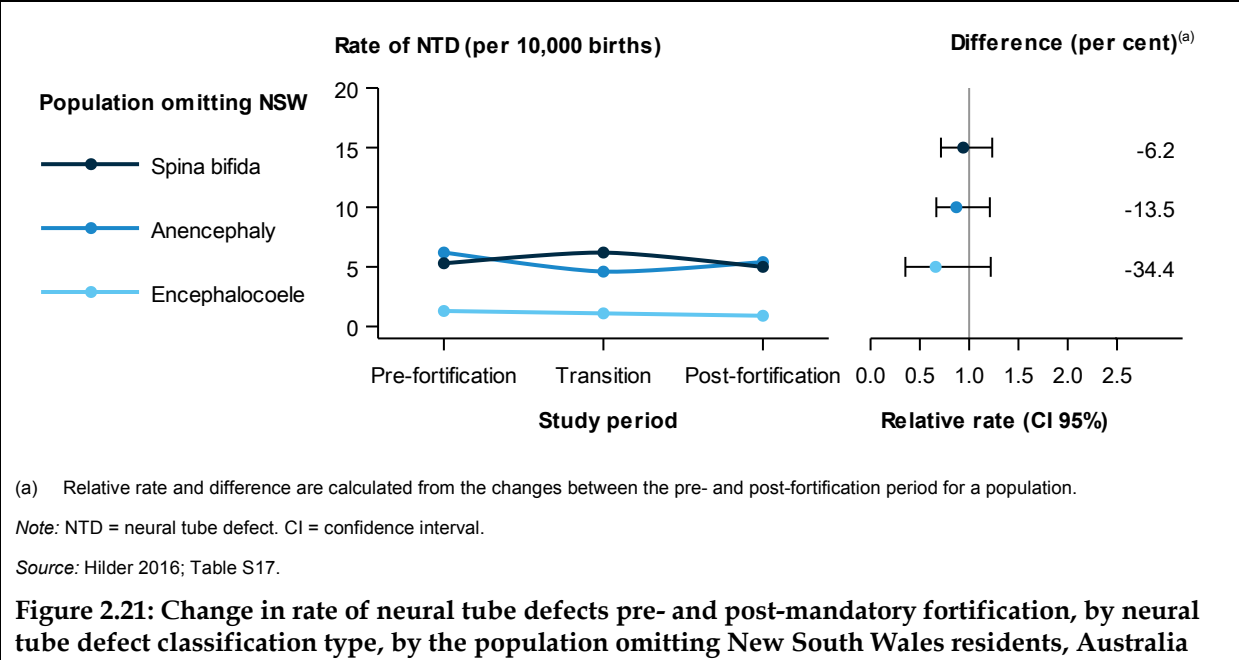
**Figure 2.20: Change in rate of neural tube defects pre- and post-mandatory fortification, by coexisting abnormality, by total study population and the population omitting New South Wales residents, Australia**

**NTD rates by classification type**

Results for the change in NTD rates pre- and post-mandatory fortification according to NTD type (anencephaly, spina bifida and encephalocele) are presented only for the population omitting New South Wales residents because of the substantially lower ascertainment of anencephaly relative to spina bifida observed in New South Wales.

NTD rates for all classification-specific types (spina bifida, anencephaly and encephalocele) decreased from pre- to post-mandatory fortification for the population

omitting New South Wales residents; however, the differences were not statistically significant (Figure 2.21). There was a 13.5% decrease in the rate of anencephaly, a 6.2% decrease in the rate of spina bifida and a 34.4% decrease in the rate of encephalocoele. The NTD rate for babies affected by encephalocoele decreased across all three periods, whereas rates for babies affected by anencephaly or spina bifida showed no consistent pattern.



**Figure 2.21: Change in rate of neural tube defects pre- and post-mandatory fortification, by neural tube defect classification type, by the population omitting New South Wales residents, Australia**

**NTD rates by maternal age**

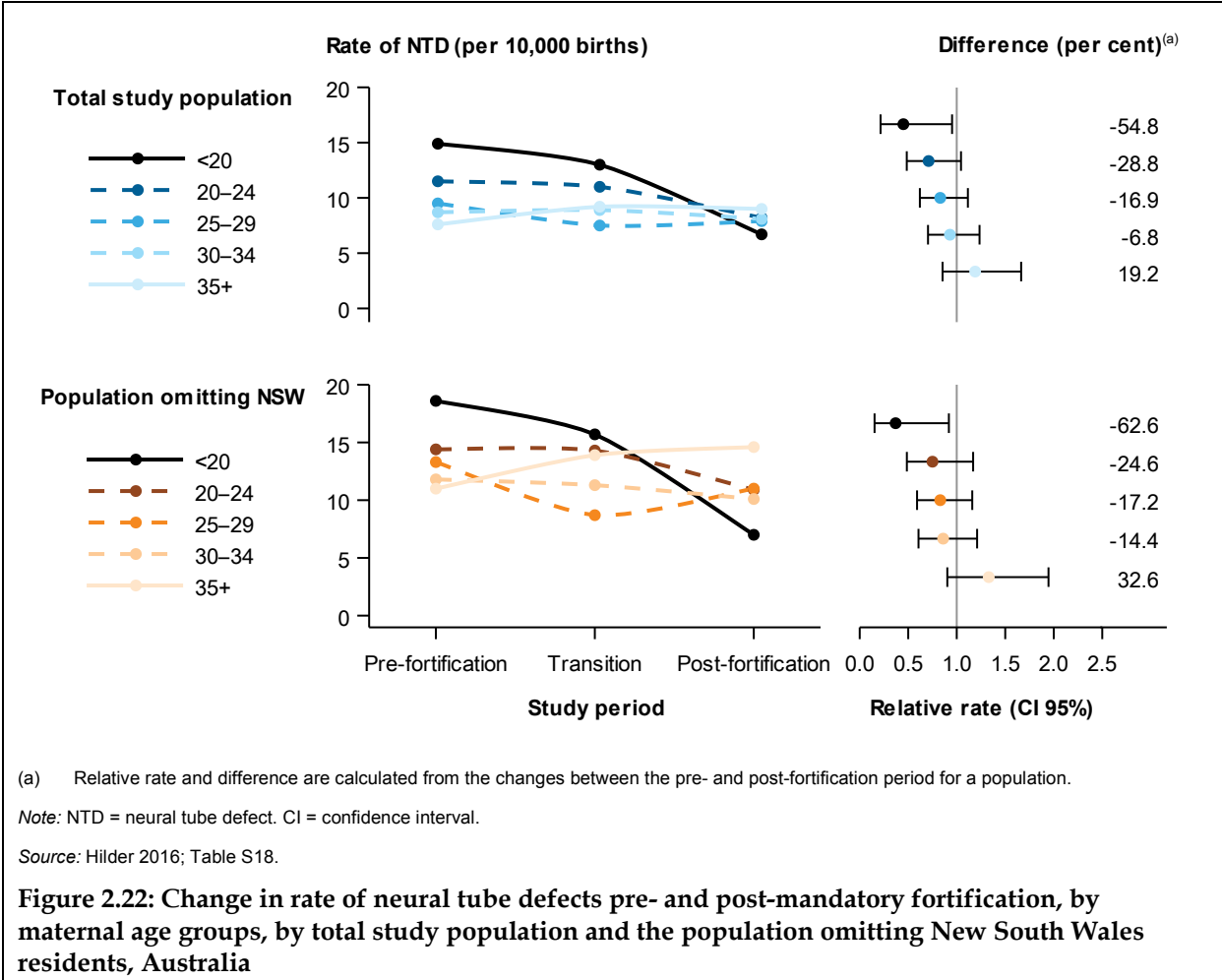
In both the total study population and the population omitting NSW residents, NTD rates decreased for all age groups from pre- to post-fortification, except for women aged 35 and over, where a non-significant increase was observed (19.2% and 32.6%, respectively) (Figure 2.22).

There was a substantial statistically significant decrease in NTD rates among teenagers in both the total study population and the population omitting NSW residents (54.8% and 62.6%, respectively) (Figure 2.22). The level of protection was progressively lower for older maternal age groups, with the noted exception for women aged 35 and over where a non-significant increase was observed.

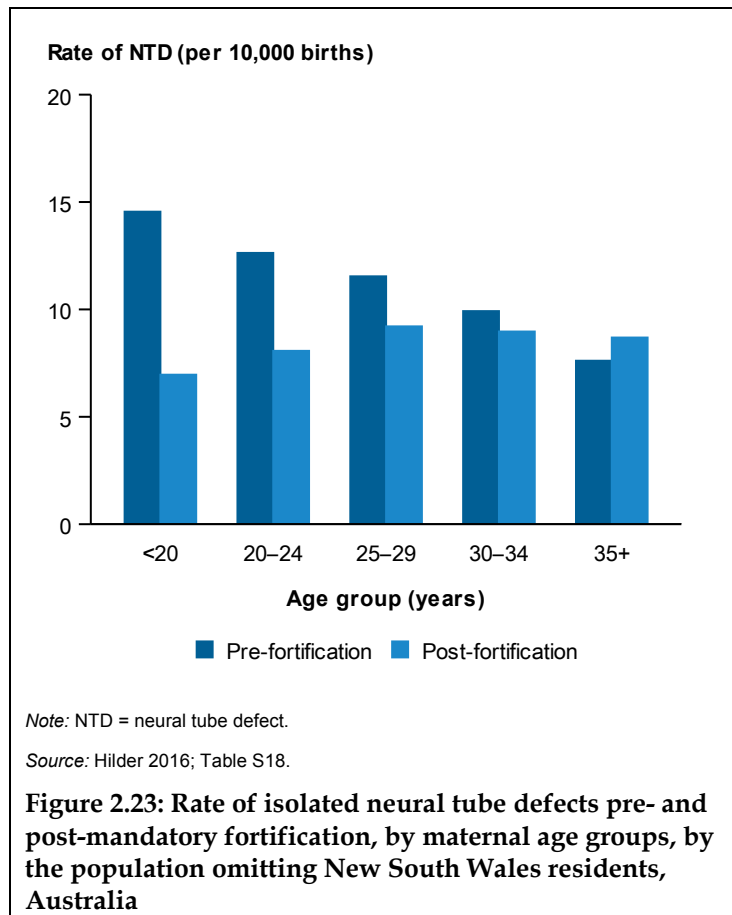
Hilder (2016) notes that several factors could contribute to the findings of an increase in NTD rates among older women (women aged 35 and over). Older women may be more likely than younger women to increase periconceptional folate intake as per the recommendations. This is supported by data from the NNPAS regarding supplement use and data from the NHMS, which show a trend for higher folate status in older age groups, particularly for red blood cell folate. As such, mandatory fortification would be expected to have a smaller effect in this group.

Another factor is that other known causes of NTDs are less common but more likely to affect older women and these may be driving the increase in NTD rates among older women. This view is supported by data restricting analysis of reported NTDs in maternal age groups to only isolated NTDs. Restricting the analyses to isolated NTDs (which are more closely associated with folate insufficiency) for the population omitting NSW residents reduced differences between age groups, especially in the post-fortification period. Also, restricting analysis in this way reduced the increased rate of NTDs between pre- and post-mandatory

fortification for older women (Figure 2.23). Hilder (2016) highlights that this analysis shows that the increasing rates of NTDs post-fortification among women aged 35 and over can be attributed to non-isolated NTDs.







### NTD rates by maternal Indigenous status

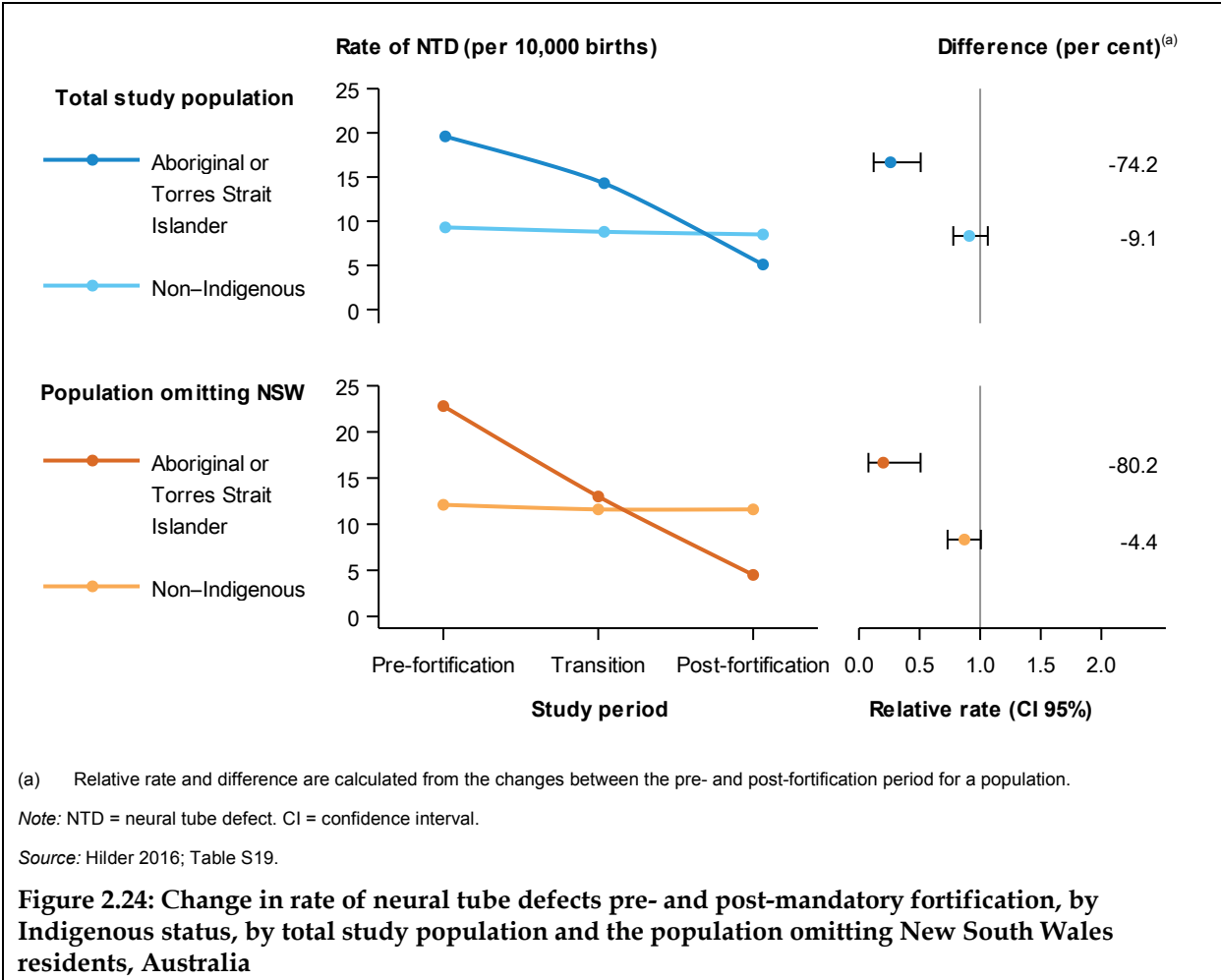
In both the total study population and the population omitting NSW residents, NTD rates decreased among Aboriginal and Torres Strait Islander women from pre- to post-mandatory fortification (Figure 2.24). In the total study population, the NTD rate among Indigenous women decreased by 74.2% (from 19.6 per 10,000 conceptions that resulted in a birth to 5.1), while in the population omitting NSW residents the NTD rate among Indigenous women decreased by 80.2% (from 22.8 to 4.5). These differences were statistically significant. The number in the sample was too small to support an analysis for younger Indigenous mothers only.

There was a more modest and non-significant decrease in NTD rates among non-Indigenous women (9.1% in the total study population and 4.4% in the population omitting New South Wales residents).

The relative rates of NTDs show a protective effect between the pre- and post-fortification periods among Indigenous women in the total study population (relative rate 0.26, 95% CI 0.121 to 0.549) and in the population omitting New South Wales residents (relative rate 0.20, 95% CI 0.078 to 0.508).

During the pre-fortification period, the rate of NTDs among Indigenous women was at least 80% higher than among non-Indigenous women (111% higher in the total study population and 88% higher in the population omitting NSW residents). The trend was reversed in the post-fortification period, where the rate of NTDs among Indigenous women was at least 40% lower than among non-Indigenous women.

These results should be considered in the context of the short study period post-fortification and the relative rarity of NTDs, both of which contribute to variability in NTD rates. Ongoing monitoring of Australian NTD rates are required to confirm whether these reductions will be sustained.



**Neural tube defect birth prevalence**

The annual NTD birth prevalence was 4.9 per 10,000 births in 2011 and 5.5 per 10,000 births in 2007–2008 (10.9% reduction). There has been no apparent increase in termination of NTD-affected pregnancies over time or in 2011 (Hilder 2016).

## 2.6 Adverse health effects

**Key monitoring question:** *Does mandatory folic acid fortification result in adverse health effects for the population?*

**Data sources:**

- FSANZ's 2014 dietary intake assessment.
- Systematic review undertaken by Mackerras et al. (2013) on cancer and all-cause mortality.

**Key findings:**

Post-mandatory fortification:

- Very few adults exceeded the UL for folic acid.
- For children aged 2–3, the proportion with intakes above the UL increased from 5% to 21% and for those aged 4–8 from 3% to 15%; this is not considered to pose a health risk.
- No increase in cancer or all-cause mortality in adults can be directly associated with folic acid.

Two approaches were used to assess if mandatory folic acid fortification had resulted in any adverse health effects for the population. The first approach was based on the assessment of estimated folic acid intake against the UL, and the second on a systematic review of the literature in relation to selected cancer outcomes and all-cause mortality in adults. There is literature available on the effect of folic acid and non-cancer effects; however, this is not covered here as the monitoring framework agreed by the then Ministerial Council selected outcomes for cancers as the main indicator for monitoring adverse health effects of folic acid fortification.

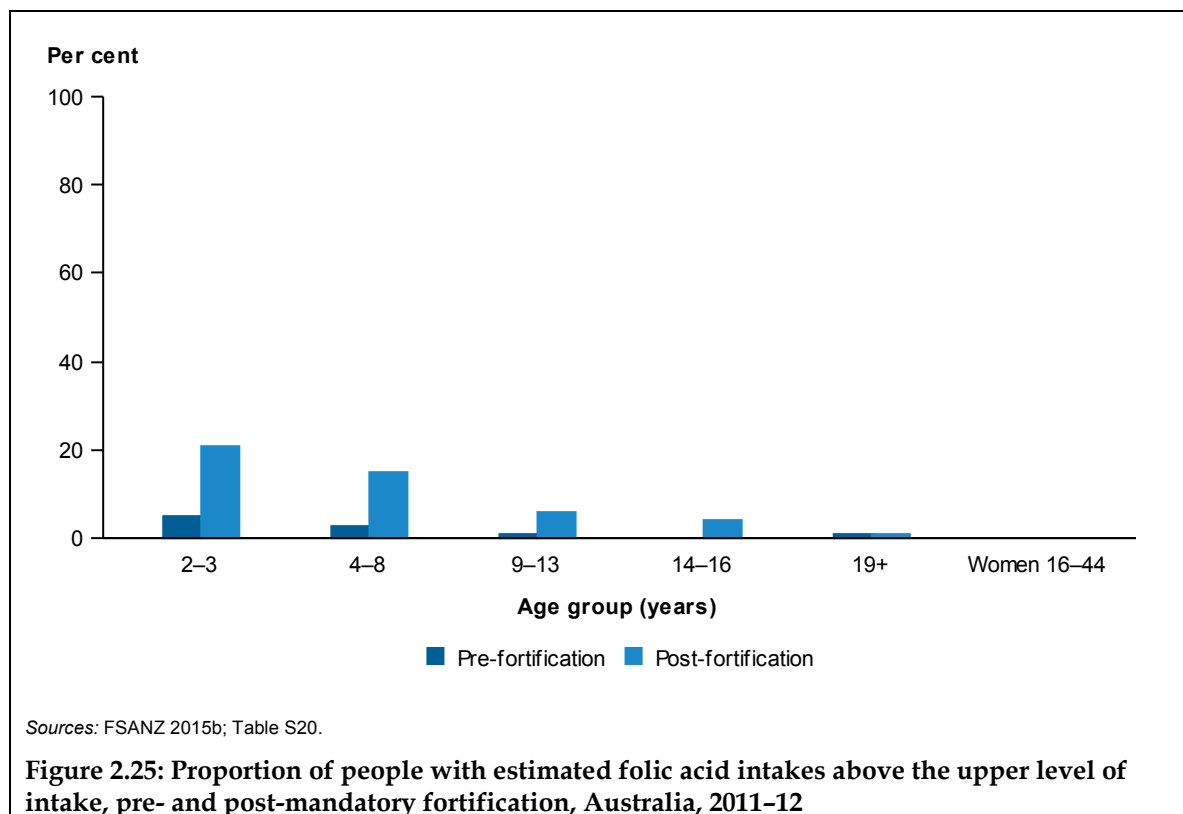
### Upper level of intake

FSANZ's assessment of estimated folic acid intakes against the UL (FSANZ 2015b) was used to determine if changes in folic acid intake following mandatory fortification might pose public health and safety concerns. This is an indicator of possible increasing risk as opposed to a direct adverse health effect.

The following assessment is based on FSANZ's dietary intake assessment, reported in Section 2.3.

### Results

Post-mandatory fortification, very few adults had estimated folic acid intakes that exceeded the UL (Figure 2.25). For those aged 2–3, the proportion above the UL increased from 5% to 21%, and for those aged 4–8 from 3% to 15%. The inclusion of supplements in FSANZ's dietary intake assessment for children aged 2–16 made little impact on overall folic acid intake and exceedance of the UL. The proportion of children exceeding the UL is not likely to pose a health risk because the UL incorporates a fivefold safety margin and is based on an end point for high intakes of folic acid in adults (see Section 5.1 for further details).



## Systematic review of selected cancer outcomes and all-cause mortality

FSANZ’s ongoing monitoring role has included reviews of epidemiological literature to assess the ongoing safety of mandatory folic acid fortification. Randomised control trials provide direct evidence for assessing the effects of selected interventions and identifying potential risks, and so are used as the primary source of evidence for folic acid-related adverse effects.

Mackerras et al. (2013) conducted a systematic review and meta-analysis of randomised control trials, examining the effects of folic acid on selected cancer outcomes in humans. It also included studies on folic acid and all-cause mortality that, by definition, included all other reasons for death. Folic acid is the only permitted form of folate used in mandatory fortification and for this reason only studies looking at folic acid were included in the review.

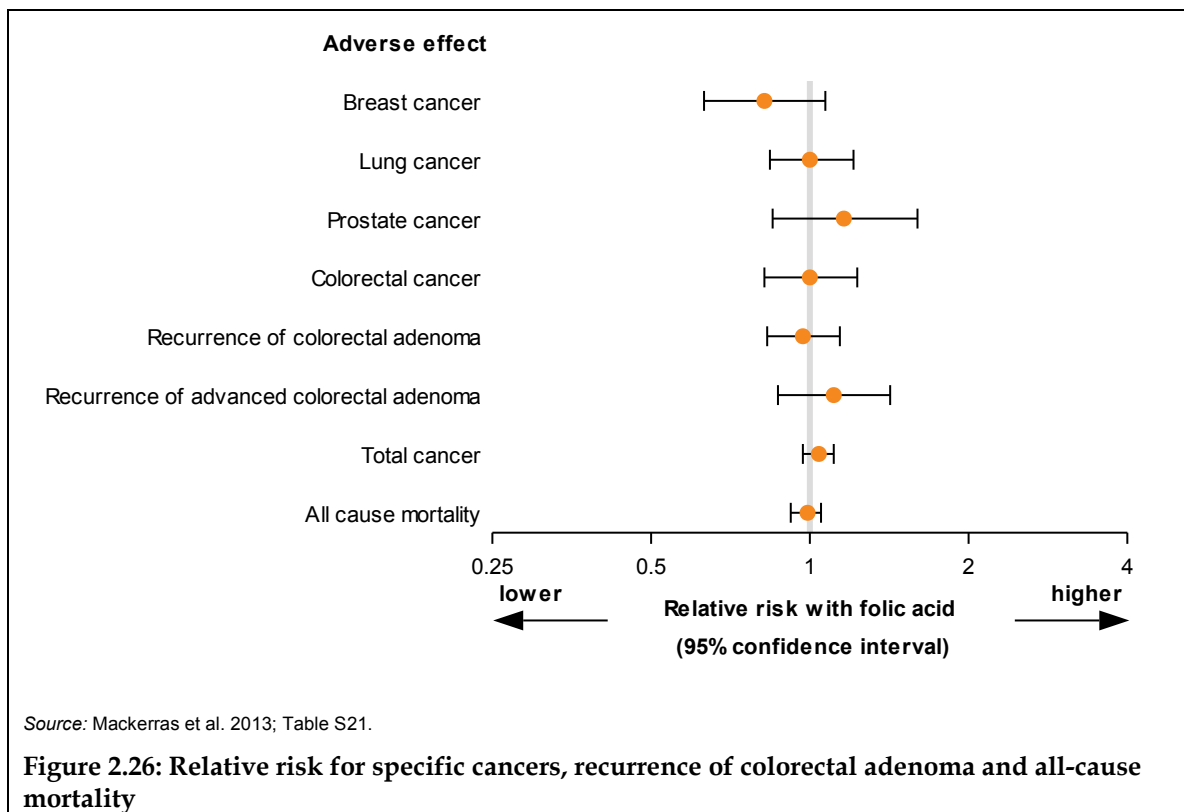
In total, 26 studies were identified that met the selection criteria, and included outcomes for cancers of the four most common sites – colorectal, lung, prostate, and breast – and combined total cancer incidence. Other studies that had outcomes for the recurrence of colorectal adenoma, and for all-cause mortality, were also included.

Most available data came from large-scale cardiovascular trials conducted where the majority of participants were male and all were adults. Additionally, folic acid doses used in these studies were at a 10-fold higher dose than the mean folic acid intakes intended as a result of Australia’s mandatory fortification program. As such, the risks detected in the meta-analysis would be higher than those posed with the amount of folic acid used in mandatory fortification.

## Results

Overall, there was no effect on all-cause mortality (relative risk 0.99) in those taking up to 5 mg of folic acid/day for up to 7 years (Figure 2.26). For the four most common cancer sites, there were no differences in relative risk for colorectal or lung cancer (relative risk 1.00), a decrease in risk for breast cancer (relative risk 0.82), and a slight increase in relative risk for prostate cancer (relative risk 1.16) and for total cancer (relative risk 1.04).

There was a small decrease in risk for adenoma recurrence (relative risk 0.97) and an increase for advanced adenomas in those who had had a prior colorectal adenoma removed (relative risk 1.11). However, none of these results were statistically significant as shown on the error bars in Figure 2.26.



# 3 Mandatory iodine fortification in Australia

## 3.1 Food composition

**Key monitoring question:** *Has the level of iodine in our food supply increased?*

**Data sources:** 2010, 2012 and 2013 FSANZ bread analytical surveys.

**Key findings:**

Post-mandatory fortification:

- The mean level of iodine in commonly consumed bread ranged from 53–70 µg per 100 g.
- These levels were substantially higher than the <2 µg/100 g of bread at baseline and exceeded the 46 µg/100 g predicted when developing the mandatory fortification requirement.

### Bread analytical surveys

As noted in Section 2.1, FSANZ conducted several analytical surveys of bread and bread products, as part of the Implementation Subcommittee on Food Regulation’s National Coordinated Food Survey Plan, to determine the levels of folic acid and iodine in commonly consumed breads available in Australia. The iodine component of the survey was conducted in three phases in 2010, 2012 and 2013 (FSANZ 2015a). The analysis of the sodium content of bread was also included in the survey but not the level of iodine in fortified salt.

Phase 1 of the survey, conducted in 2010, took 100 samples of bread and bread products from major supermarkets and bread shops from the capital cities of all Australian states and territories. Samples were grouped into 7 bread types (white, wholemeal, multigrain and seeds, flat, English muffins, organic and gluten free), with most samples coming from the 3 most commonly consumed bread types (white, wholemeal and multigrain).

Phase 2, conducted in 2012, sampled 96 breads selected from the 3 most commonly consumed bread types from all Australian states and territories (white, wholemeal and multigrain and seeds bread).

Phase 3, conducted in 2013, sampled 95 breads selected from the 3 most commonly consumed bread types from Western Australia, Victoria, Queensland and the Australian Capital Territory (white, wholemeal and multigrain and seeds bread).

As well as those commercial breads sampled, FSANZ prepared 4 samples of white, wholemeal and multigrain bread made with unfortified wheat flour for analysis as blank samples. The blank samples were used to determine the amount of naturally occurring iodine they contained.

Iodine values from Phases 1, 2 and 3 for the commonly consumed bread types were incorporated into the Australian food composition database that is compiled by FSANZ and used for modelling iodine intakes (see Section 2.3).

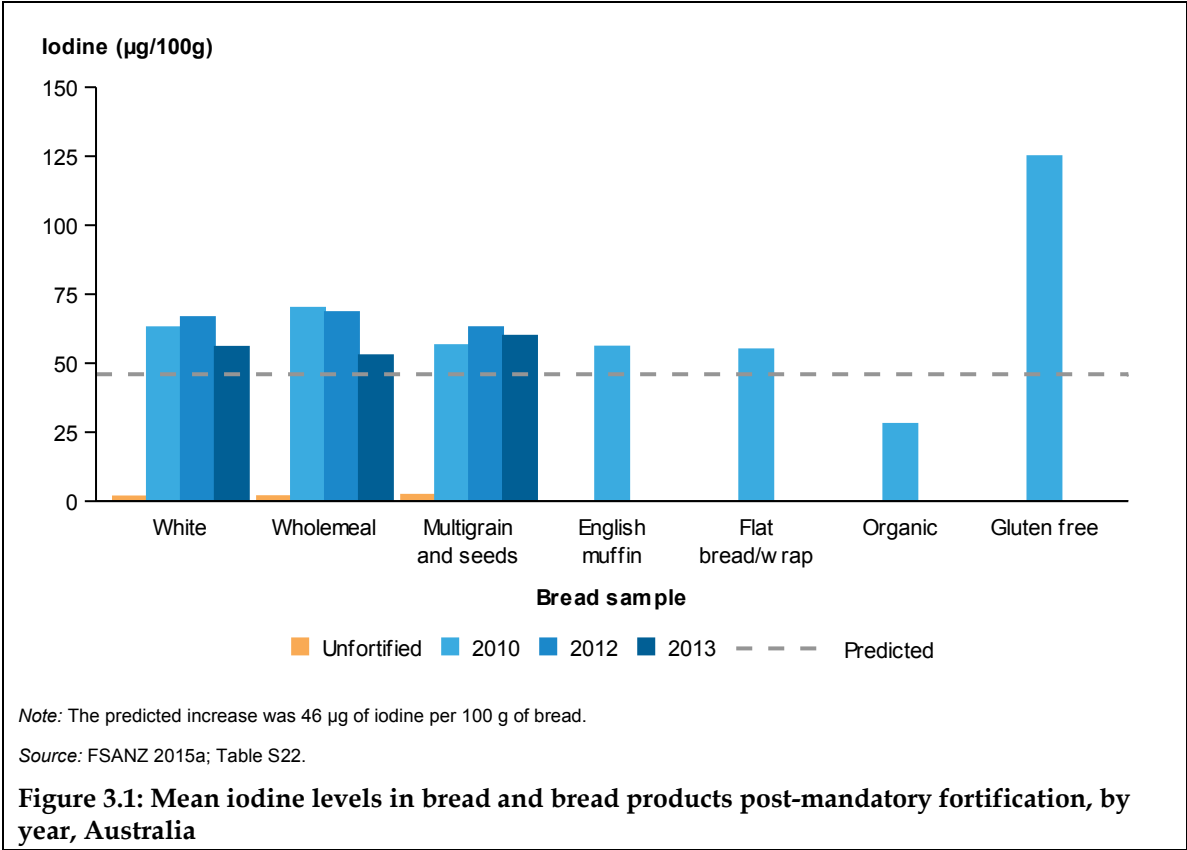
**Results**

Of the most commonly consumed bread groups, the mean iodine content ranged from 53–70 µg/100 g of bread across the survey periods (Figure 3.1). This level exceeded the estimate of 46 µg/100 g of bread initially predicted when developing the mandatory fortification requirement and showed an increase from the mean value of less than 2 µg/100 g before mandatory fortification (FSANZ 2008a). The iodine levels of the 4 unfortified bread samples (‘blanks’) ranged from 1.7–2.3 µg/100 g.

Some small variation was observed for commonly consumed bread products sampled in 2010, 2012 and 2013; however, overall, mean iodine was similar between all three periods. The sodium content of bread decreased following mandatory fortification, likely due to other government interventions to reduce salt levels in bread (FSANZ 2015a).

Possible reasons for differences in the analysed levels of iodine in the post-mandatory fortification surveys include:

- the uneven distribution of iodine in bags of salt
- the range of 25–65 mg added iodine per 1 kg of salt permitted by the fortification Standard
- the influence of varied constituents of the bread displacing bread flour in a recipe, such as wholegrain flour or seed-containing flour
- water loss from the dough during baking
- differing amount of salt required for different bread recipes (FSANZ 2015a).



## 3.2 Food industry compliance

**Key monitoring question:** *Are the food industries adequately complying with the mandatory fortification standards?*

**Data source:** 2015 Catalyst Ltd review.

**Key finding:**

- Post-mandatory fortification, Australian salt manufacturers and bakers have systems in place to ensure compliance with the mandatory iodine fortification requirement.

### Compliance and enforcement review

As identified in Section 2.2, Catalyst Ltd undertook a compliance and enforcement assessment (Catalyst Ltd 2015). The main food industries affected by mandatory iodine fortification requirements are salt manufacturers and bread producers. This review is based on feedback from 2 Australian salt manufacturers and 8 Australian bakers, representing the major market providers.

### Results

Both salt manufacturers reported having quality assurance programs and systems in place to ensure compliance with the mandatory iodine requirement. Iodine addition was automated, with equipment routinely calibrated and products tested. Both salt manufacturers had external third party audits of their systems.

All baking companies reported having quality management systems in place specifying their salt requirements. Suppliers had contractual requirements to meet product specifications. Some companies required a certificate of analysis and others also tested the iodine levels in their products. Bread and baked goods manufacturers supplying products to supermarkets reported being subject to third party external auditing. Respondents not subject to external auditing reported having internal auditing practices in place.

Based on information from the baking and bread mix industry, Catalyst Ltd estimated an increase of 300–455 kg of iodine per annum in the food supply, as a result of mandatory iodine fortification.



### 3.3 Nutrient intake

**Key monitoring question:** *Have iodine intakes in the population increased, particularly in women of child-bearing age and young children?*

**Data sources:**

- FSANZ's 2014 dietary intake assessment.
- Supporting information from the ABS 2011–12 NNPAS.

**Key findings:**

Post-mandatory fortification:

- All population groups increased their estimated mean iodine intakes.
- Estimated mean iodine intake for women aged 16–44 increased by 51 µg/day (98 µg to 149 µg/day; a 52% increase) and for children aged 2–3 by 37 µg/day (127 µg to 164 µg/day; a 29% increase). These increases are greater than the predicted increases for these population groups of 46 µg/day and 38 µg/day, respectively.
- Aboriginal and Torres Strait Islander people had estimated iodine intakes similar to those for the general Australian population.
- The proportion of the population with inadequate intakes (below the EAR) substantially decreased for all population groups, including for non-pregnant women aged 16–44 (from 60% to 9%) and for children aged 2–3 (from 9% to less than 1%).
- For women aged 16–44, 65% and 85%, respectively, still had estimated iodine intakes below the EARs for pregnancy and lactation.
- Cereal and cereal products became the largest contributor to estimated iodine intakes for all population groups.

#### Dietary iodine intake

FSANZ conducted a dietary intake assessment to estimate iodine intakes for the Australian population after the implementation of mandatory fortification (FSANZ 2015a). This assessment was used to determine adequacy for the target population (women of child-bearing age and young children) and safety for the total population.

FSANZ used its DIAMOND program for the analysis. The weighted mean iodine level in all breads sampled during the three phases of the FSANZ bread analytical surveys were incorporated into its food composition database to provide current levels of iodine in the food supply. The revised food composition data were then combined with food consumption data from reported Day 1 and Day 2 food intakes from the 1995 NNS and the 2007 Children's Survey to determine usual iodine intakes. The 5th and 95th percentiles were calculated to provide estimates of very low and very high iodine intakes in the population.

FSANZ used these nutrition surveys to determine baseline intake of iodine and predict future levels when developing the mandatory iodine fortification requirement. Combined with updated food composition data on iodine levels (from the 2010, 2012 and 2013 bread surveys), these data provide the best methodology for comparing the impact of mandatory iodine fortification. As noted previously, more recent food consumption data from the 2011–12 NNPAS have not yet been incorporated into DIAMOND and so could not be used in this FSANZ dietary assessment.

The accurate measurement of dietary iodine intakes is problematic because the contribution of iodised salt used at the table and in cooking is difficult to quantify. Two models were used to account for the contribution of iodine from discretionary salt intake given the lack of direct information in the 1995 NNS on the use of discretionary iodised salt: a market weighted model and a consumer behaviour model.

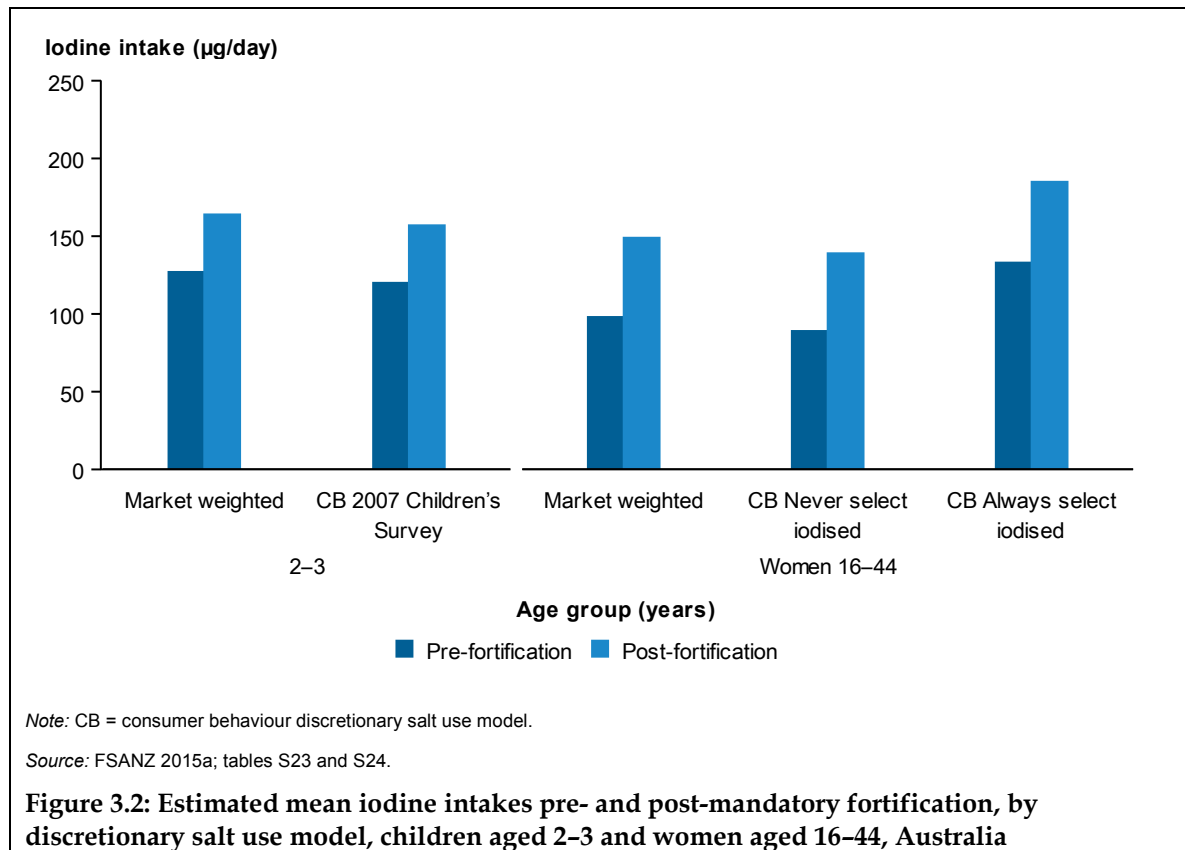
The market weighted model is representative of mean population intakes over a period of time and reflects the proportion of discretionary salt that is iodised in Australia. In contrast, the consumer behaviour model accommodates the polarity in the population's consumption of discretionary iodised salt (those who never select iodised salt versus those who always select iodised salt). For the 2007 Children's Survey, the consumer behaviour model is slightly different as it included only those who reported consuming discretionary iodised salt.

The consumer behaviour model for those who never select iodised salt provides the best representation of how fortification alone affects iodine intakes following fortification. This is because no iodised salt external to the food consumed is included in the model. The consumer behaviour model for those who always select iodised salt for discretionary salt demonstrates the most optimistic iodine intakes possible. Consequently, the consumer behaviour model provides a range that represents the top and bottom end of individual iodine consumption patterns. For further details of the methods used, see *Principles and practices of dietary exposure assessment for food regulatory purposes* (FSANZ 2009).

## **Results**

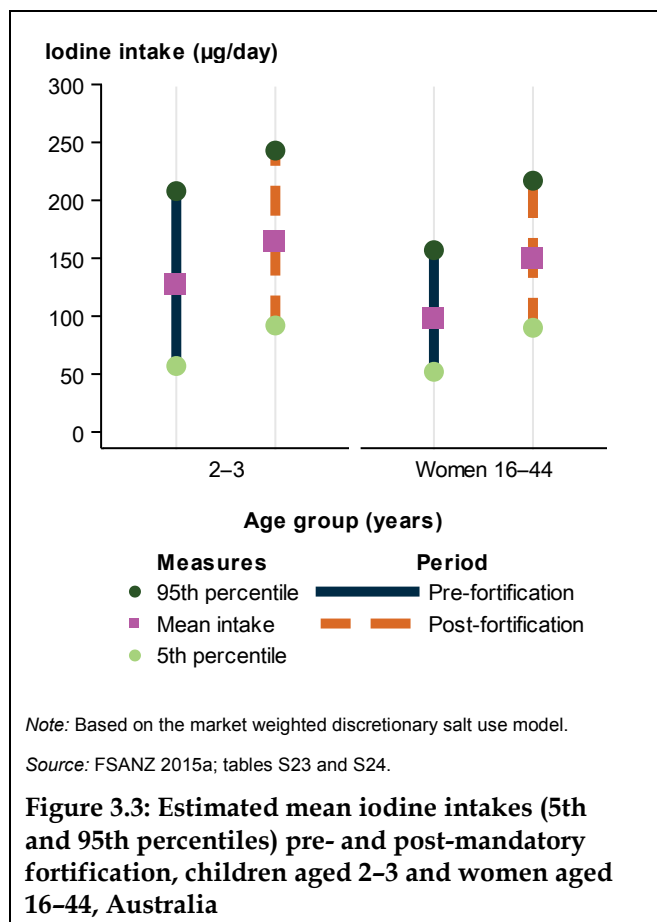
### **Change in iodine intake for the target populations**

Based on the market weighted model, estimated mean iodine intakes increased for both target populations following the implementation of mandatory iodine fortification in October 2009 (Figure 3.2). Estimated mean iodine intakes for women aged 16–44 increased by 52% (98 to 149 µg/day) and for children aged 2–3 increased by 29% (127 to 164 µg/day). The expected increase for these population groups was 46 µg and 38 µg/day, respectively (FSANZ 2008b).



The consumer behaviour model for women aged 16-44 who always select iodised salt showed a 24% increase in estimated iodine intakes compared with the market weighted model post-fortification, showing the contribution of iodised discretionary salt to iodine intakes.

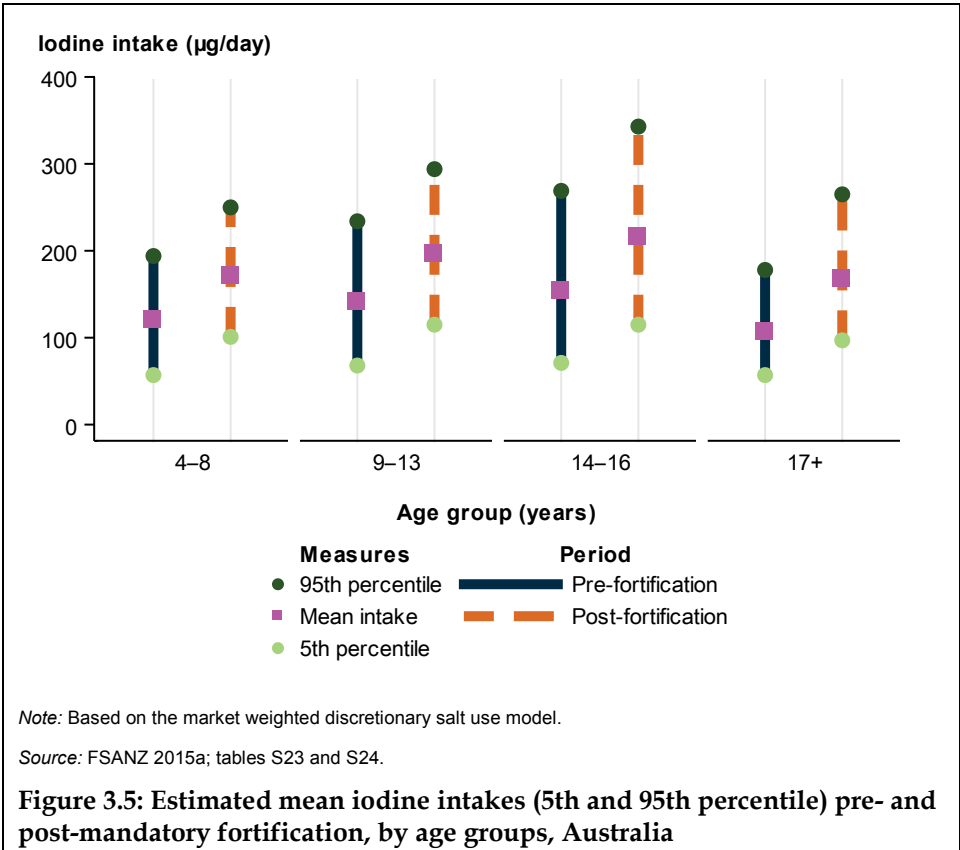
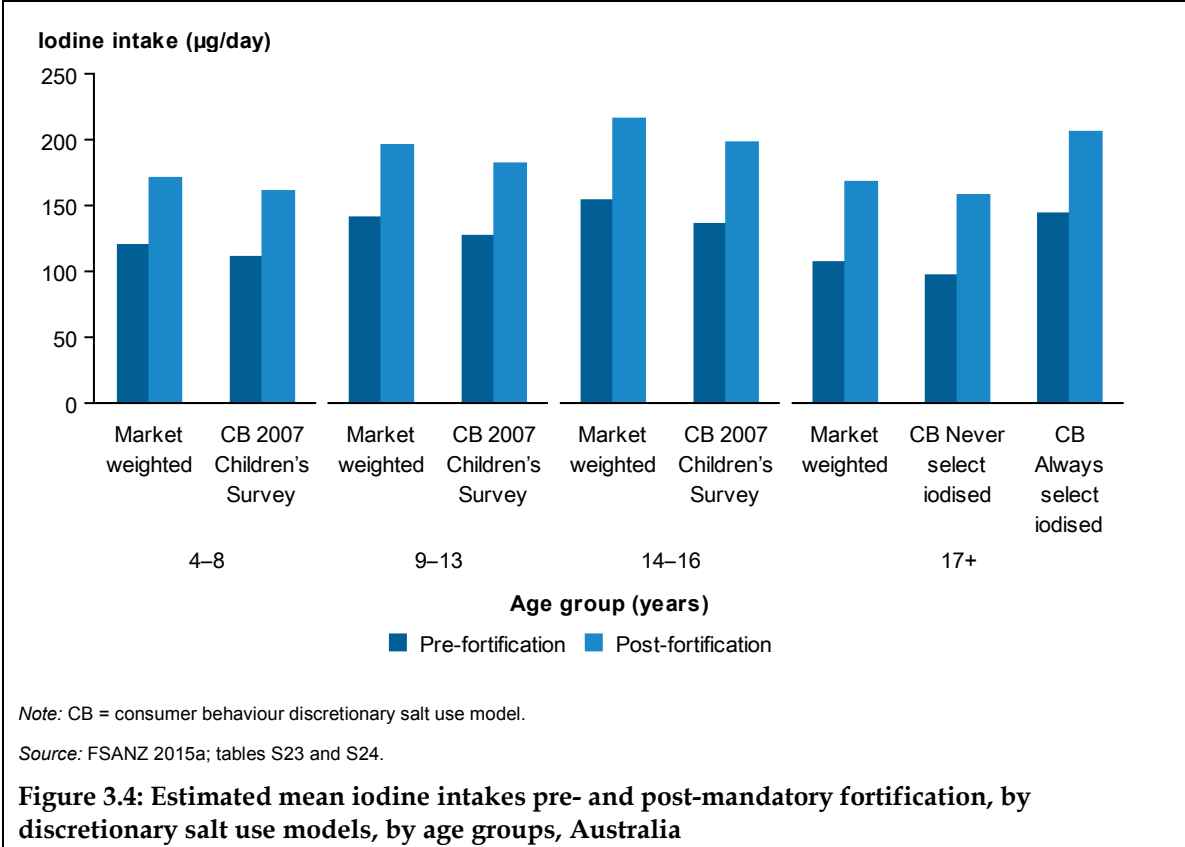
Based on the market weighted model, estimated dietary iodine intakes at the 5th and 95th percentile showed the range of intakes pre- and post-mandatory fortification for women aged 16-44 and children aged 2-3 (Figure 3.3).



### Change in iodine intake for the general population

Based on the market weighted model, estimated mean iodine intakes increased post-fortification for people aged 17 and over by 57% (107 to 168  $\mu\text{g}/\text{day}$ ) and for children aged 4–16 by between 39% and 43% (Figure 3.4). Based on the consumer behaviour model for people aged 17 and over, mean iodine intakes were 206  $\mu\text{g}/\text{day}$ , which is 23% higher than the market weighted mean intake of 168  $\mu\text{g}/\text{day}$ . This difference demonstrates the contribution of iodised discretionary salt to iodine intakes.

Based on the market weighted model, estimated iodine intakes at the 5th and 95th percentile show the range of intakes pre- and post-mandatory fortification for the non-target populations (Figure 3.5).

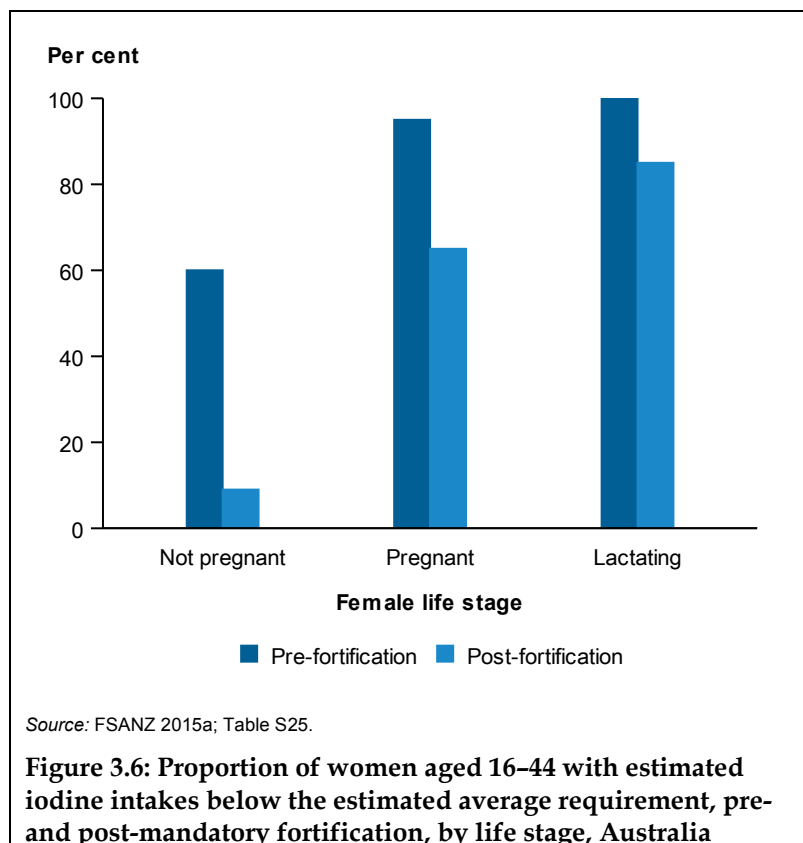


### Adequacy of iodine intake for the target populations

The proportion of the population with estimated usual iodine intakes below the EAR reflects the prevalence of inadequate intakes. The iodine EAR for women is defined by the requirements for special life stages. The iodine EAR for non-pregnant women is 100 µg/day, while the iodine EARs for pregnancy and breastfeeding are 160 µg/day and 190 µg/day, respectively, to account for the increased requirements during these life stages. For children aged 2–3, the EAR for iodine is 65 µg/day.

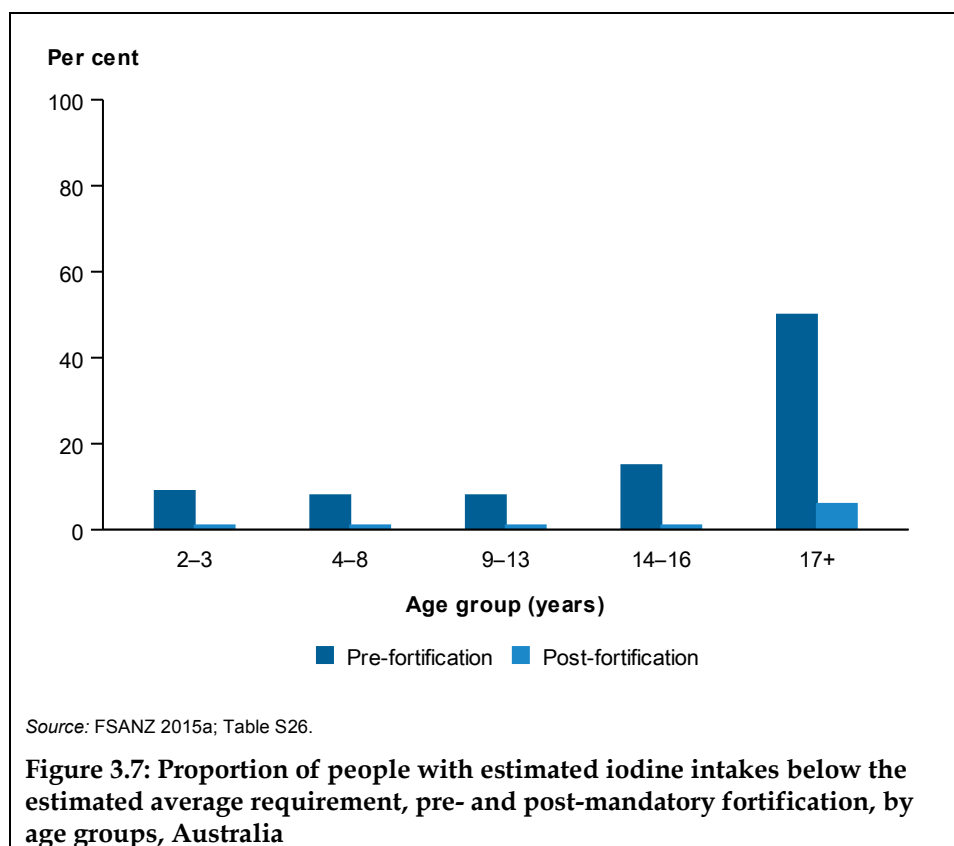
Based on the market weighted model, before fortification, 60% of women aged 16–44 had estimated iodine intakes that were below the EAR for non-pregnant women, 95% below the EAR for pregnancy and 100% below the EAR for breastfeeding. Post-mandatory fortification, all but 9% of women aged 16–44 were below the EAR for non-pregnant women but 65% were still below the EAR for pregnancy and 85% still below the EAR for breastfeeding (Figure 3.6).

Post-fortification, the proportion of children with inadequate iodine intakes decreased from 9% to less than 1% (Figure 3.7).



### Adequacy for the general population

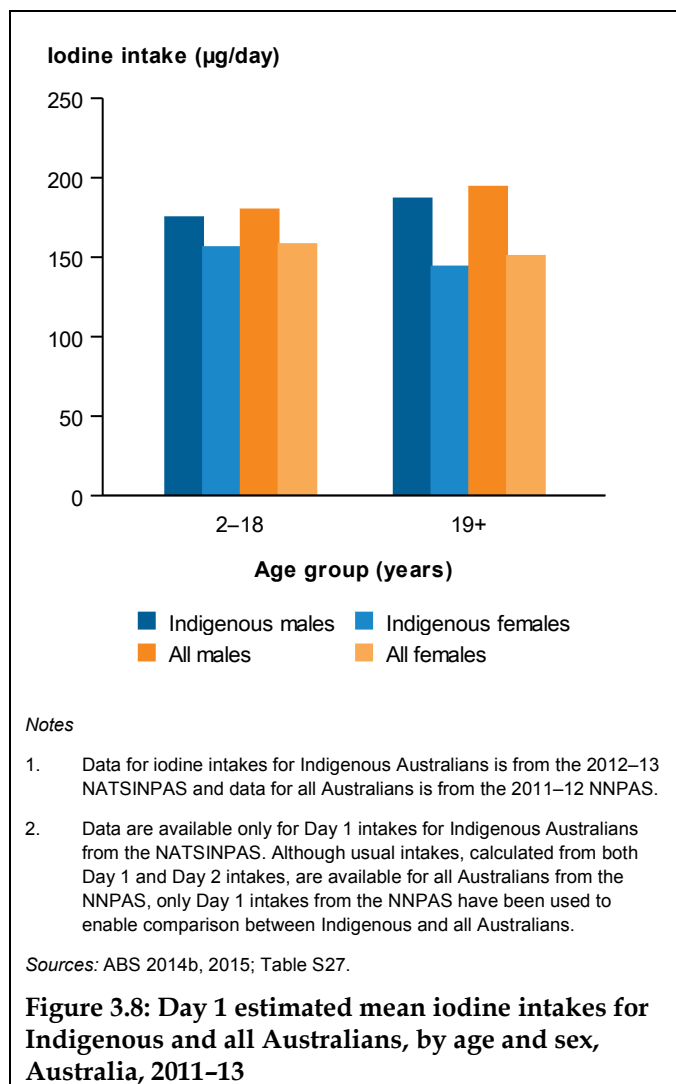
Post-fortification estimates show a substantial decrease in the proportion of the general population with estimated iodine intakes below the iodine EAR (Figure 3.7). Half of people aged 17 and over had insufficient intakes before mandatory fortification, which decreased substantially to 6% post-mandatory fortification (an 88% reduction). Children aged 2–16 also showed a decrease in the proportion with inadequate intakes, with those aged 14–16 having the largest decrease in this age range (from 15% to 1%).



### Iodine intake for Aboriginal and Torres Strait Islander people

Summary data from the 2012–13 NATSINPAS provide an indication of estimated iodine intake for Indigenous Australians. Data for the comparator group (all Australians) comes from the 2011–12 NNPAS (1-day intakes).

Overall, the general Australian population aged 2 and over consumed 4% more iodine than Indigenous Australians of the same age group (172 µg versus 165 µg/day) based on Day 1 intakes (Figure 3.8).



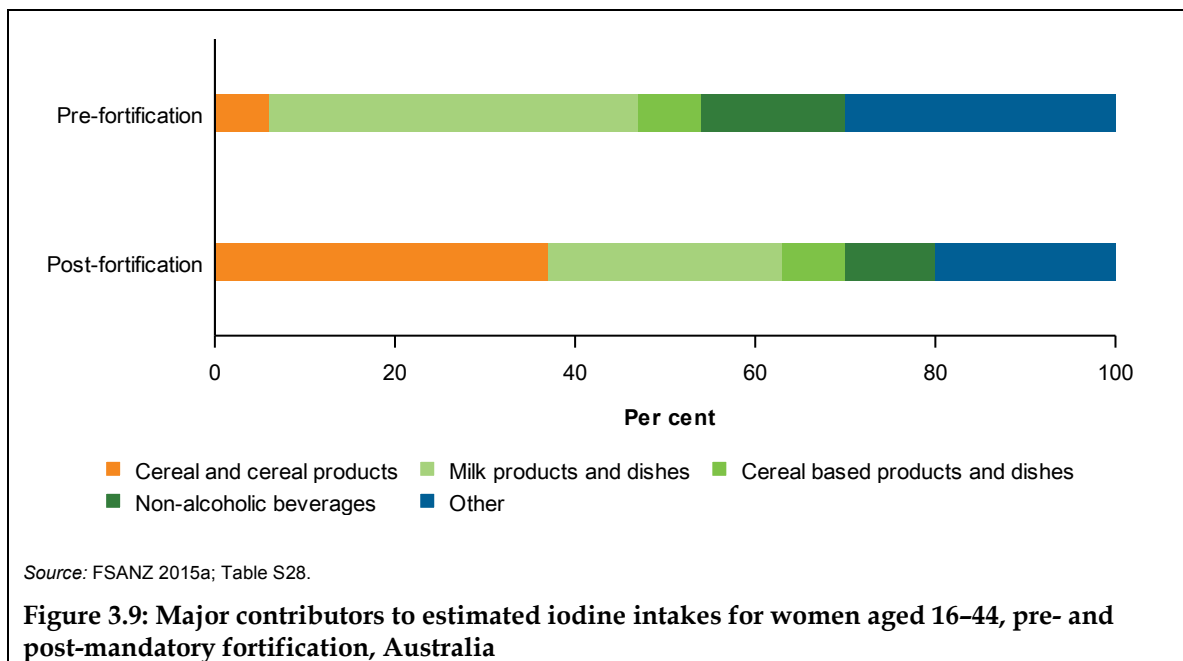
## Food contributors to iodine intake

The FSANZ dietary intake assessment was used to investigate the foods contributing to iodine intake pre- and post-mandatory fortification.

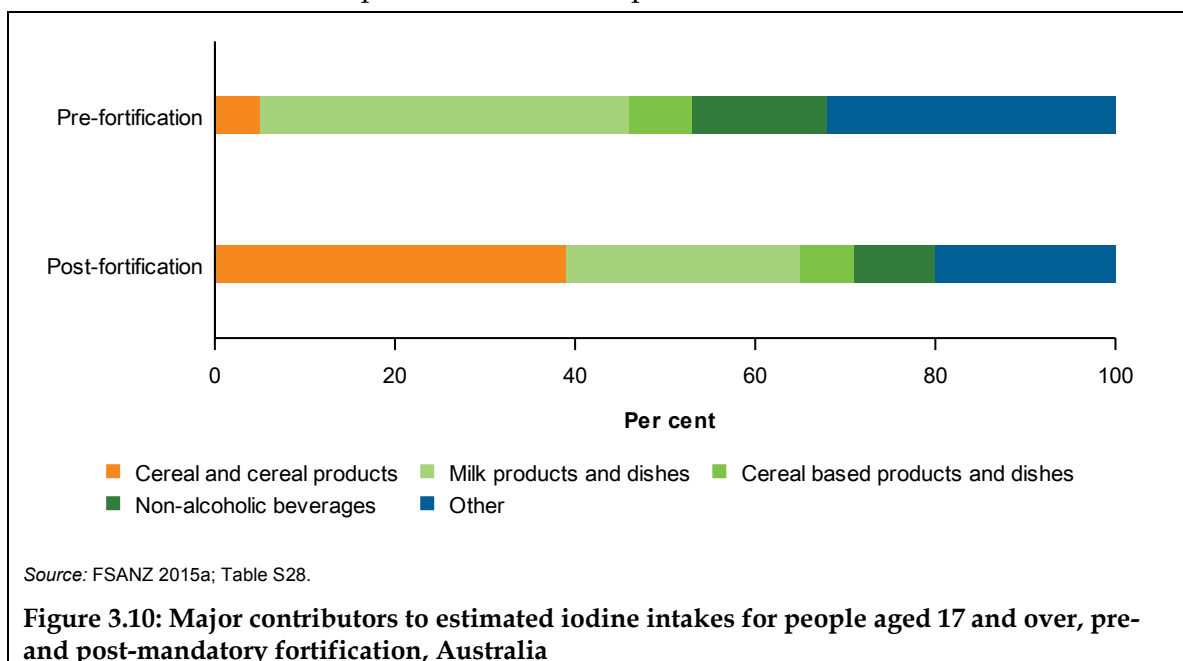
### Results

Before mandatory iodine fortification, milk products and dishes was the main contributing food group to estimated iodine intake (41%) for women aged 16–44 (Figure 3.9). Post-fortification, cereal and cereal products became the largest overall contributor to iodine intakes for this target population, increasing from 6% to 37%, resulting in a subsequent decrease in contribution from other foods.





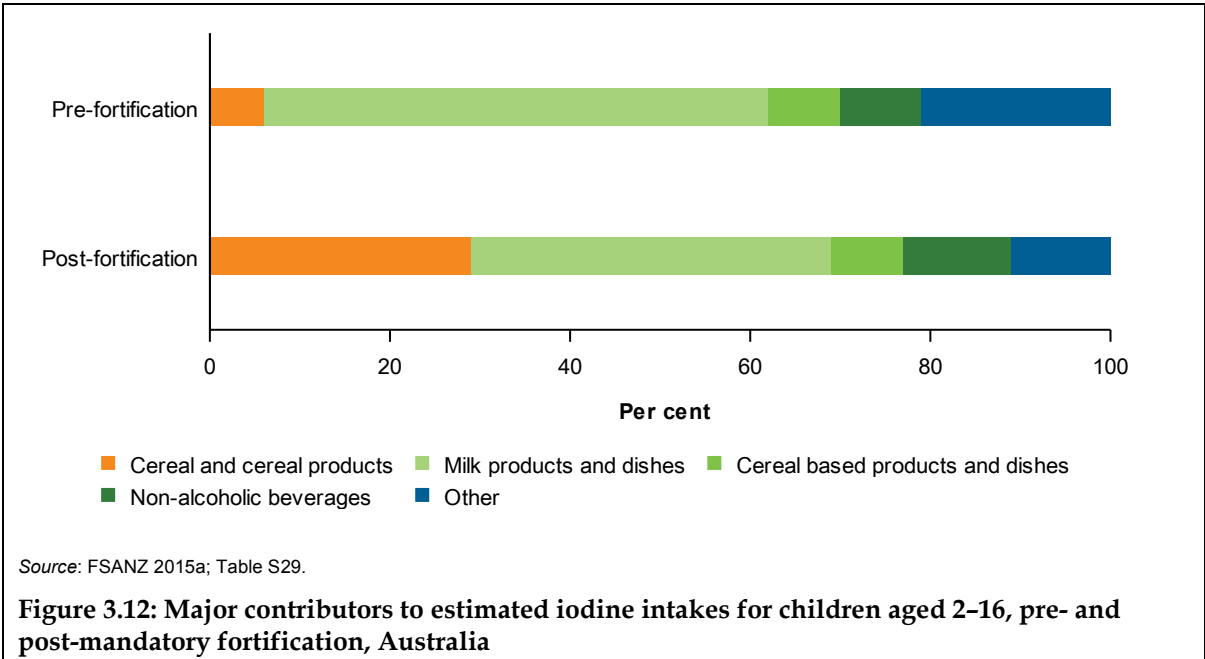
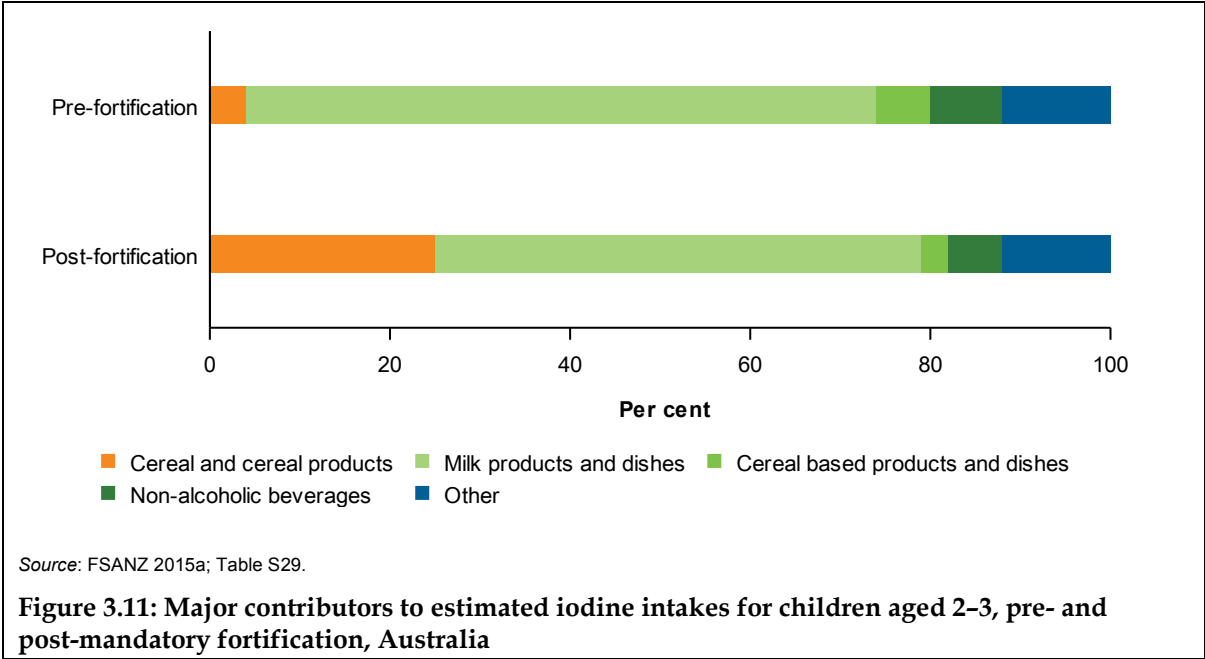
The change in the contribution for all Australian adults mirrored what was seen for women aged 16–44. The contribution from cereal and cereal products to estimated iodine intakes increased from 5% to 39% post-fortification (Figure 3.10). Dairy products, cereals and fish continue to be important contributors post-fortification for all adults.



Pre-fortification, the primary food group contributing to estimated iodine intake for all children aged 2–16 was milk products and dishes, contributing 56% to total intake. For the target group (children aged 2–3), milk products and dishes contributed around 70% to total iodine intake.

Post-fortification, the contribution of iodine from milk products and dishes decreased to 54% for children aged 2–3 and to 40% for all children (figures 3.11 and 3.12). The post-fortification change in children’s dietary iodine intake from milk products and dishes was due to the substantial increases in the contribution from cereal and cereal products, increasing from 4%

to 25% for children aged 2–3, and from 6% to 29% for children aged 2–16. Milk products and dishes continues to be the primary food group contributor of iodine for children aged 2–3 and for all children.



**Comparison with recent food consumption data**

As noted, while recent food consumption data are available from the 2011–12 NNPAS, these data have not been incorporated into DIAMOND and so could not be used in the FSANZ dietary assessment.

While it is generally recognised that people’s consumption of staple foods does not change markedly over time (Cox & Anderson 2004), some changes in bread consumption

(‘regular breads and rolls’) were found between the 1995 NNS and 2007 Children’s Survey, and the 2011–12 NNPAS.

As noted in Section 2.3, for children aged 2–16, the proportion of bread consumers and mean consumption of bread were similar between surveys. However, for adults aged 19 and over and women aged 16–44, the proportion of people consuming bread and the mean consumption of bread were lower between surveys (about 20 g less per day in 2011–12 compared with 1995, with 1 slice of bread equivalent to about 30 g) (FSANZ 2015a).

## **Supplement use**

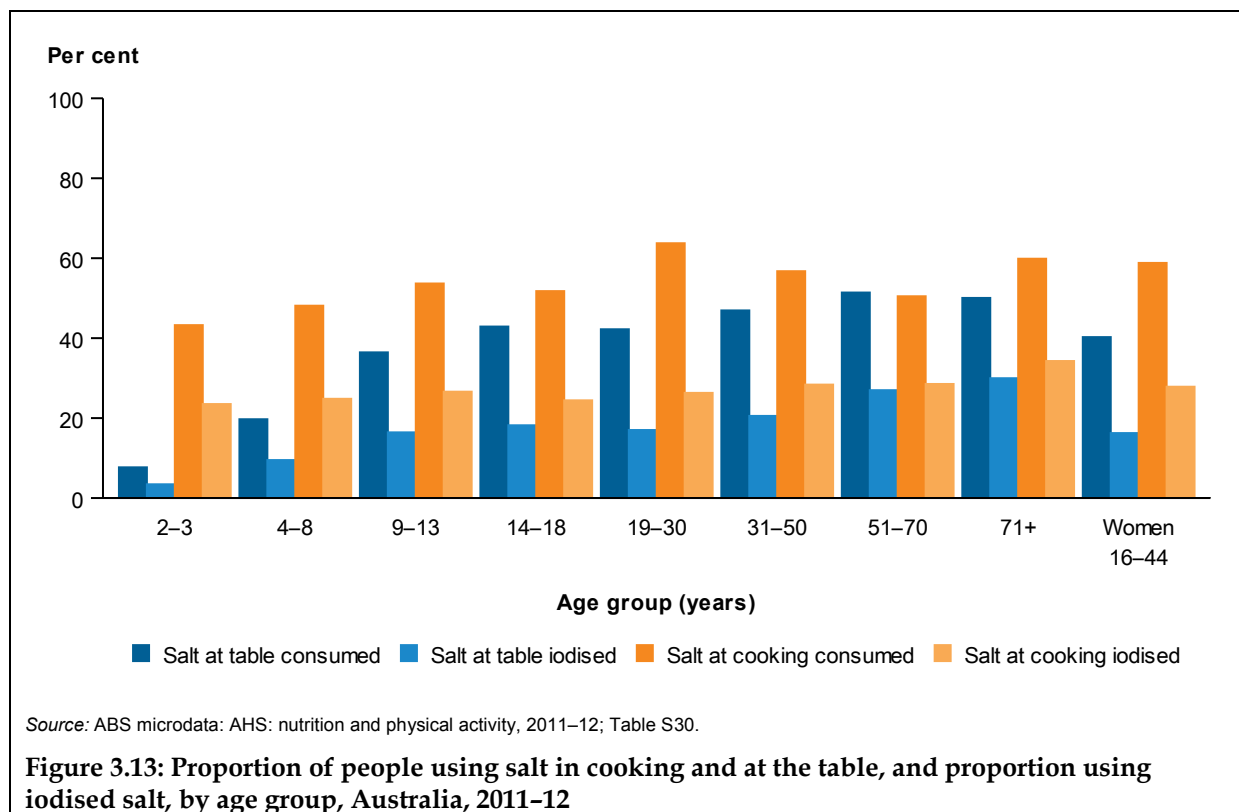
The use of dietary supplements was discussed in Chapter 2. Specific mineral supplements such as for iodine make up only a very small portion of supplement intakes, and consumption of iodine supplements was not measured directly. Most supplemental iodine is likely to come from combined multivitamin and mineral supplements.

## **Salt and iodised salt consumption**

Results from the 2011–12 NNPAS show that the average daily amount of sodium consumed from food for all persons aged 2 and over was 2,404 mg (or around 6 g of salt). Sodium intake mainly came from cereal-based products and dishes (25%) and cereal products (18%) (ABS 2014b).

For the target populations (women aged 16–44 and children aged 2–3), most reported using salt during cooking rather than adding it at the table. Around two-thirds of women aged 16–44 reported adding salt during cooking (59%) and over a third reported adding salt at the table (40%) (Figure 3.13). Children reported lower use of added salt at the table and during cooking compared with adults. This was especially so for younger children aged 2–3 and aged 4–8, where only 8% and 20%, respectively, used table salt. Generally, salt use increased with age, with the effect more pronounced for adding salt at the table.

Just under a third of all Australians reported using iodised salt during cooking (27%), and less than 1 in 5 reported using iodised salt at the table (18%). Women aged 16–44 were more likely to report using iodised salt during cooking than at the table (28% and 16%, respectively). For children aged 2–3, most iodised salt was being supplied during cooking, with only 3% adding it at the table.



## Consumers' awareness of, attitudes towards and behaviours in respect to food fortification

As identified in Section 2.3, in 2013, FSANZ published the results of its population consumer survey investigating the awareness of, attitudes towards and behaviours of Australian and New Zealander consumers in respect to food fortification (FSANZ 2013). As well as the generic fortification results for Australia already described, the survey showed that, when asked what vitamins or minerals were mandated for use in bread, a quarter (25%) of respondents correctly identified iodine.

Women were more likely to provide a specific and correct response on the intended benefits of iodine fortification than men, with 16% of Australian women aged 16-44 giving a specific and correct response.

Most Australian consumers reported eating a type of bread that would be fortified with iodine (91%), with 86% of women aged 16-44 reporting that they consumed iodine-fortified bread.

## 3.4 Nutrient status

**Key monitoring question:** *Has the iodine status of the population improved, particularly in women of child-bearing age and young children?*

**Data sources:**

- ABS 2011–12 NHMS.
- ABS 2011–13 NATSIHMS.

**Key findings:**

Post-mandatory fortification:

- The Australian population was consuming sufficient iodine to prevent deficiency at a population level, including women of child-bearing age (MUIC of 121 µg/L) and children aged 5–8 (MUIC of 175 µg/L).
- The MUIC for pregnant women aged 16–44 (MUIC of 116 µg/L) was still indicative of insufficient iodine intake (based on the higher requirements for pregnancy).
- Iodine status varied by location, with Tasmania, Victoria and the Australian Capital Territory having the lowest iodine status and Western Australia, the Northern Territory and South Australia having the highest status.
- Generally, the MUIC for adult Aboriginal and Torres Strait Islander people was higher for most age groups compared with the general population.
- Data for children suggest an increase in MUIC.

### Biomedical assessment of iodine

Spot urine samples were collected from respondents aged 5 and over as a part of the 2011–12 NHMS and 2011–13 NATSIHMS (see Appendix D for further details on these surveys). These samples were used to measure MUIC. Data were available for women aged 16–44 but not for young children aged 2–3 as the minimum age of participants was 5 in the NHMS and 18 in the NATSIHMS.

To outline possible changes pre- and post-fortification, data are provided on MUIC from the National Iodine Nutrition Study (pre-fortification) and the 2011–12 NHMS. Data are also provided from the Tasmanian Iodine Monitoring Program, which allow a comparison of MUIC pre- and post-fortification.

### Results from the National Health Measures Survey

#### Iodine status for women aged 16–44

The MUIC for all women aged 16–44 and for those who reported being pregnant or breastfeeding were above the general population WHO cut-offs for mild iodine deficiency (50–99 µg/day) (Figure 3.14) (see Appendix C for details of assessment criteria for iodine status). The MUIC for pregnant women was slightly lower than that for all women aged 16–44 (116 µg/L compared with 121 µg/L). The MUIC for breastfeeding women was the lowest (103 µg/L), which is expected, due to losses of iodine in breast milk as well as in urine.

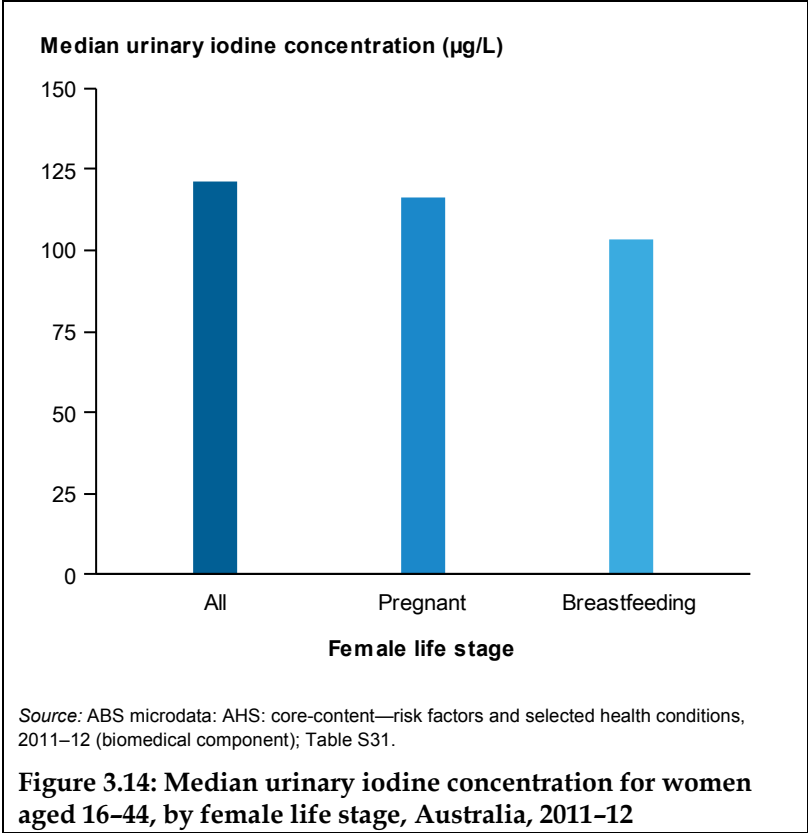
While the MUIC for pregnant women aged 16–44 was indicative of iodine sufficiency when assessed against the general population WHO cut-offs, this was not the case when assessed

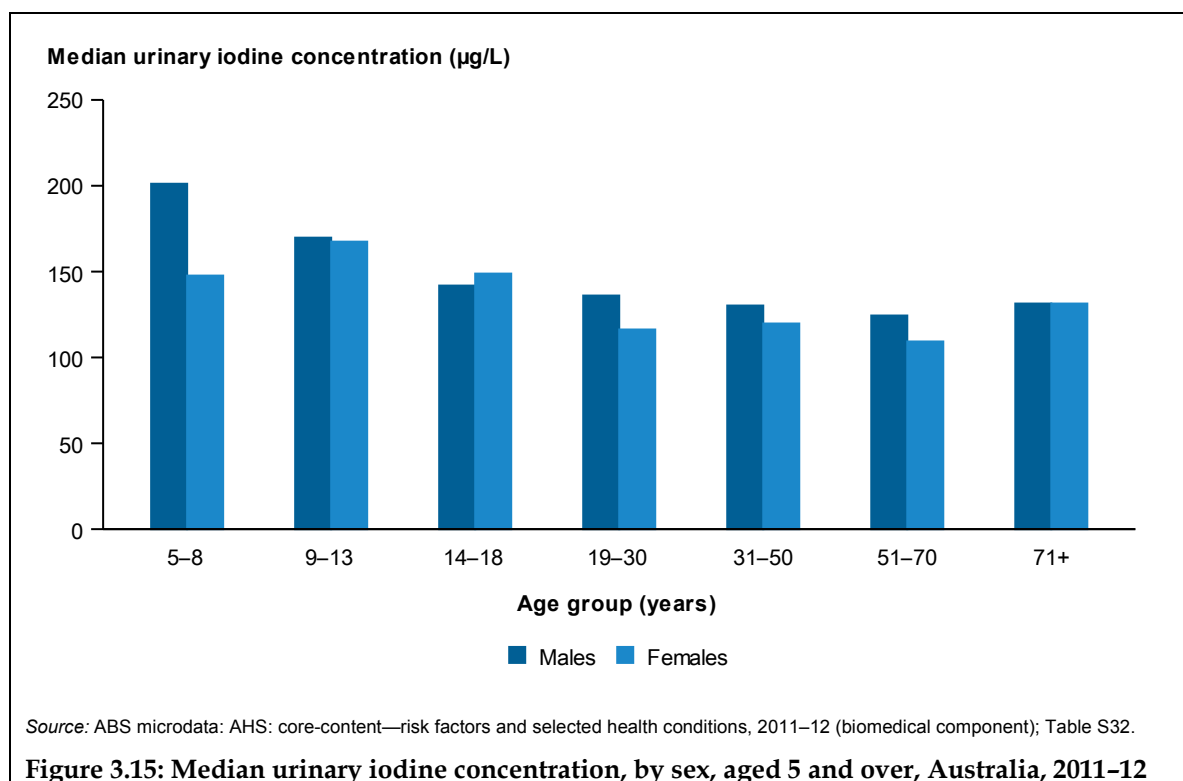
against the pregnancy WHO cuts-offs (150–249 µg/L) (WHO 2007), where the MUIC of 116 µg/L for pregnant women is indicative of insufficient intake.

**Iodine status for children and adults**

The MUIC for all age groups in the general population was 131 µg/L, indicative of iodine sufficiency (100–199 µg/L) (Figure 3.15). Males had, on average, a higher MUIC than females (138 µg versus 125 µg/L), and younger people aged 5–18 had a higher MUIC than older people aged 19 and over (163 µg versus 124 µg/L). Children aged 5–8 had the highest MUIC (175 µg/L) and females aged 51–70 the lowest (109 µg/L).

The MUIC assumes that urinary output is around 1L/day as determined from samples in school-aged children. Adult urinary output is likely to be higher than that for children, which may explain the higher MUIC detected in younger age groups (Mackerras et al. 2008).

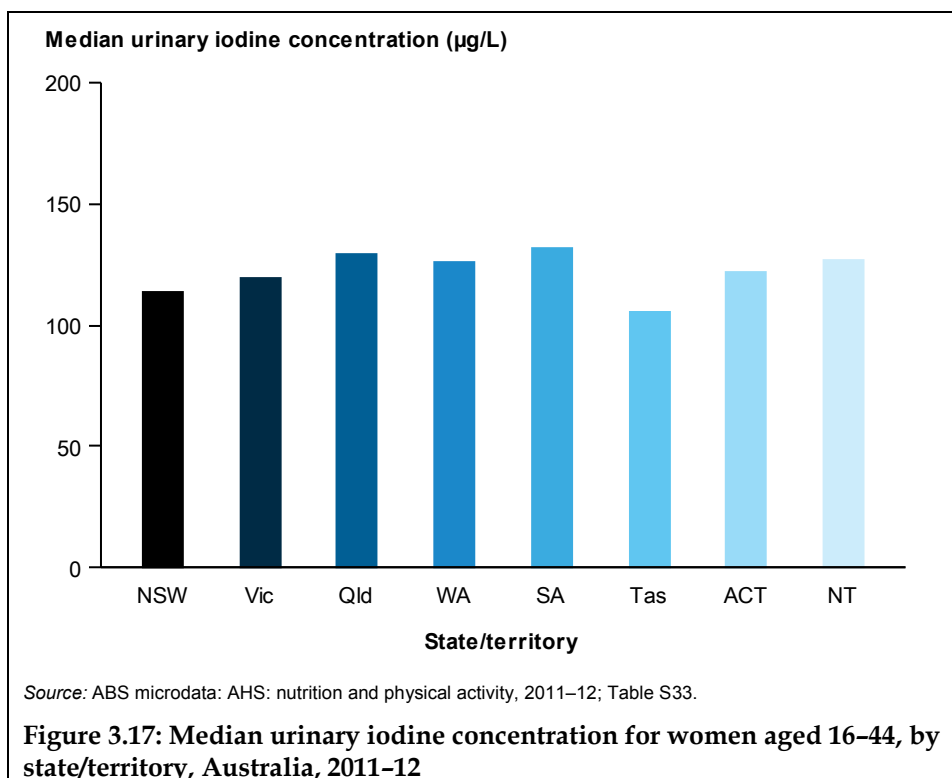
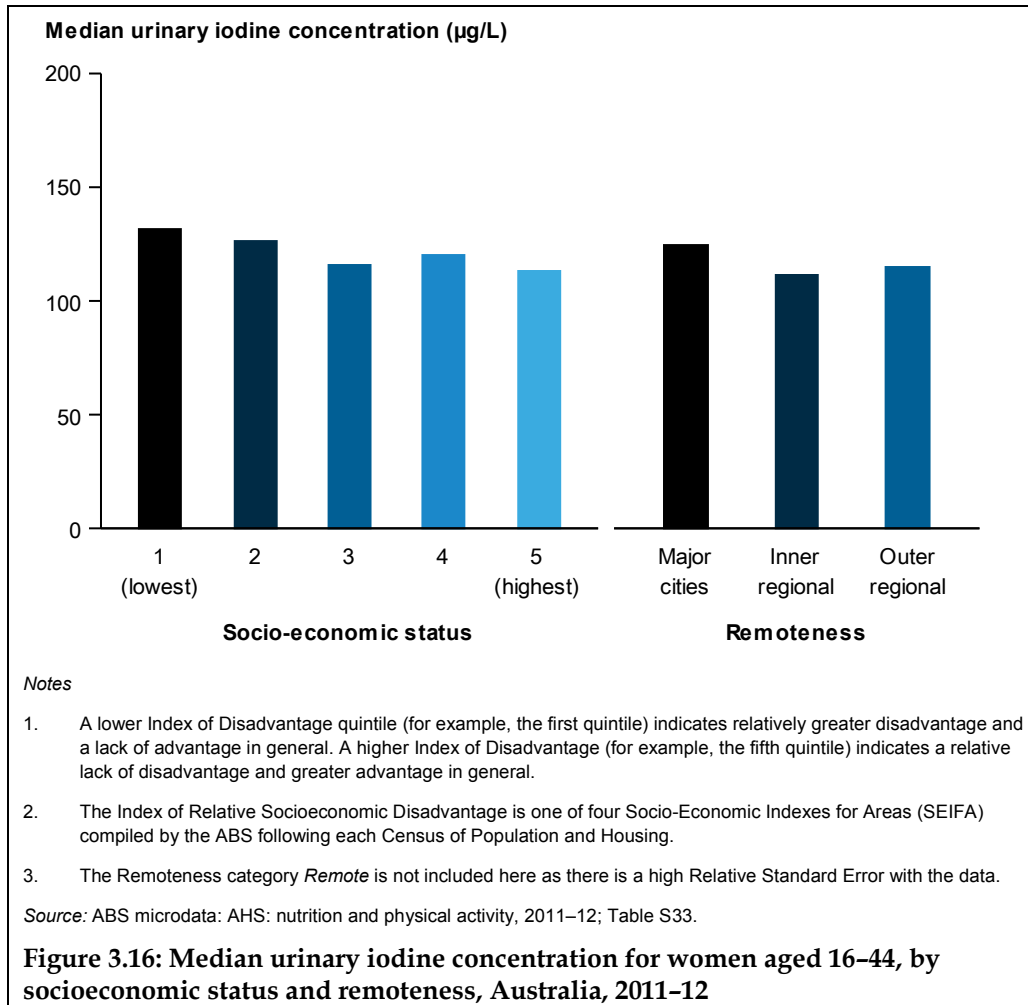




### Iodine status for women aged 16–44 by demographic characteristics

Measures of disadvantage and remoteness of residence both had an impact on iodine status for Australian women aged 16–44 (Figure 3.16). Those with the lowest SES had a 17% higher MUIC than women with the highest SES (132 µg and 113 µg/L), with a general trend for decreasing iodine status with decreasing quintiles of SES. Women aged 16–44 living in *Major cities* had, on average, a 9–13% higher MUIC those living in *Inner regional* and *Outer regional* areas (125 µg, 111 µg and 115 µg/L, respectively).

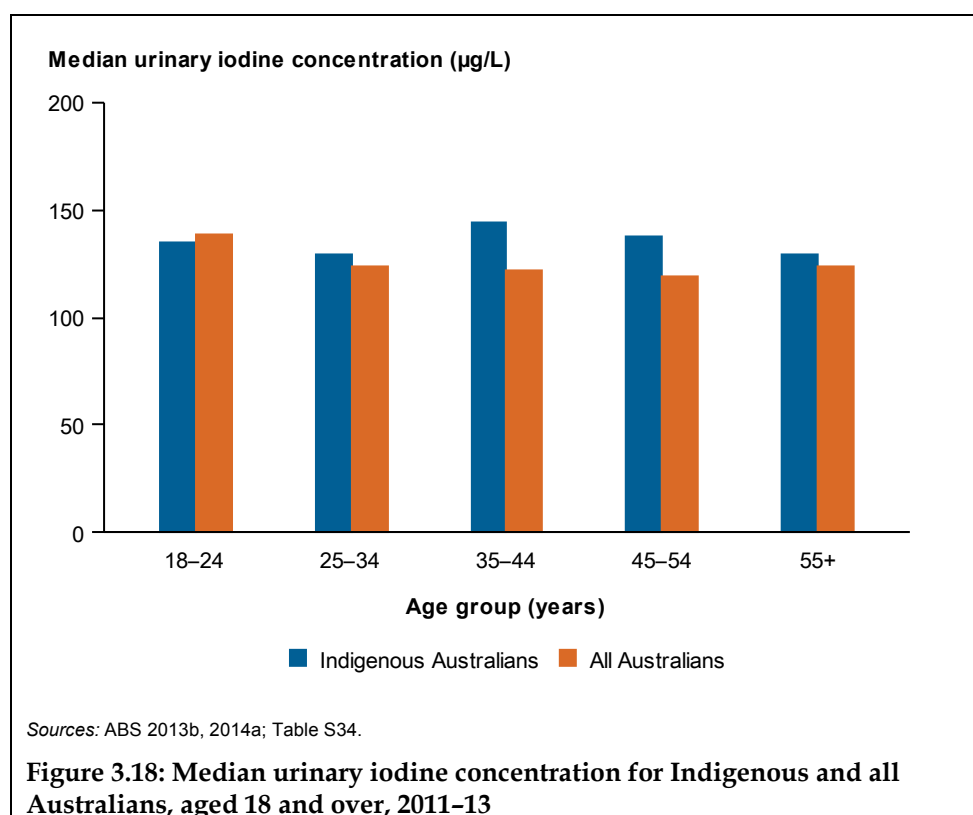
Previously, state or territory of residence has been an important factor influencing iodine status. Results from the 2011–12 NHMS showed that state of residence continues to have an impact on iodine status (Figure 3.17). The difference between the highest (South Australia) and lowest (Tasmania) reported MUICs was 26% (132 µg versus 105 µg/L). Tasmania, Victoria and the Australian Capital Territory had the lowest MUIC, while South Australia, Queensland and Western Australia had the highest. The median for all jurisdictions was above the cut-off for mild iodine deficiency.





### Iodine status for Aboriginal and Torres Strait Islander people

Generally, the MUIC for adult Indigenous Australians was higher for most age groups compared with the general population. Only Indigenous Australians aged 18–24 had a slightly lower MUIC than the general Australian population in that age group (Figure 3.18).



### Additional criteria for assessment of iodine status

As well as the general population WHO cut-offs for assessing iodine status, the WHO also recommends that no more than 50% of a studied population be below 100 µg/L (mild deficiency), and no more than 20% be below 50 µg/L (moderate deficiency) (WHO 2007). In this instance, 40% of women aged 16–44 were below 100 µg/L, and 19% below 50 µg/L, and therefore met the additional criteria for iodine adequacy at the population level (Table 3.1).

For children and adolescents aged 18 and below, 22% were below 100 µg/L and 7% below 50 µg/L. For people aged 19 and over, 38% were below 100 µg/L and 13% below 50 µg/L; therefore, indicating iodine adequacy for both population groups.

**Table 3.1: Proportion of the population meeting the World Health Organization targets for population iodine adequacy**

Age group (years)	<50 µg/L (%)	Target met? <sup>(a)</sup>	<100 µg/L (%)	Target met? <sup>(a)</sup>
16–44 (women)	19	Yes	40	Yes
18 and under	7	Yes	22	Yes
19 and over	13	Yes	38	Yes

(a) The World Health Organization recommends no more than 20% of a studied population be below 50 µg/L (moderate deficiency) and no more than 50% be below 100 µg/L (mild deficiency).

Source: ABS microdata: AHS: nutrition and physical activity, 2011–12.

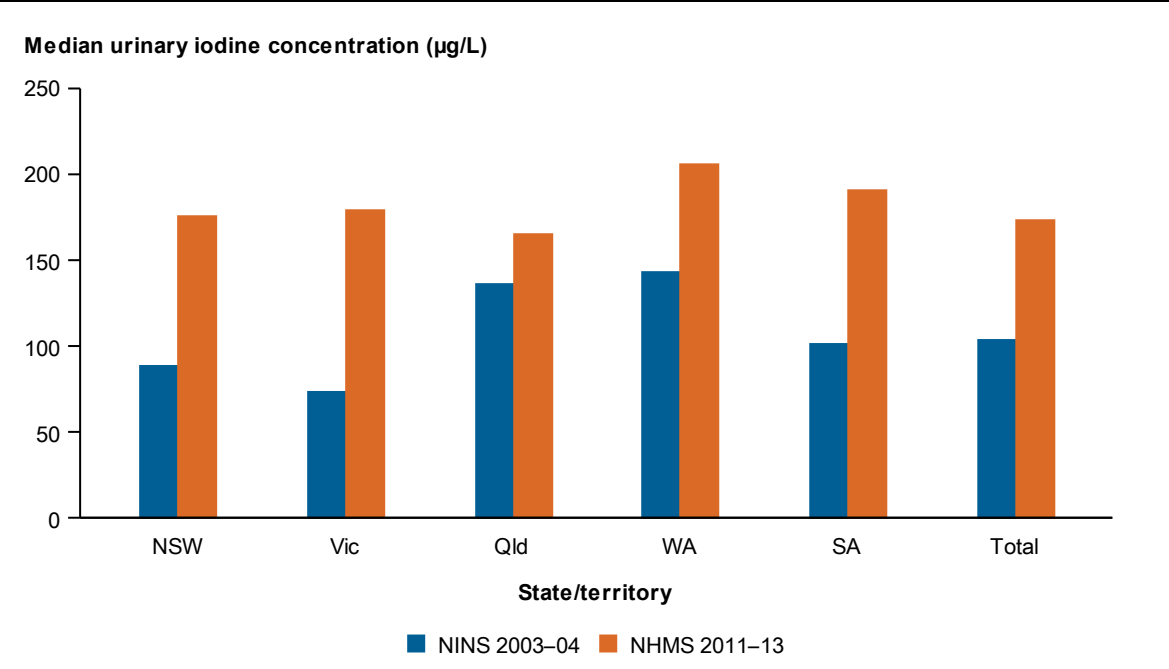
### Australian National Iodine Nutrition Study

The Australian National Iodine Nutrition Study examined the iodine status of schoolchildren aged 8–10 between July 2003 and December 2004 from New South Wales, Victoria, Queensland, Western Australia and South Australia (Li et al. 2006, 2008). Tasmania and the Northern Territory were not included due to the existing voluntary fortification program in Tasmania and logistical issues in the Northern Territory.

The average MUIC was 96 µg/L across all analysed states (Figure 3.19). The highest MUIC results were found in Western Australia and Queensland, and the lowest in New South Wales and Victoria. The MUIC of children in the 2011–12 NHMS was two-thirds (66%) higher than that of children of the same age in the Australian National Iodine Nutrition Study (ABS 2013b).

The MUIC was higher in the 2011–12 NHMS for all states but increases varied between states. Although Western Australia had the highest MUIC detected for children aged 8–10, the difference between pre- and post-mandatory fortification was smaller than for states where the MUIC was lowest during the 2003–2004 period. The Victorian population had the largest change observed between surveys and Queensland the smallest.

While these data indicate a possible increase in MUIC following mandatory iodine fortification, results must be interpreted with caution. This is due to the different sampling methods and iodine analysis methodologies. These data provide only an indicative assessment of change in iodine status pre- and post- mandatory iodine fortification.



Note: NINS = the 2003–04 Australian National Iodine Nutrition Study. NHMS = the 2011–13 National Health Measures Survey.

Sources: ABS microdata: AHS: core-content—risk factors and selected health conditions, 2011–12 (biomedical component); Li et al. 2006, 2008; Table S35.

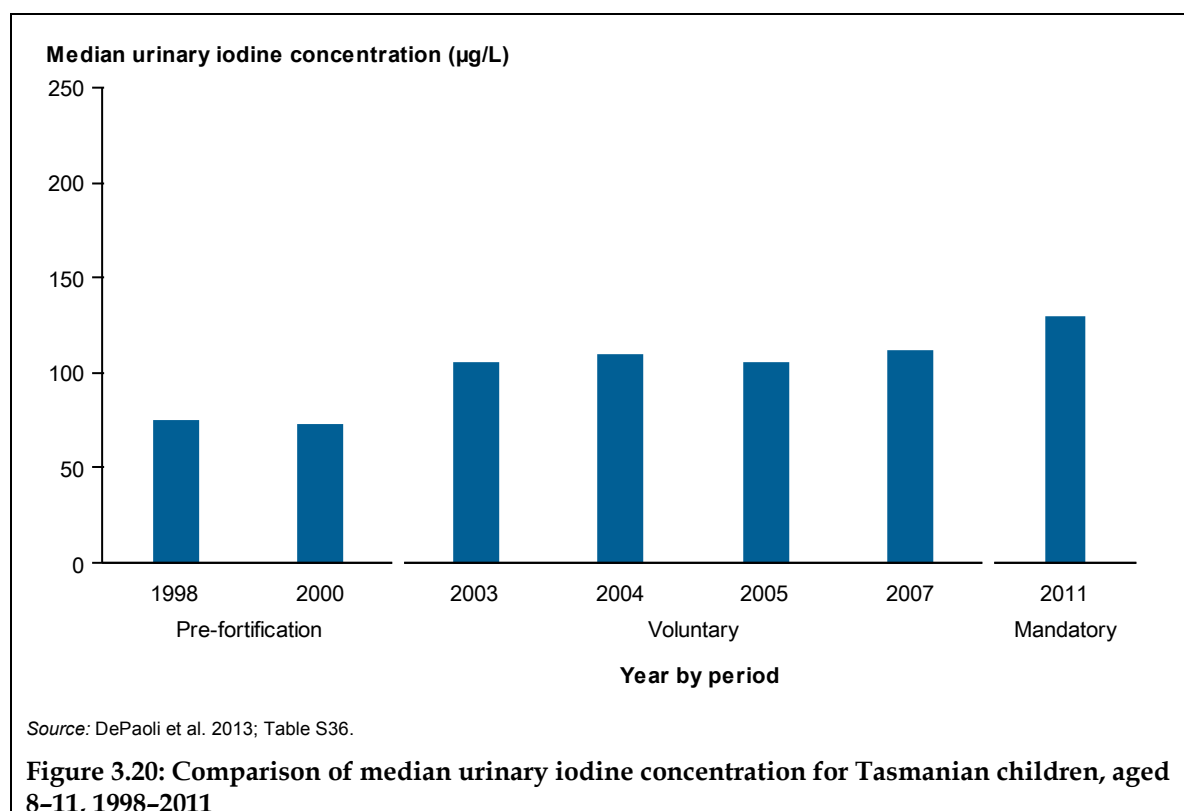
**Figure 3.19: Comparison of median urinary iodine concentration, by state/territory, by survey period, children aged 8–10, Australia**

## Tasmanian Iodine Monitoring Program

DePaoli et al. (2013) assessed the MUIC in Tasmanian schoolchildren aged 8–13 in the following intervention periods:

- pre-fortification (1998, 2000)
- state-based voluntary fortification (2003, 2004, 2005, 2007)
- mandatory fortification (2011).

The MUIC in 2011 was significantly higher than in the period of voluntary fortification (129  $\mu\text{g/L}$  versus an average of 108  $\mu\text{g/L}$ ), which, in turn, was significantly higher than the MUIC in the years pre-fortification (73  $\mu\text{g/L}$ ) (DePaoli et al. 2013) (Figure 3.20).



## 3.5 Health benefits

The desired health benefit from mandatory iodine fortification was a reduction in iodine deficiency across much of the Australian population. This assessment is provided in Section 3.4.

## 3.6 Adverse health effects

**Key monitoring question:** *Does mandatory iodine fortification result in adverse health effects for the population?*

**Data sources:**

- FSANZ's 2014 dietary intake assessment.
- ABS 2011-12 NHMS.

**Key findings:**

Post-mandatory fortification:

- The increase in iodine intakes had minimal effect on the proportion of the population with estimated intakes exceeding the UL.
- A higher proportion of children had estimated iodine intakes that exceeded the UL for iodine; for children aged 2-3, the proportion increased from 7% to 20%. This is not likely to pose a health risk, however, as the thresholds have been extrapolated to children from adults and the proportion of young children exceeding the UL decreases with age.
- No population group had an MUIC above the level indicative of excessive iodine intake.

The term 'adverse health effects' is used in the monitoring framework. However, the two measures under this component are indicators of possible increasing risk as opposed to direct adverse health effects. These measures are the assessment of estimated iodine intake against the UL, and MUIC against the criteria for excessive intake.

### Upper level of intake

The following assessment is based on FSANZ's dietary intake assessment, reported in Section 3.3.

#### Results

Based on the market weighted salt intake model, the increase in estimated iodine intakes following mandatory fortification had minimal effect on the proportion of most population groups exceeding the UL (see Supplementary Table S37).

The increase in iodine intake for children aged 2-3 resulted in a higher proportion exceeding the UL (from 7% to 20%). Despite this, the proportion of children exceeding the UL is not considered to pose a health risk because the thresholds have been extrapolated to children from adults and the proportion of young children exceeding the UL decreases with age, with less than 1% exceeding the UL after age 4 (see Section 5.2 for details).

### Median urinary iodine concentration

As identified in Section 1.1, an MUIC of more than 300 µg/L represents excessive iodine intake and could pose a risk of adverse health consequences. In addition, the MUIC for pregnant women should not exceed 500 µg/L.

## **Results**

As indicated in Section 3.4, data from the 2011–12 NHMS showed that no population group had an MUIC above 300 µg/L and the MUIC for pregnant women was well below 500 µg/L (at 116 µg/L).

# 4 Mandatory iodine fortification in New Zealand

## 4.1 Food composition

**Key monitoring question:** *Has the level of iodine in our food supply increased?*

**Data sources:** 2010 and 2012 MPI data.

**Key findings:**

Post-mandatory fortification:

- The median level of iodine in commonly consumed bread ranged from 28–49 µg per 100 g.
- These levels were similar to the 46 µg/100 g (mean) predicted when developing the mandatory fortification requirement.

### Bread analytical surveys

The New Zealand Ministry for Primary Industries (MPI) (formally the New Zealand Ministry of Agriculture and Forestry) manages an ongoing program to measure the performance of its regulatory food program. The program includes assessing the mandatory replacement of non-iodised salt with iodised salt in bread products.

In 2010 and 2012, the MPI undertook analytical surveys to examine the level of iodine and sodium in a representative sample of breads consumed in New Zealand (MAF 2012; MPI 2014). The level of iodine in fortified salt was not monitored as part of this survey.

The initial sampling period in 2010 surveyed 526 bread samples limited to generic breads, organic breads and crumpets. The second sampling period in 2012 examined 428 breads with an expanded sampling frame to include breads manufactured by private label brands and a larger range of bread products, such as hamburger buns and pita breads. All breads, regardless of market share, were grouped into 8 categories for the 2010 results and grouped into 14 categories for the 2012 results for analysis of iodine content.

Both the mean and median iodine level were calculated for each bread category. In the 2012 sample, the median was used for reporting due to skewed results for certain breads. The mean of a studied variable is particularly susceptible to the influence of outlying data, while the median is less affected. For this report, the median is reported for all bread samples to enable comparison between the 2010 and 2012 results.

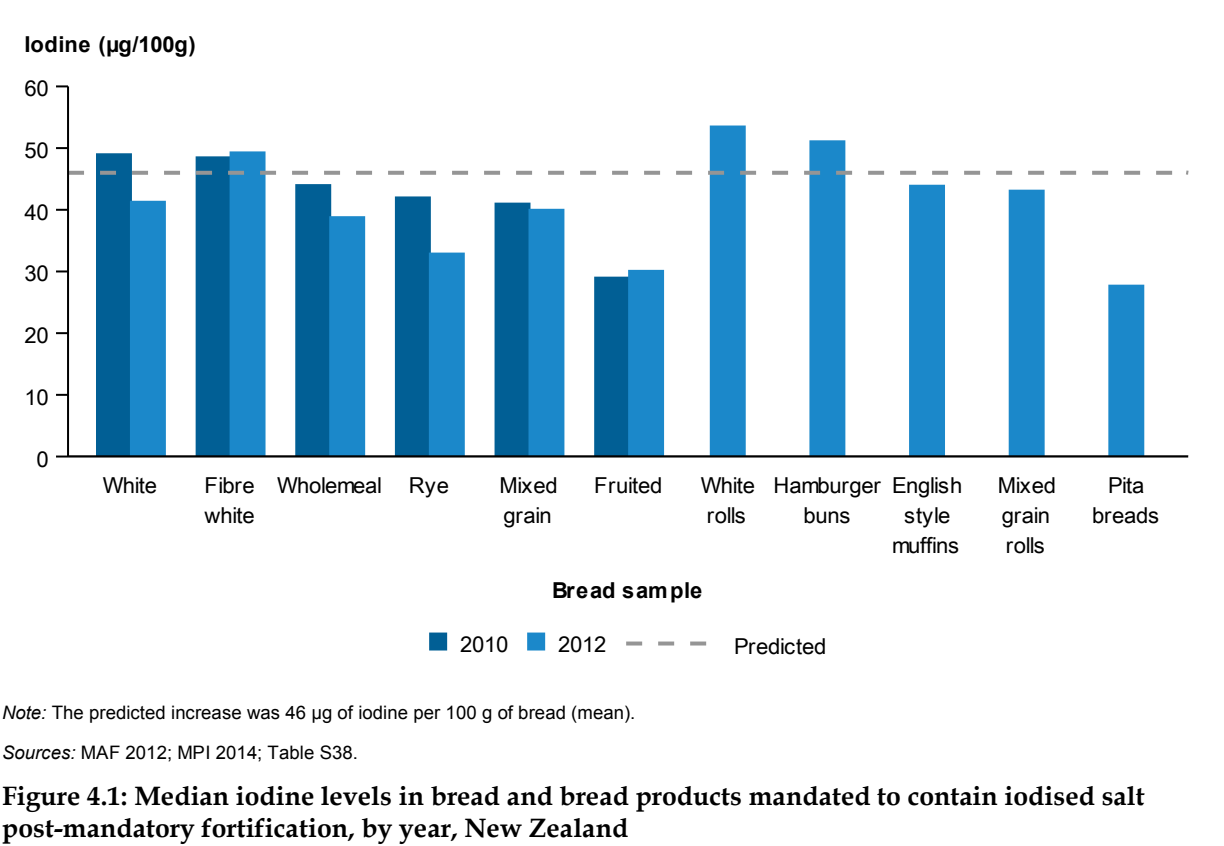
### Results

#### Post-fortification iodine levels in bread and bread products

Breads expected to contain iodised salt in 2010 (fibre white, fruited, mixed grain, rye, white and wholemeal) and in 2012 (fibre white, fruited, mixed grain, rye, white, wholemeal, white and mixed grain bread rolls, English style muffins, hamburger buns and pita breads) were found to contain median iodine levels between 28–49 µg/100 g (Figure 4.1). Overall, the median iodine levels in breads required to use iodised salt were around, or slightly below,

the estimate of 46 µg/100 g (mean) initially predicted when developing the mandatory fortification requirement (FSANZ 2008b).

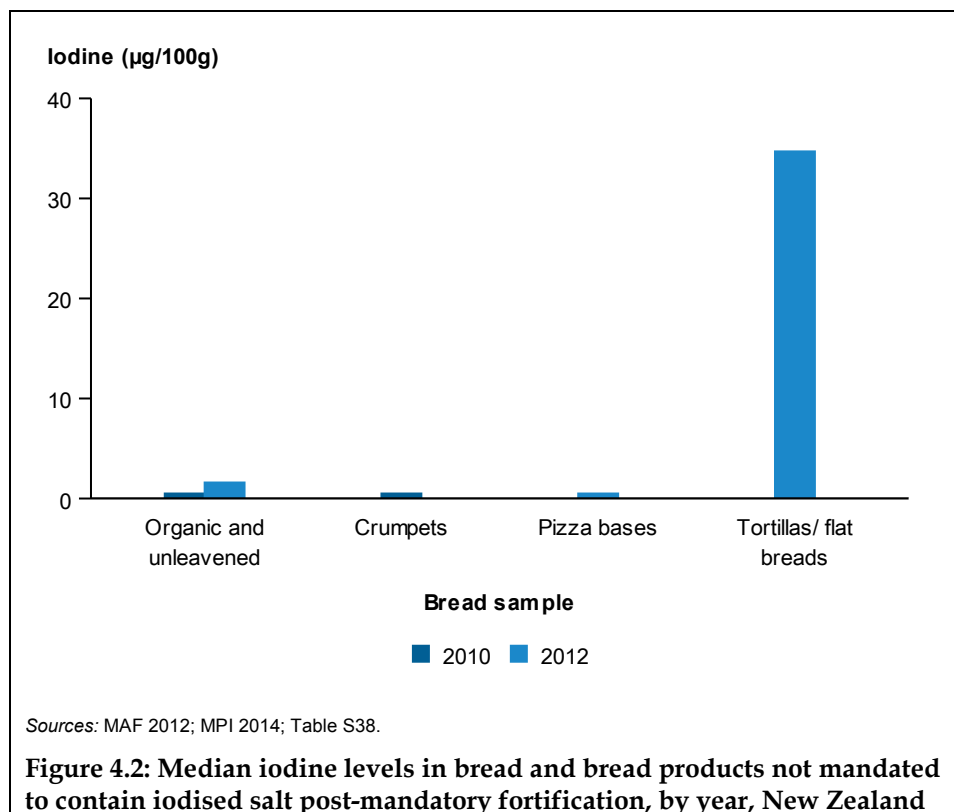
Of these breads, fruited bread contained the lowest median iodine concentration in 2010, and pita breads in 2012. In 2010, white and fibre white bread products had the highest median concentrations of iodine, while fibre white bread, white bread rolls and hamburger buns had the highest concentrations in 2012. Mixed grain breads were found to have the greatest variation in the range of iodine concentrations in 2010 (3–380 µg/100 g) and in 2012 (2–144 µg/100 g).



**Figure 4.1: Median iodine levels in bread and bread products mandated to contain iodised salt post-mandatory fortification, by year, New Zealand**

Of bread products not expected to meet fortification requirements, crumpets, organic breads and pizza bases had very low iodine concentrations or below detectable limits (Figure 4.2). Tortillas and flat breads, which are not required to be fortified, were still found to have a median of 35 µg/100 g. The MPI notes that the levels found in tortillas and flat breads may imply that manufacturers are choosing to voluntarily fortify these bread products by using iodised salt, or that communication regarding mandatory fortification requirements may be unclear (MPI 2014).

Median iodine levels were consistent between most sampled bread categories. Of those sampled in both surveys, only rye, white and wholemeal breads had the largest differences in median iodine concentrations between surveys. Variation in iodine concentrations within and between bread products can be attributed to a number of factors as outlined in Section 3.1.



## 4.2 Food industry compliance

**Key monitoring question:** *Are the food industries adequately complying with the mandatory fortification standard?*

**Data source:** 2015 Catalyst Ltd review.

**Key finding:**

- Post-mandatory fortification, New Zealand salt manufacturers and bakers have systems in place to ensure compliance with the mandatory iodine fortification requirement.

### Compliance and enforcement review

For Stage 1 of the mandatory fortification review, Catalyst Ltd was commissioned to review compliance with, and the enforcement impacts of, the mandatory fortification of bread with folic acid and iodine (Catalyst Ltd 2015). The main food industries affected by the mandatory iodine fortification requirements are salt manufacturers and bread producers. This review is based on feedback from 1 New Zealand major salt manufacturer and 7 New Zealand bakers.

### Results

The salt manufacturer reported having quality assurance programs and systems in place, including external third party audits, to ensure compliance with the mandatory iodine requirement. Iodine addition was automated, with equipment routinely calibrated and products tested.



Similar to Australia, all baking companies reported having quality management systems in place specifying salt requirements. Suppliers had contractual requirements to meet product specifications. Some companies require a certificate of analysis and others also test the iodine levels in their products. Bread and baked goods manufacturers supplying products to supermarkets are subject to third party external auditing. Respondents not subject to external auditing reported having internal auditing practices in place.

Based on information from the baking and bread mix industry, Catalyst (2015) estimated an increase of 115 kg of iodine per annum in the New Zealand food supply, as a result of mandatory iodine fortification.

### 4.3 Nutrient intake

**Key monitoring question:** *Have iodine intakes in the population increased, particularly in women of child-bearing age and young children?*

**Data source:**

- MPI data (2013, 2014) for women aged 18–44 and adults aged 18–64 (urinary iodine measurements) and for children aged 5–14 (dietary intake estimates).

**Key findings:**

Post-mandatory fortification:

- Estimated mean iodine intakes for women of child-bearing age were higher than those reported at baseline, but less than the predicted increase of 73 µg/day. However, because of uncertainty in the ability to directly compare studies, these results must be interpreted with caution.
- Estimated mean iodine intakes for children aged 5–14 increased by 48 µg/day to 93 µg/day.
- Almost two-fifths (39%) of women aged 18–44 had inadequate iodine intakes (below the EAR for non-pregnancy). This is less than the 68% below the EAR at baseline for women aged 16–44 but above the 0% predicted post-fortification.
- The proportion of children with inadequate intakes (below the EAR) reduced from 95% to 21% when iodine intake from food only was estimated, and from 7% to <1% when 1 g of iodised discretionary salt was included in modelling estimates.
- Bread and bread products became the largest contributor (about 45%) to iodine intakes for children aged 5–14, followed by milk and dairy products (21%).

Unlike the Australian national data sources used to assess iodine intake and status, the data sources for New Zealand are based on smaller subnational surveys. As such, the New Zealand results may not be as representative for the whole population, or the findings as robust, as the Australian results. Therefore, caution is needed when making direct comparison between countries.

Results from the 2014–15 New Zealand Health Survey (which cover the population aged 15 and over) were not available at the time of drafting this report. The results are expected to be publicly released in mid-2016 and will be an important adjunct to the existing available New Zealand data on iodine intake and status, providing a more complete picture for the population and key target groups.

## **Biomedical assessment of dietary iodine intake for adults**

Between February and November 2012, the MPI measured iodine status in 301 randomly sampled New Zealand adults aged 18–64 from Dunedin and Wellington to complement their other monitoring activities (MPI 2013). Compared with the 2006 New Zealand Census data for Dunedin and Wellington citizens, the data for this study had a higher percentage of New Zealand European and other ethnicity participants and with incomes greater than NZ\$50,000. Also, 20% of participants lived in the least deprived areas, while less than 10% lived in the most deprived areas.

Iodine status was measured over a 24-hour period through urine samples collected from participants' homes. Urine samples were used to calculate urinary excretion volumes and assess 24-hour UIE. UIE can be used to estimate iodine intakes with the assumption that approximately 90% of dietary iodine is excreted. The approximate value can then be compared against NRVs to evaluate the adequacy of iodine intakes. The authors note that using UIE to determine iodine intake is a more accurate and objective method than traditional dietary assessment methods, especially for a nutrient like iodine, where iodised salt intake is difficult to accurately quantify in the diet (MPI 2014).

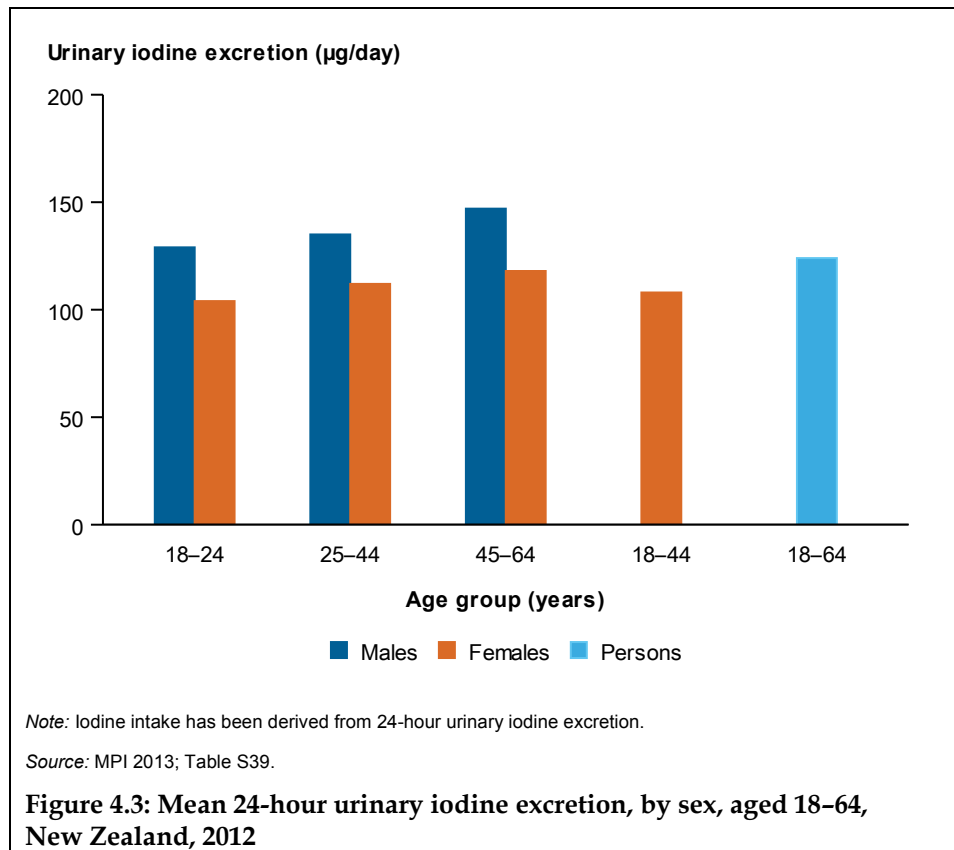
Iodine intake data were unavailable from the 2008–09 New Zealand Adult Nutrition Survey. Therefore, estimates from FSANZ's final assessment report (FSANZ 2008c) were used to provide context for pre-fortification iodine intakes for assessing changes for adults.

Given the different methods used to estimate iodine intake pre- and post-fortification (survey size and derivation of intakes from food intake versus UIE), the data are not directly comparable and are used as a guide only.

## **Results**

### **Change in iodine intake for women aged 18–44 and adults aged 18–64**

The mean 24-hour UIE of women aged 18–44 was 108 µg/day, and 124 µg/day for all studied New Zealand adults, following the implementation of mandatory iodine fortification in September 2009 (Figure 4.3) Compared with pre-fortification estimates determined when developing the mandatory fortification requirement, iodine intake estimates calculated from the UIE show a small improvement in iodine intake for both women aged 18–44 and the whole population.



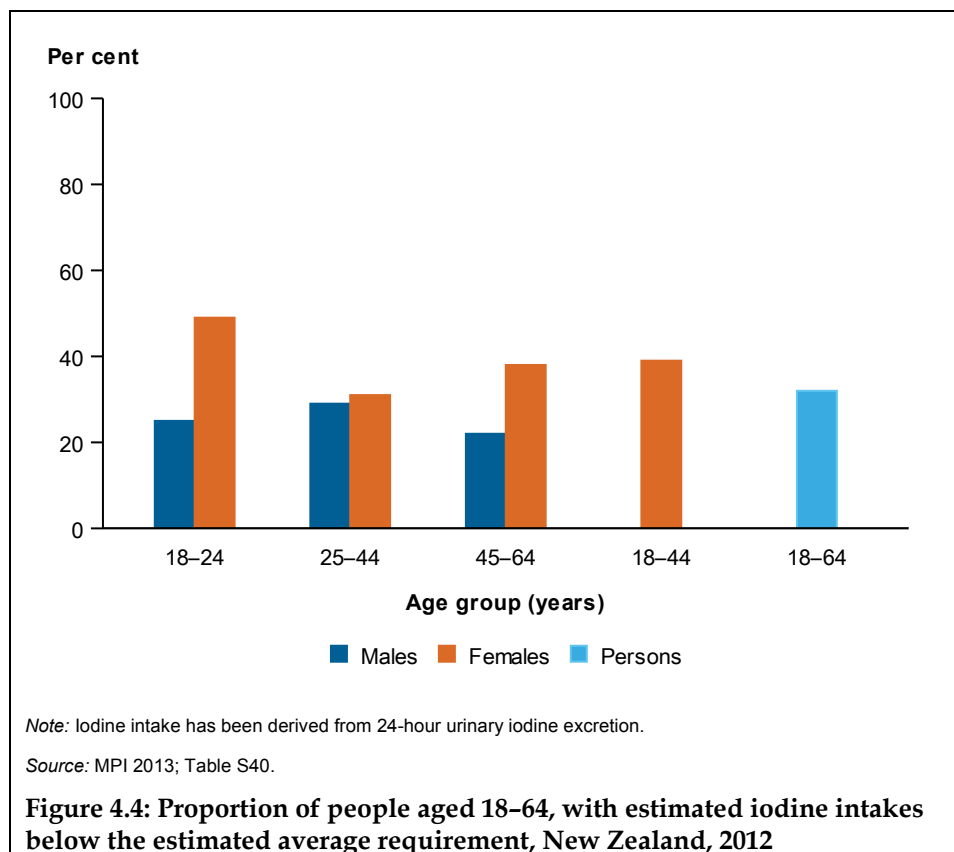
Pre-fortification, the mean baseline iodine estimate for women aged 16-44 was 99 µg/day, with a predicted increase to 172 µg/day post-fortification. Likewise, the estimate for the population aged 15 and over was 105 µg/day at baseline, with a predicted increase to 189 µg/day (FSANZ 2008c). Although the pre-fortification estimates are not directly comparable due to different methods used to estimate intakes, iodine intakes based on the UIE appear to be lower than those predicted when developing the fortification requirement.

Males aged 18-64 had a higher 24-hour UIE than women aged 18-64 (137 µg versus 112 µg/day). The authors report an association between the number of bread serves consumed each week and 24-hour UIE, but no difference between 24-hour UIE and age.

### Adequacy

Pre-fortification, 68% of women aged 16-44 had estimated iodine intakes derived from 1997 New Zealand NNS data below the non-pregnant EAR and it was predicted this proportion would reduce to 0% post-fortification. Twenty-four (24)-hour UIE data were compared with the appropriate EAR for iodine post-fortification. This showed that 39% of women aged 18-44 and 49% of younger women were still at risk of inadequate iodine intakes post-fortification (Figure 4.4). Estimates of the proportion of women aged 16-44 meeting the pregnancy and breastfeeding EARs for iodine were lower.

The proportion of the population aged 18-64 with intakes below the EAR for iodine was 32%. Men were less likely to be below the EAR than women of comparable age groups. These results demonstrate that a substantial proportion of the New Zealand adult population were at risk of inadequate iodine intakes, despite mandatory iodine fortification.



## Dietary iodine intake for children

Dietary iodine intakes of children aged 5–14 were estimated using the revised iodine values obtained from the 2010 and 2012 analytical bread and bread products surveys (outlined in Section 4.1). School-aged children were selected as they are one of the primary targets of the New Zealand Domestic Food Review to determine the success of the mandatory fortification program.

FSANZ’s DIAMOND computer program was used to conduct dietary iodine intake estimates. Dietary intakes were calculated using second-day adjusted 24-hour food intake data for 3,275 children aged 5–14 in the 2002 New Zealand Children’s Nutrition Survey (2002 Children’s Survey). Baseline data on iodine intakes pre-fortification were calculated by attributing all foods consumed in the 2002 Children’s Survey to iodine concentration data from the New Zealand Food Composition Database and the New Zealand Total Diet Study data. Post-fortification mean iodine consumption was calculated by assigning each bread consumed in the 2002 Children’s Survey to one of the breads in each of 2010 and 2012 samples separately.

General iodised salt use data were provided as part of questions in the 2002 Children’s Survey, but these data were not detailed enough to determine the quantity of discretionary salt, or proportion of total salt used, that was iodised. Discretionary salt use can contribute a substantial amount of iodine to total dietary intake. Two models to account for possible iodine from discretionary salt intake were constructed, similar to those derived by FSANZ for estimating Australian iodine intakes: a 2002 Children’s Survey salt behaviour model and a consumer behaviour model (Table 4.1).

The 2002 Children’s Survey salt behaviour model was excluded from the analysis using the 2012 bread survey results. This was due to concern that the questionnaire responses

regarding the use of iodised salt in the home had not been verified using packaging, a method subsequently used in recent New Zealand surveys (MPI 2014). Estimated mean iodine intakes for each model were then compared with the EAR for iodine for the 5–8, 9–13 and 14 year age groups, respectively.

**Table 4.1: Summary of discretionary salt models used by the Ministry for Primary Industries to estimate dietary iodine intake for children aged 5–14**

Model	Description
Food only (never select iodised salt)	In this model, it was assumed that none of the respondents in the 2002 Children's Survey consumed discretionary iodised salt. Therefore, no discretionary iodised salt was added to the total intake of iodine consumed from food.
Food plus iodised discretionary salt (always select iodised salt)	In this model, it was assumed that all respondents in the 2002 Children's Survey consumed discretionary iodised salt. Therefore, for all respondents, 1 g of iodised salt with an iodine concentration of 48 µg was added to the total iodine intake consumed from food.
2002 Children's Survey salt behaviour model*	In this model, only those respondents who were identified as iodised salt consumers in the 2002 Children's Survey were assigned an estimated intake of discretionary salt. For identified respondents, 1 g of iodised salt with an iodine concentration of 48 µg was added to the total iodine intake consumed from food.

\*This model was used only for analysis of 2010 sampling results presented in Dietary iodine intake of New Zealand children following fortification of bread with iodine (MPI 2012).

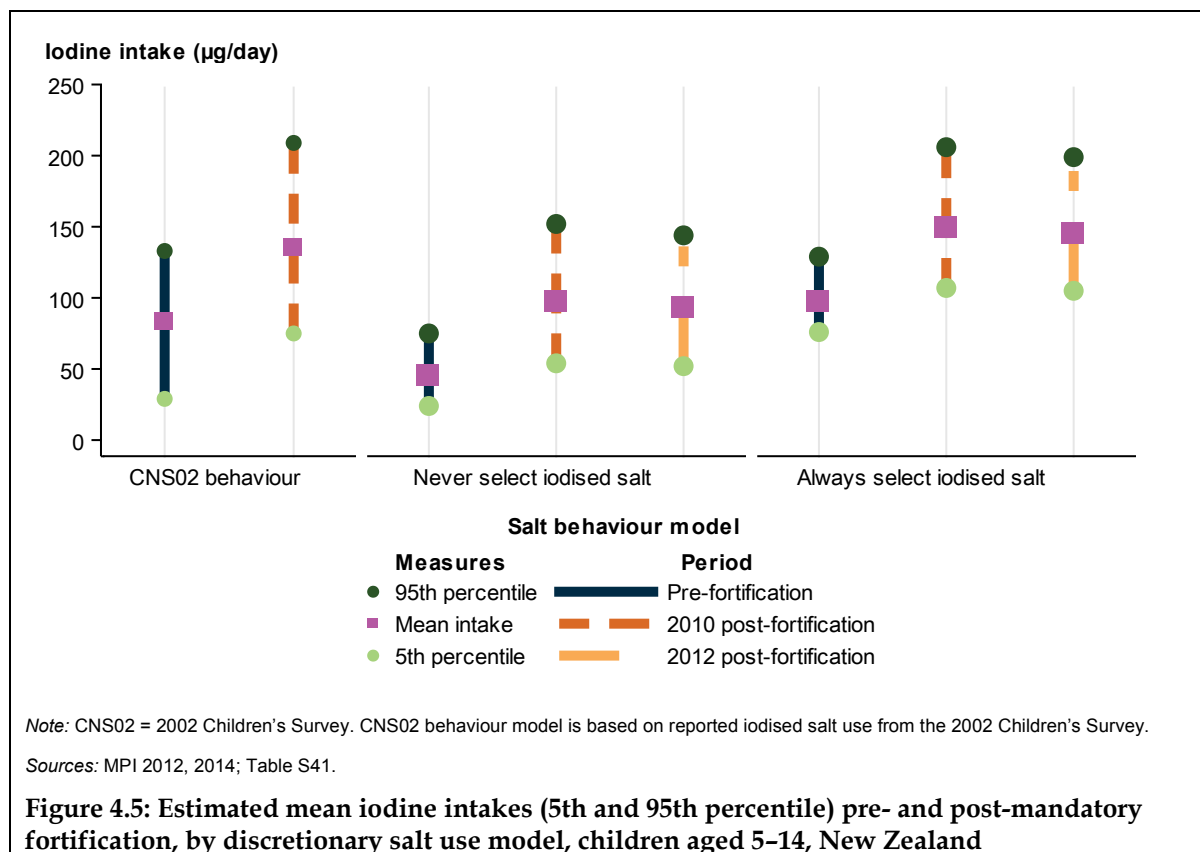
Sources: MPI 2012, 2014.

## Results

### Iodine intakes for children

Estimated mean iodine intakes for all age groups of children aged 5–14 increased between pre- and post-mandatory fortification, for all salt behaviour models, for both the 2010 and 2012 sampling periods. Mean iodine intake increased from 45 µg/day pre-fortification to 93 µg/day in 2012 (when iodine intake from food only is estimated), and from 97 to 145 µg/day (when 1 g of iodised discretionary salt is added to estimates) (Figure 4.5).

Overall, using the 2012 survey resulted in slightly lower estimated mean iodine intakes post-fortification compared with using the 2010 results. The difference in mean intake between the 2010 and 2012 post-fortification estimates was likely to reflect the broader sampling frame in 2012, as this provided iodine concentrations in a larger selection of bread products. This allowed researchers to assign more specific breads and bread categories to foods consumed in the 2002 Children's Survey, thereby giving more accurate intake estimates.



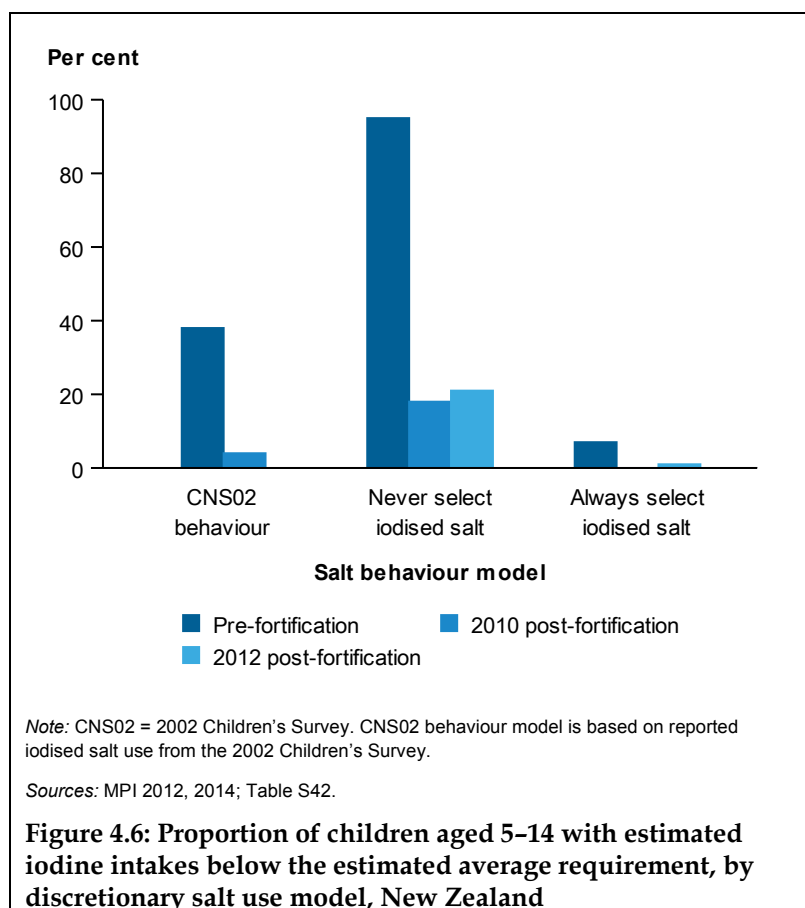
The non-iodised salt model best reflects the change in iodine intakes pre- and post-mandatory fortification as a result of mandatory fortification, whereas the iodised salt model reflects the most optimistic model of changes in iodine intake, based on the assumptions that all discretionary salt in the diet is iodised.

All models show a consistent improvement in estimated iodine intake post-fortification. As expected, the iodised salt model predicted the highest values for both pre- and post-mandatory fortification estimates, and the non-iodised salt model the lowest.

In all discretionary salt models, females across all age groups had lower mean estimated iodine intakes than males from comparable age groups. The results from the 2002 Children's Survey salt behaviour model were slightly below the iodised salt model – with daily estimated mean iodine intakes increasing from 79 µg to 126 µg/day for children aged 5–8, from 85 µg to 138 µg/day for those aged 9–13, and from 93 µg to 151 µg/day for those aged 14.

### Adequacy

Post-mandatory fortification, the proportion of children with estimated iodine intakes below the EAR decreased considerably across all groups in both the 2010 and 2012 assessments (Figure 4.6). The proportion of children with inadequate intakes (below the EAR) in 2012 reduced from 95% to 21% when iodine intake from food only was estimated, and from 7% to <1% when 1 g of iodised discretionary salt was included in modelling estimates.



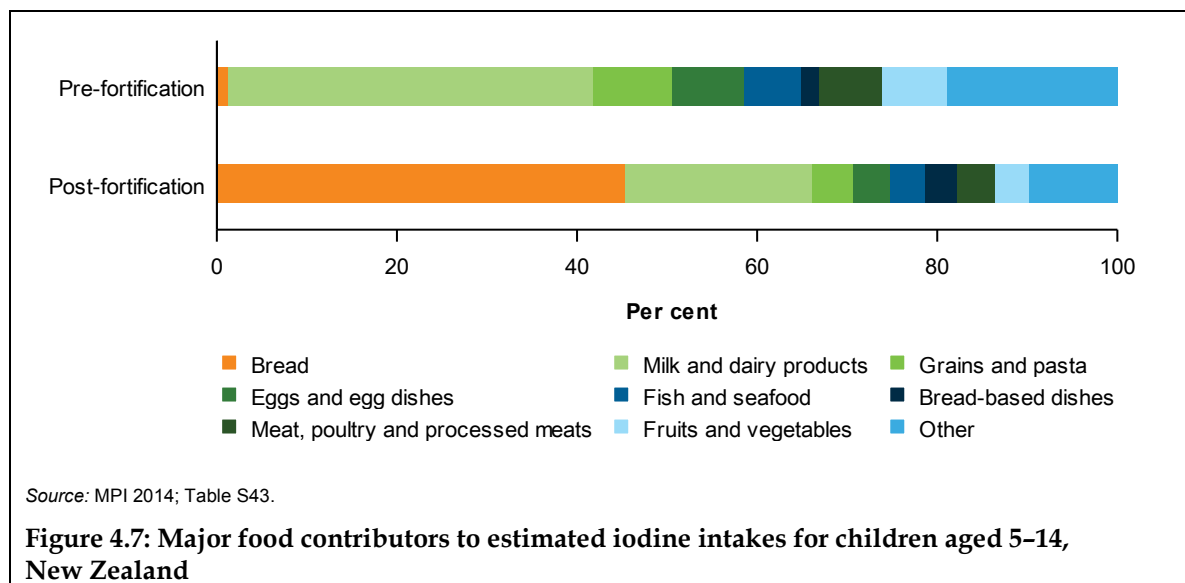
## Food contributors to iodine intake

The FSANZ dietary intake assessment prepared in collaboration with the MPI assessed the foods contributing to iodine intake pre- and post-mandatory fortification. Data from the 2010 and 2012 bread analytical survey were similar; only the 2012 results have been analysed as the most recent food contributor data.

### Results

Post-fortification, the contribution of bread to estimated iodine intake increased substantially from just over 1% to 45% (Figure 4.7). Before mandatory fortification, milk and dairy products was the primary contributing food group of iodine (40%), followed by grains and pasta (9%), egg and egg dishes (8%), poultry and processed meats (7%) fruit and vegetables (7%), meat and fish and seafood (6%).

Post-fortification, milk and dairy products continue to be important contributors to children's iodine intake (21%), along with minor contributions from grains and pasta (5%); meat, poultry and processed meats (4%); and egg and egg dishes (4%).



## Consumers’ awareness of, attitudes towards and behaviours in respect to food fortification

As identified in Section 2.3, in 2013, FSANZ published the results of its population consumer survey investigating the awareness of, attitudes towards and behaviours of Australian and New Zealander consumers in respect to food fortification (FSANZ 2013).

### Results

Awareness of mandatory bread fortification in New Zealand was low. Around a third of all New Zealanders surveyed (34%) and women of child-bearing age (32%) were able to identify bread as being mandatorily fortified. When asked what vitamins or minerals were mandated for use in bread, a third (33%) correctly identified iodine.

Women were more likely to provide a specific and correct response on the intended benefits of iodine fortification than men, with 17% of women aged 16–44 giving a specific and correct response.

Most consumers reported eating a type of bread that would be fortified with iodine (94%), with 90% of women of aged 16–44 reporting they consumed iodine-fortified bread. More women reported that they do not normally consume bread (8%) compared with men (2%).



## 4.4 Nutrient status

**Key monitoring question:** *Has the iodine status of the population improved, particularly in women of child-bearing age and young children?*

**Data sources:**

- Changes in adults' iodine status using MPI data (2013).
- Changes in children's iodine status using data from Skeaff & Lonsdale-Cooper (2013).

**Key findings:**

Post-mandatory fortification:

- The MUIC of women aged 18–44 increased from 48 µg/L pre-fortification to 68 µg/L; however, it is still indicative of mild iodine deficiency.
- Women aged 25–44 had the lowest MUIC of all groups (60 µg/L).
- The MUIC for all adults aged 18–64 was 73 µg/L (indicative of mild iodine deficiency).
- The MUIC of children aged 8–10 increased from 68 µg/L pre-fortification to 113 µg/L, which falls within the range of iodine adequacy (100–199 µg/L). However, thyroid hormone levels suggest iodine status is marginal.

### Biomedical assessment of iodine for adults

As noted in Section 4.3, the MPI undertook research to measure iodine status in 301 randomly sampled New Zealand adults aged 18–64 (MPI 2013).

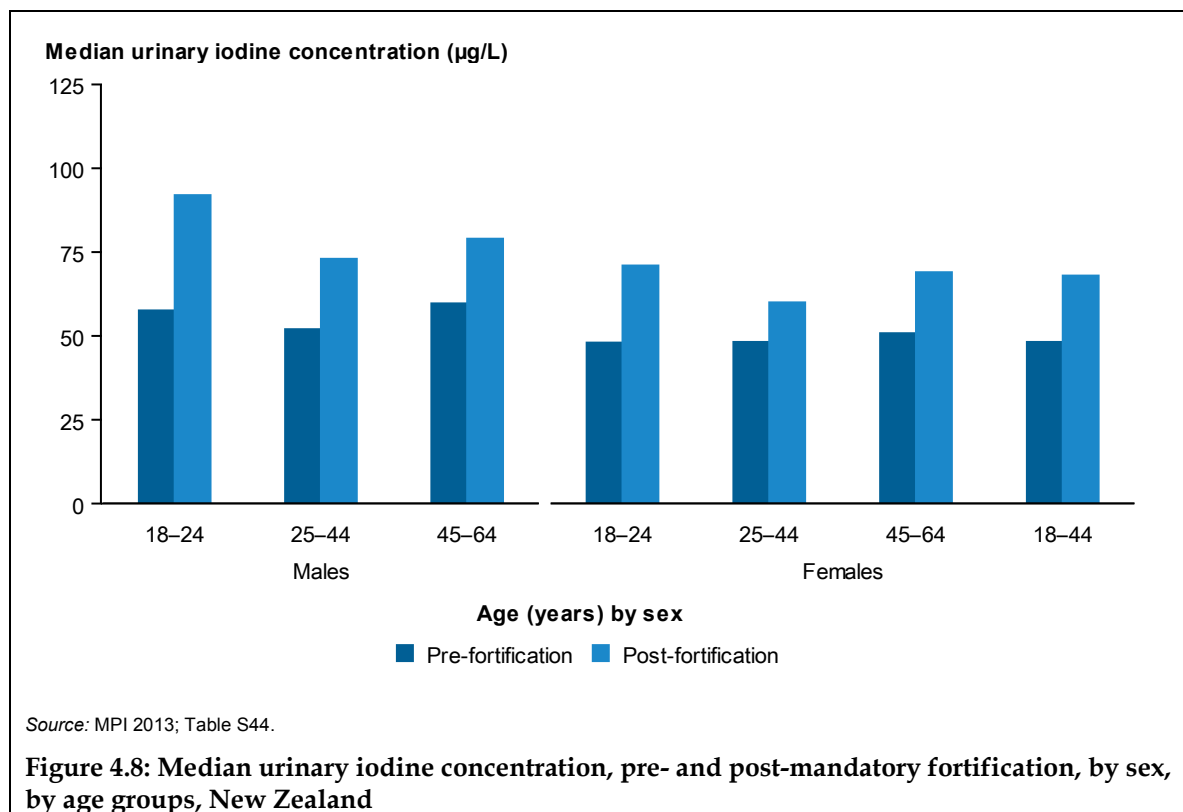
Iodine status was measured by collecting 24-hour urine samples to determine urinary iodine concentration. Participants were also asked to complete a questionnaire to determine socio-demographic characteristics and dietary behaviours, including consumption of bread and bread products containing iodised salt, and use of iodised salt in cooking and at the table. Survey responses were used to examine the effect of demographic characteristics and reported dietary behaviours on iodine status.

### Results

#### Iodine status for women of child-bearing age and adults aged 18–64

Post-mandatory fortification, the MUIC for women aged 18–44 was 68 µg/L (Figure 4.8). This concentration was 42% higher than the pre-fortification concentration of 48 µg/L for women aged 18–44, as measured in the 2008–09 New Zealand Adult Nutrition Survey. However, iodine status post-fortification was still below the recommended range of 100–199 µg/L for the general population and 150–249 µg/L for pregnant women. Women aged 25–44 were particularly at risk, having the lowest MUIC of all groups (60 µg/L) post-mandatory fortification.

The MUIC for all adults post-mandatory fortification aged 18–64 was 73 µg/L, higher than the MUIC of 52 µg/L pre-fortification. Post-fortification, males had a higher MUIC than women (75 µg versus 65 µg/L), with males aged 18–24 having the highest MUIC of any group (92 µg/L).



#### Additional criteria for assessment of iodine status

For women aged 18–44, 31% were below the cut-off for moderate deficiency in the general population (0–49 µg/L) and 81% below the cut-off for moderate and mild deficiency (0–99 µg/L). These figures are improvements on iodine status found during the 2008–09 New Zealand Adult Nutrition Survey, where 52% of women aged 18–44 were below the cut-off for moderate deficiency and 81% below the cut-off for mild deficiency. Despite improvements, New Zealand women of child-bearing age may be at risk of having inadequate iodine intakes (Table 4.2).

In total, 70% of all adults aged 18–64 were below the cut-off for moderate and mild deficiency and 31% were below the cut-off for moderate deficiency in the general population. Across all adults, males were less likely to be deficient than women across all age groups. There were no statistical associations between reported MUIC and age, reported iodised salt use or number of serves of bread consumed per week.

**Table 4.2: Proportion of adults meeting the World Health Organization targets for population iodine adequacy, post-fortification, New Zealand**

Age group (years)	<50 µg/L (%)	Target met? <sup>(a)</sup>	<100 µg/L (%)	Target met? <sup>(a)</sup>
18–44 (women)	31	No	81	No
18–64	31	No	70	No

(a) The World Health Organization recommends no more than 20% of a studied population be below 50 µg/L (moderate deficiency) and no more than 50% be below 100 µg/L (mild deficiency).

Source: MPI 2013.

## Biomedical assessment of iodine for children

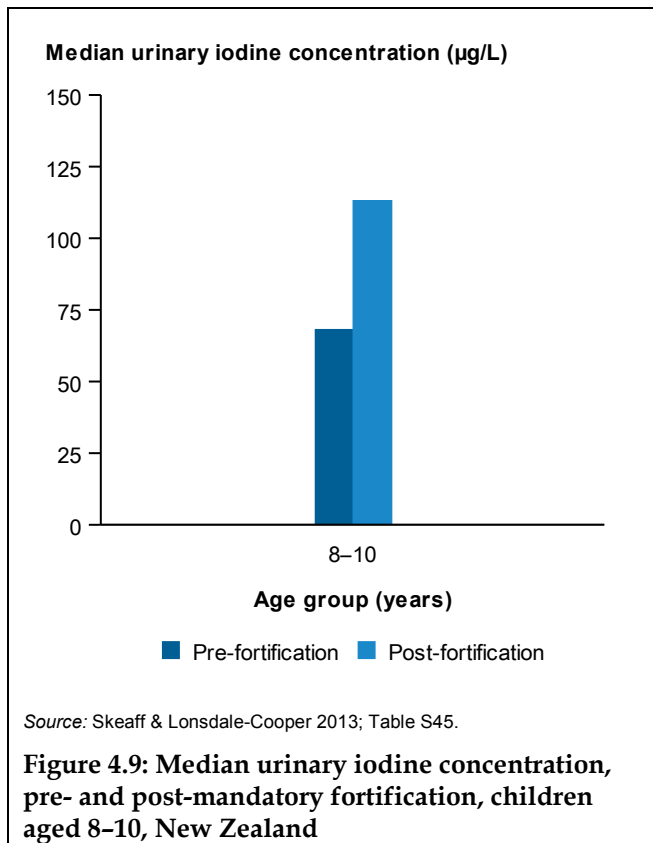
A school-based cluster survey was used to randomly select children from two New Zealand cities for the purpose of assessing their iodine status and intakes, post-mandatory fortification (between November 2010 and February 2011) (Skeaff & Lonsdale-Cooper 2013). A total of 147 children aged 8–10 provided consent to participate in the study. The researchers gathered data on iodine consumption through food frequency questionnaires. Participants were also asked to provide a casual urine sample to assess MUIC, and a finger prick blood sample to assess two serum measures associated with iodine status: thyroglobulin and thyroxine.

Results were compared with pre-fortification values from published studies.

### Results

#### Iodine status for children aged 8–10

Post-fortification, the MUIC of children aged 8–10 increased from 68 µg/L pre-fortification to 113 µg/L following fortification (Figure 4.9). This post-fortification result was within the range of 100–199 µg/L for adequate iodine status.



#### Additional criteria for assessment of iodine status

The proportion of children below the cut-offs for mild and moderate iodine deficiency also substantially reduced (Table 4.3). Pre-fortification, 82% and 28% of schoolchildren aged 8–10 had iodine status below 100 µg/L and 50 µg/L, respectively. Post-fortification, 39% and 12%, respectively, were below these cut-offs, within the ranges suggested by the WHO for adequacy. No differences were found between children when assessed by age, ethnicity or reported iodine intake.

**Table 4.3: Proportion of children aged 8–10 meeting the World Health Organization targets for population iodine adequacy, New Zealand**

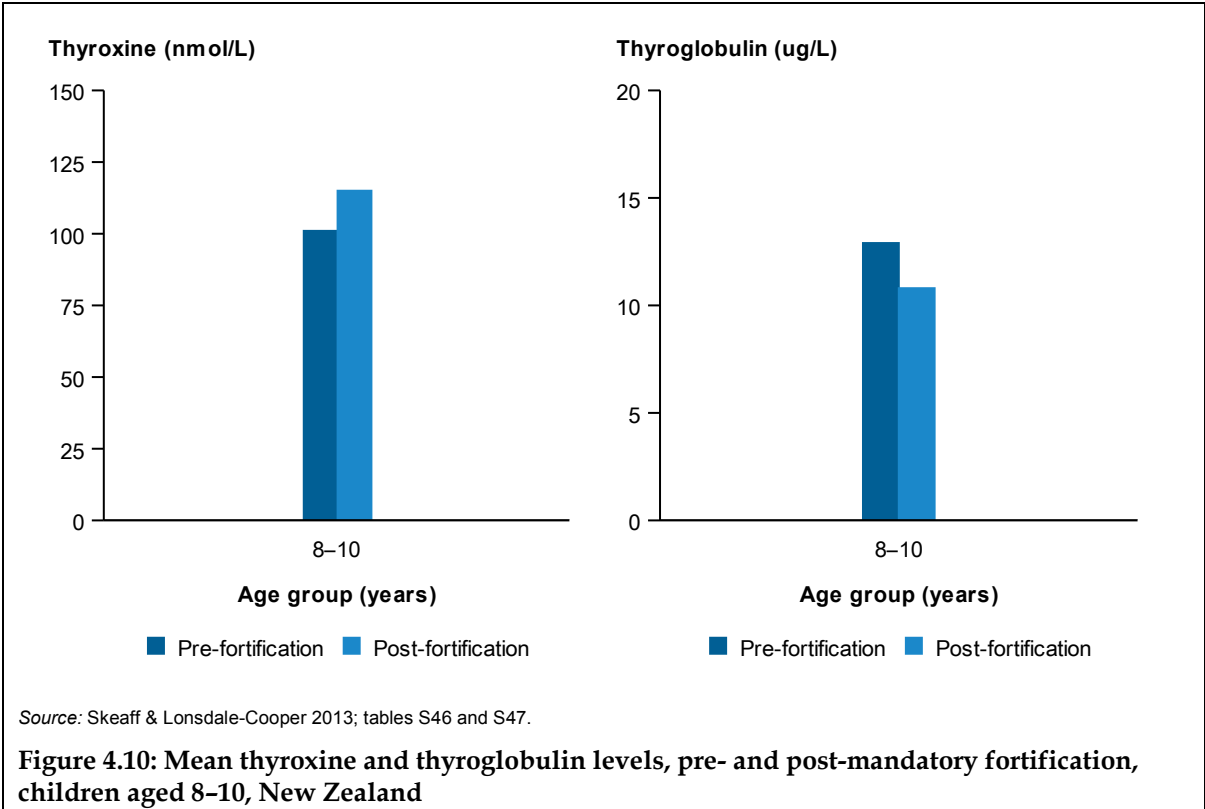
<50 µg/L (%)	Target met? <sup>(a)</sup>	<100 µg/L (%)	Target met? <sup>(a)</sup>
12	Yes	39	Yes

(a) The World Health Organization recommends no more than 20% of a studied population be below 50 µg/L (moderate deficiency) and no more than 50% be below 100 µg/L (mild deficiency).

Source: Skeaff & Lonsdale-Cooper 2013.

Thyroid hormone levels were also assessed (Skeaff & Lonsdale-Cooper 2013) (Figure 4.10). Low iodine status has been shown to increase thyroglobulin and decrease thyroxine. Both measures of iodine status improved from pre- to post-fortification, with median serum thyroglobulin concentration decreasing by 16% (12.9 µg to 10.8 µg/L) and median serum thyroxine concentration increasing by 14% (101 µg to 115 nmol/L). Boys had lower thyroxine levels than girls (111 nmol versus 120 nmol) and Maori or Pacific children were found to have higher thyroglobulin levels than New Zealanders of other origin (15.9 µg versus 11.8 µg/L), indicating lower iodine status for boys and Maori or Pacific children.

Despite improvements to MUIC and thyroid hormone levels, the median thyroglobulin concentration of 10.8 µg/L for all children is within the range of 10.0 µg to 19.9 µg/L, which is indicative of mild iodine deficiency. The results may indicate that post-fortification iodine status for children was still not adequate.



Source: Skeaff & Lonsdale-Cooper 2013; tables S46 and S47.

**Figure 4.10: Mean thyroxine and thyroglobulin levels, pre- and post-mandatory fortification, children aged 8–10, New Zealand**

## 4.5 Health benefits

The desired health benefit from mandatory iodine fortification is a reduction in iodine deficiency across much of the New Zealand population. This assessment is provided in Section 4.4.

## 4.6 Adverse health effects

**Key monitoring question:** *Does mandatory iodine fortification result in adverse health effects for the population?*

**Data sources:**

- New Zealand MPI data (2013, 2014).

**Key findings:**

Post-mandatory fortification:

- No assessment of intakes against the UL was performed for adults aged 18–64. As intakes were lower than expected, iodine intakes for adults were not expected to be above the UL.
- Fewer than 1% of children aged 5–14 were at risk of consuming excessive iodine.

The term ‘adverse health effects’ is used in the monitoring framework. However, the two measures under this component are indicators of possible increasing risk as opposed to direct adverse health effects. These are the assessment of iodine intake against the UL, and MUIC against the criteria for excessive intake.

### Upper level of intake

The following assessment is based on the nutrient intake assessments, reported in Section 4.3.

### Results

The dietary intake estimates undertaken when developing the mandatory fortification requirement predicted intakes that were higher than estimated levels post-mandatory fortification. As no population group aged 15 and over was expected to have iodine intakes above the UL, this is likely to be the current situation.

The 2010 and 2012 results from the dietary intake assessments show no children aged 5–14 had estimated iodine intakes above the UL for the no iodised salt model. The iodised salt and 2002 Children’s Survey salt behaviour models found fewer than 1% of children had iodine intakes above the UL at baseline and post-fortification. These results suggest that mandatory fortification does not increase the risk of consuming too much iodine for the vulnerable population group.

### Median urinary iodine concentration

As identified in Section 1.1, an MUIC of more than 300 µg/L represents excessive iodine intake and could pose a risk of adverse health consequences. In addition, MUIC for pregnant women should not exceed 500 µg/L.

## **Results**

As indicated in Section 4.4, no population group had an MUIC above 300 µg/L. Data for pregnant women were not available.

## 5 Discussion

In response to Ministerial Council requests, FSANZ developed two mandatory fortification requirements to address two important public health issues: to reduce the prevalence of NTDS, and to address the re-emergence of iodine deficiency.

In agreeing to the changes to Standard 2.1.1 *Cereals and cereal products* of the Code, the Ministerial Council asked that an independent review consider the health impacts, effectiveness, costs and adequacy of the monitoring framework for mandatory fortification. This report is the second stage of the three-stage independent review and examines the health effects of mandatory folic acid and iodine fortification, using the monitoring framework developed by the Food Regulation Standing Committee (see Appendix B).

The monitoring framework is based on a step-wise progression from the first action (the policy change) to the policy objective (a reduction in both NTDs and iodine deficiency). As such, it uses the available data sources to note changes in nutrient content in bread, nutrient intake, nutrient status and health benefits pre- and post-mandatory fortification. The limitations of the specific data sources are noted below and provide context for the strength of the overall findings.

### 5.1 Mandatory folic acid fortification in Australia

#### Health impact

Despite the limitations of each individual data source (see 'Data limitations' in this section), collectively, the data support that mandatory folic acid fortification has led to increases in folic acid in the food supply, nutrient intake and folate status, and a decrease in NTDs. These changes are consistent with those predicted when developing the mandatory folic acid fortification requirement.

Post-mandatory fortification, breads became the main contributor to estimated folic acid intake (50%) for women aged 16–44 (the target population), compared with 19% pre-mandatory fortification. Foods voluntarily fortified with folic acid continued to be important contributors to folic acid intake, notably breakfast cereals (11%) and yeast and meat extracts (10%).

Estimated mean folic acid intake increased in the target population (from 102 µg to 247 µg/day), below the 400 µg/day recommended to help prevent NTDs as expected, but still greater than the increase of 100 µg/day predicted when developing the fortification requirement. For the target and general population, DFE and folic acid intakes increased and, accordingly, the proportion with inadequate intakes substantially decreased.

Due to differences in folate testing methodologies and the representativeness of the baseline data, it was difficult to accurately quantify changes in folate status in the target population post-mandatory fortification. However, available data sources suggest improvements in mean serum folate levels.

There has been a decrease in NTD rates following the introduction of mandatory folic acid fortification. There was a statistically significant 14.4% decrease in the rate of NTDs rates in the total study population (10.2 to 8.7 per 10,000 conceptions that resulted in a birth) and a non-statistically significant 12.5% decrease in the rate of NTDs in the population omitting New South Wales residents (12.8 to 11.2 per 10,000 conceptions that resulted in a birth). As

reported by Hilder (2016), the rates omitting New South Wales residents are better absolute measures of NTD risk, but have wider CIs. Inclusion of New South Wales provided a much larger population and improved the study power. The decrease in both population groups, however, was still within the predicted rate decrease.

More substantial reductions were observed for Aboriginal and Torres Strait Islander women and teenagers. The reduction in NTDs in the Indigenous population is of particular interest given that previous strategies to increase folic acid intake and reduce NTDs in this population have not been successful. Hilder (2016) notes that, despite experiencing the largest reduction in NTD rates, Indigenous women did not account for most of the decrease in NTD rates among teenagers. Likewise, teenagers did not account for most of the decrease in NTDs among Indigenous women.

Some of the reduction in NTD rates is likely to reflect the continuing decline observed before the introduction of mandatory fortification. It is important to recognise, however, that the predicted average decrease of 14% when developing the fortification requirement considered mandatory fortification combined with existing voluntary folic acid permissions and supplement use.

These results should be considered in the context of the short study period post-fortification and the relative rarity of NTDs, both of which contribute to variability in NTD rates. Ongoing monitoring of Australian NTD rates are required to confirm whether these reductions will be sustained.

## **Safety**

As noted in Section 2.6, two approaches were used to assess adverse health effects resulting from mandatory folic acid fortification: an assessment of estimated folic acid intake against the UL, and a meta-analysis of the literature for selected cancer outcomes and all-cause mortality.

### **Upper level of intake**

The proportion of the population exceeding the UL for folic acid is considered to be an indicator of increasing risk rather than a direct adverse health effect. While very few adults had estimated folic acid intakes that exceeded the UL post-mandatory fortification, this was not the case for children, particularly young children. The proportion of children aged 2–3 with intakes above the UL increased from 5% to 21% and for those aged 4–8, from 3% to 15%.

Despite these increases, the proportion exceeding the UL is not considered to pose a health risk (FSANZ 2015b). This is because the UL for folic acid incorporates a fivefold margin of safety and is based on high supplemental intakes being related to adverse neurological effects in older people with vitamin B<sub>12</sub> deficiency (NHMRC & NZMoH 2006). The adult UL has been applied to younger age groups on a relative body weight basis. As vitamin B<sub>12</sub> deficiency is rare in children, the end point does not relate to young children. Although exceeding the UL is undesirable, it is not considered a health concern in young children, especially as this proportion exceeding the UL decreases as children age (FSANZ 2006b).

The fortification of staple foods means it is more likely for children to exceed the UL for folic acid. This is due to children having a lower body weight and consuming more food per kilogram of body weight than adults. FSANZ considered this potential risk when selecting an appropriate food vehicle and fortification level in order to achieve maximum intake in the target population while still ensuring safe levels for other population groups.



## **Selected cancer outcomes and all-cause mortality**

Results from the FSANZ meta-analysis showed no increase in cancer or all-cause mortality in adults directly associated with folic acid. This is consistent with the WHO statement that 'high folic acid intake has not reliably been shown to be associated with negative health effects' (WHO 2015:6).

## **Data limitations**

### **Currency of food consumption data**

The FSANZ methodology to estimate dietary intakes used food consumption data based on the 1995 NNS for adults and the 2007 Children's Survey for children and adolescents.

Although the consumption of staple foods, such as bread, generally do not change much over time, new food consumption data from the most recent nutrition survey (2011–12 NNPAS) shows that bread consumption ('regular breads and rolls') has decreased slightly for adults by an average of around 20 g per day, with little change for children.

Changes in bread consumption between surveys may reflect actual decreases in consumption amounts but may also reflect changes in data collection methods and analysis. Some composite foods (for example, sandwiches and bread-based dishes) were coded and recorded slightly differently in both surveys, and an increase in under-reporting in the 2011–12 NNPAS compared with the 1995 NNS was noted (FSANZ 2015b).

### **Representativeness of the target population for estimating dietary intakes**

It is best practice to compare usual nutrient intakes with NRVs, as they relate to intake over a period of time. The second-day adjustment method provides a better estimate of usual intakes than using only single-day intake data, but could not be applied to folic acid intake estimates due to a skewed distribution of intakes. FSANZ estimated folic acid dietary intakes of the target population using an average of 2 days' food consumption data from the 1995 NNS to reduce the variation in food intake within and between individuals.

However, only 10% of respondents in the 1995 NNS provided food consumption data for the second day and so this restricted the number of respondents for FSANZ's dietary intake assessment. FSANZ noted that dietary folic acid and DFE estimates may not be fully representative of the target population (women aged 16–44) but did further validation work to investigate the issue. Its investigation concluded that the data were of sufficient quality to represent this population group (FSANZ 2015b).

### **Methodologies for measuring serum and red blood cell folate**

It is difficult to compare values for folate status obtained by different methodologies. Folate analysis can be performed using a variety of methods, including microbiological assays, protein-binding assays (such as the automated chemiluminescent immunoassay used in the NHMS) and chromatography-based assays. As microbiological assays are more labour intensive and time consuming, commercial protein-binding assays on automated clinical analysers have become increasingly popular for folate analysis.

There are large differences among assays for red blood cell folate and various assays are yet to be standardised (Pfeiffer et al. 2010). Generally, the automated chemiluminescent immunoassays underestimate folate concentrations (WHO 2015); however, some produce higher results than the microbiologic assay. As such, it is undesirable to make comparisons when folate values have been obtained by different methods (Nakazato et al. 2012).

The WHO advises that, to achieve the greatest reduction in NTDs, blood cell folate concentrations in women of reproductive age should be above 906 nmol/L (WHO 2015). However, this cut-off is based on a microbiological assay for red blood cell folate and so it is not appropriate to apply to the NHMS folate status data generated using a chemiluminescent immunoassay, without knowing the relationship between the two assays (C Pfeiffer 2015, pers. comm., 4 August).

### **Representativeness of folate status baseline data**

While the CDAH Study provides baseline data on folate status in women of child-bearing age, it is considered to be only 'broadly representative' of the target group. This study was initially designed to provide benchmark data on the health and fitness of Australian schoolchildren. As part of this study, serum folate was analysed to investigate links between cardiovascular risk and folate status. Subsequently, it provided a retrospective opportunity to determine folate status among a national cohort of women aged 26–36 before mandatory fortification.

While these data provide baseline estimates on serum folate status for a subgroup of the target population, caution is needed when attempting to quantify changes post-mandatory fortification (by comparing with the NHMS data). There is potential for participation bias in the CDAH Study. The number of female participants with serum folate samples in this study was 25% of the original 1985 study population and these participants were generally better educated and smoked less than the general population. Consequently, results may overestimate population serum folate levels, based on evidence from the NHMS that status tends to increase with SES.

In addition, there is a lack of knowledge regarding the comparability of the two different folate assays; the CDAH analysis was performed on an Abbott Architect Analyser and the NHMS analysis was performed on a Modular E170 Analyser.

### **Representativeness of the neural tube defect data**

The study by Hilder (2016) benefited from the inclusion of all available NTD data in Australia from 2007 to 2011. For the first time, data were available from Queensland and the Northern Territory. However, the omission of Victorian data is noteworthy, since nearly one-quarter of the nation's maternal population reside in this state and, as reported by Hilder (2016), women are known to travel to Victoria for late termination of pregnancy. Tasmanian data were also excluded from the calculation of NTD rates because ascertainment in this state is from live births only. For these reasons, when interpreting the NTD data, it is important to be aware that the data may not be fully representative of the Australian population.

## **5.2 Mandatory iodine fortification in Australia**

### **Health impact**

Post-mandatory fortification, cereal and cereal products became the main food group contributor to estimated iodine intake for all population groups. While cereal and cereal products are important contributors to iodine intake for young children aged 2–3, dairy foods continue to be the main contributor.

Estimated mean iodine intake for women aged 16–44 increased by 51 µg/day, slightly more than the 46 µg/day predicted during the development of the fortification requirement. For

children aged 2–3, iodine intakes increased by 37 µg/day, just below the predicted increase of 38 µg/day. While mandatory fortification delivered sufficient amounts of iodine to the general population, intakes for many pregnant and breastfeeding women were insufficient due to their increased requirements (as expected when developing the fortification requirement).

Results from the 2011–12 NHMS showed that the MUIC for children, adolescents and adults was indicative of adequate iodine status. Iodine status varied by location: Tasmania, Victoria and the Australian Capital Territory had the lowest iodine status; Western Australia, the Northern Territory and South Australia had the highest.

## **Safety**

The level of iodisation in salt was selected to maximise iodine intakes in the target group, while preventing sizeable proportions of young children from exceeding the UL for iodine. Although FSANZ's dietary intake assessment estimated that about one-fifth of children aged 2–3 had intakes above the UL, this is considered unlikely to lead to adverse health outcomes.

The age-specific ULs for iodine are not absolute thresholds of toxicity; instead, they represent values derived from adverse findings in adults (elevated thyroid stimulating hormone concentrations, which is an adaptive response to increased iodine intakes that is reversible). These thresholds have been extrapolated to children based on their respective metabolic body weights. The proportion of young children exceeding the UL also decreases with age, with less than 1% exceeding the UL after age 4. Although estimated iodine intakes are not considered to be a safety risk for young children (FSANZ 2008a), the margin of safety has been reduced.

## **Data limitations**

### **Currency of food consumption data**

As noted in Section 5.1, the FSANZ methodology for estimating dietary intakes is based on food consumption data from the 1995 NNS for adults and the 2007 Children's Survey for children and adolescents. As such, these data may not reflect possible recent changes in food consumption patterns that may have an impact on the accuracy of estimating iodine intakes.

### **Methodologies for estimating discretionary salt intake**

One of the difficulties in accurately estimating iodine intakes is determining the contribution from discretionary salt intakes. Better methods of quantifying discretionary salt use would improve the accuracy of dietary iodine intake assessments.

## **5.3 Mandatory iodine fortification in New Zealand**

### **Health impact**

Unlike the Australian national data sources used to assess iodine intake and status, the New Zealand data sources are based on smaller subnational surveys, as noted in Section 4.3 and further discussed in this section. As such, the New Zealand results may not be as representative or as robust as those for Australia, and so caution is needed when making direct comparison between these two countries.

Post-mandatory fortification, breads became the main contributor to estimated iodine intake for children aged 5–14. There were modest improvements in iodine intakes and iodine status for adults aged 18–64 and more substantial improvements for children aged 5–14. However, the MUIC for adults was still indicative of mild iodine deficiency and a large proportion of women of child-bearing age (especially younger women) were at risk of having inadequate iodine intakes.

While the MUIC of children was indicative of iodine adequacy, thyroid hormone levels were still borderline for mild iodine deficiency. The results may indicate that post-mandatory fortification iodine status for children is still not adequate. Further research is needed to assess the impact of mandatory fortification on the iodine status of other vulnerable population groups such as pregnant women.

## **Safety**

Increases in iodine intake from mandatory iodine fortification have minimal effect on estimated intakes exceeding upper levels of intake in the New Zealand population.

## **Data limitations**

### **Currency of food consumption data**

The most recent national consumption data for children aged 5–14 in New Zealand is the 2002 Children's Survey and for the general population aged 15 and over it is the 2008–09 New Zealand National Nutrition Survey; however, these data were not available when developing the fortification requirement. FSANZ used data from the 1997 New Zealand National Nutrition Survey to estimate pre- and post-fortification iodine intakes. This review found that estimated iodine intakes, especially for women, were less than predicted during the development of the mandatory fortification requirement. If bread consumption in New Zealand has recently reduced (as observed in the most recent 2011–12 NNPAS), the impact of this public health intervention will be reduced.

### **Methodologies for estimating iodine intake**

As noted in Section 5.2, one of the challenges in estimating iodine intakes is determining the contribution from discretionary salt intakes. The New Zealand data sources used two different methods to assess iodine intake. For adults aged 18–64, iodine intakes were calculated from 24-hour urine samples because about 90% of dietary iodine is excreted in the urine and so can be used to estimate daily intakes. This overcomes the difficulty in quantifying the amount of iodine from iodised salt used at the table and in cooking (discretionary salt).

For children aged 5–14, iodine intakes were calculated using dietary intake assessments based on three models to account for iodine intakes from discretionary salt consumption: the *Food only* model, the *Food plus iodised salt* model and the *Salt behaviour* model. Only the results from the *Food only* model and the *Food plus iodised salt* model have been included in this report to highlight the range of possible iodine intakes. As noted previously, better methods of quantifying discretionary salt use could improve the accuracy and comparability of dietary iodine intake assessments.

As well, due to the different methods used to estimate iodine intake pre- and post-fortification for adults (population versus subnational data, and derivation of intakes

from food intake versus UIE), the data are not directly comparable and are used as a guide only.

### **Representativeness of iodine status data**

When estimating iodine status for the Australian population post-mandatory fortification, it was possible to draw on a large nationally representative data source (the 2011–12 NHMS). In contrast, when estimating the iodine status for the New Zealand population, only smaller subnational data sources were available (a study of 147 children aged 8–10 and a study of 301 adults aged 18–64). As such, the applicability of the conclusions that can be inferred to the total New Zealand population is reduced. When the results of the 2014–15 New Zealand Health Survey are released, this will provide more reliable national estimates of iodine status.

### **Criteria for population iodine status**

The epidemiological criteria for determining population iodine status are based on observed MUIC in schoolchildren. As children have lower urinary output volume than adults, this can dilute the absolute concentration of iodine in urine. The MUIC reference ranges, determined for schoolchildren, have been used to assess iodine status of the wider adult population. However, caution should be taken when interpreting results that compare adult MUIC against these cut-offs.

Research indicates that a more appropriate cut-off for adults would be 60 µg to 70 µg/L, based on adjusting for the higher volume of urine in adults (Zimmermann 2008). This cut-off would place the MUIC for New Zealand adults closer to an appropriate range for iodine adequacy.

## **5.4 Next steps**

To assess the future health impact of mandatory folic acid and iodine fortification, ongoing monitoring of these two important public health initiatives is recommended, particularly to review the impacts on the target groups (women of child-bearing age and young children). The following items are key data requirements for ongoing monitoring.

### **Analysis of folic acid and iodine in commonly consumed breads**

- 1. Up-to-date data on the levels of folic acid and iodine in bread are required to help identify potential changes in the food supply.**

Future testing of the levels of folic acid and iodine in commonly consumed breads in Australia and New Zealand will help to ensure levels continue to fall within the desired ranges. Testing will also help to monitor the impact of product reformulation undertaken by the food industry. For example, the National Heart Foundation at the time of publishing was working with New Zealand bread manufacturers to reduce the salt content in bread. As bread is now the key source of iodine in the New Zealand diet, any reductions in salt content will likely reduce future iodine intakes.

- 2. Investigation as to why current iodine levels in bread in New Zealand are less than anticipated is required to help inform any potential future health impact.**

Further investigation is required into why current iodine levels in New Zealand breads are less than anticipated. Failure to realise the predicted estimate may be undermining the effectiveness of this public health initiative for New Zealand.

## **Food consumption data**

- 3. Up-to-date data on the foods being consumed by the Australian and New Zealand populations through national nutrition surveys are required to ensure nutrient intake assessments reflect current intakes.**

Apparent decreases in bread consumption in the Australian and New Zealand populations are likely to have an impact on the ability of mandatory fortification to deliver the expected health benefits. It is important that national food consumption data are collected on a regular basis. These data are important for undertaking nutrient intake assessments, which monitor changes to folic acid and iodine intakes based on any changes to the nutrient composition of foods and the types and quantities of foods consumed by the Australian and New Zealand populations.

- 4. Consistency between national nutrition surveys is required to ensure methodological changes do not mask or confound changes in eating patterns.**

It is important that the design of national nutrition surveys and the coding for the food consumption database that underlies each survey are consistent over time. This helps to ensure confidence in the comparability of the data. It is important that any changes are clearly articulated and documented to accommodate any differences.

- 5. Better quantification of discretionary salt use will ensure more accurate data are available on iodine intake.**

For future nutrition surveys, it is suggested that methods more accurately quantify discretionary salt use to ensure the contribution of iodine from discretionary salt is better captured in nutrient intake estimates.

- 6. Specific monitoring is required of subpopulations at risk of low nutrient intake.**

This report identified particular subpopulations at continuing risk of low nutrient intake post-mandatory fortification. Ongoing monitoring for these subpopulations is required to assess the need for specific and targeted interventions in the future.

## **Consumers awareness of, attitudes towards and behaviours in respect to food fortification**

- 7. A regular consumer attitudes survey regarding mandatory fortification is required.**

Information on consumer awareness of, attitudes towards and behaviours in respect to food fortification is important for understanding the results of other data collected as part of monitoring mandatory fortification. The survey, currently undertaken by FSANZ, should be repeated periodically to assess changes in attitudes over time.

## **Nutrient status**

- 8. Further analysis could be undertaken using the current data on folate status to determine whether it can be used to compare with the cut-off for NTD risk.**

The WHO guidelines (WHO 2015) for assessing folate status in populations recommend red blood cell folate levels above 906 nmol/L in women of reproductive age to achieve the greatest reduction in NTDs. This recommended cut-off has been derived using the microbiologic assay method to measure red blood cell folate and does not apply to chemiluminescence assays, as used in the ABS 2011–12 NHMS. To improve the identification of Australian women of child-bearing age at increased risk of NTDs, additional research

could be undertaken, using regression analysis, to establish the comparability of the two assays and the appropriateness of the 906 nmol/L cut-off.

**9. Assessment of upcoming national nutrition survey data in New Zealand would provide a more complete picture of iodine intake and iodine status of the New Zealand population.**

The iodine intake and status results presented in this report for New Zealand are based on subnational studies with a relatively small sample size. As well, the age categories available do not directly correlate with the target populations for mandatory fortification (women aged 16–44 and very young children). Results from the 2014–15 New Zealand Health Survey are expected to be available towards mid-2016, which cover the population aged 15 and over. These data will be an important adjunct to the data presented here and provide a more complete picture of iodine intake and status for the New Zealand population and key target groups.

The New Zealand Ministry of Health intends to prepare a supplementary paper with these 2014–15 New Zealand Health Survey data to complement the data presented here.

## **Health benefits**

**10. The inclusion of NTD data for Victoria when available would improve the representativeness of the post-mandatory fortification national NTD estimates.**

The Victorian NTD data, omitted from Hilder (2016) for technological reasons, should be provided when available to improve the representativeness of the post-fortification NTD data.

**11. Ongoing monitoring of NTDs across all jurisdictions is important to assess the continued effectiveness of mandatory folic acid fortification in Australia.**

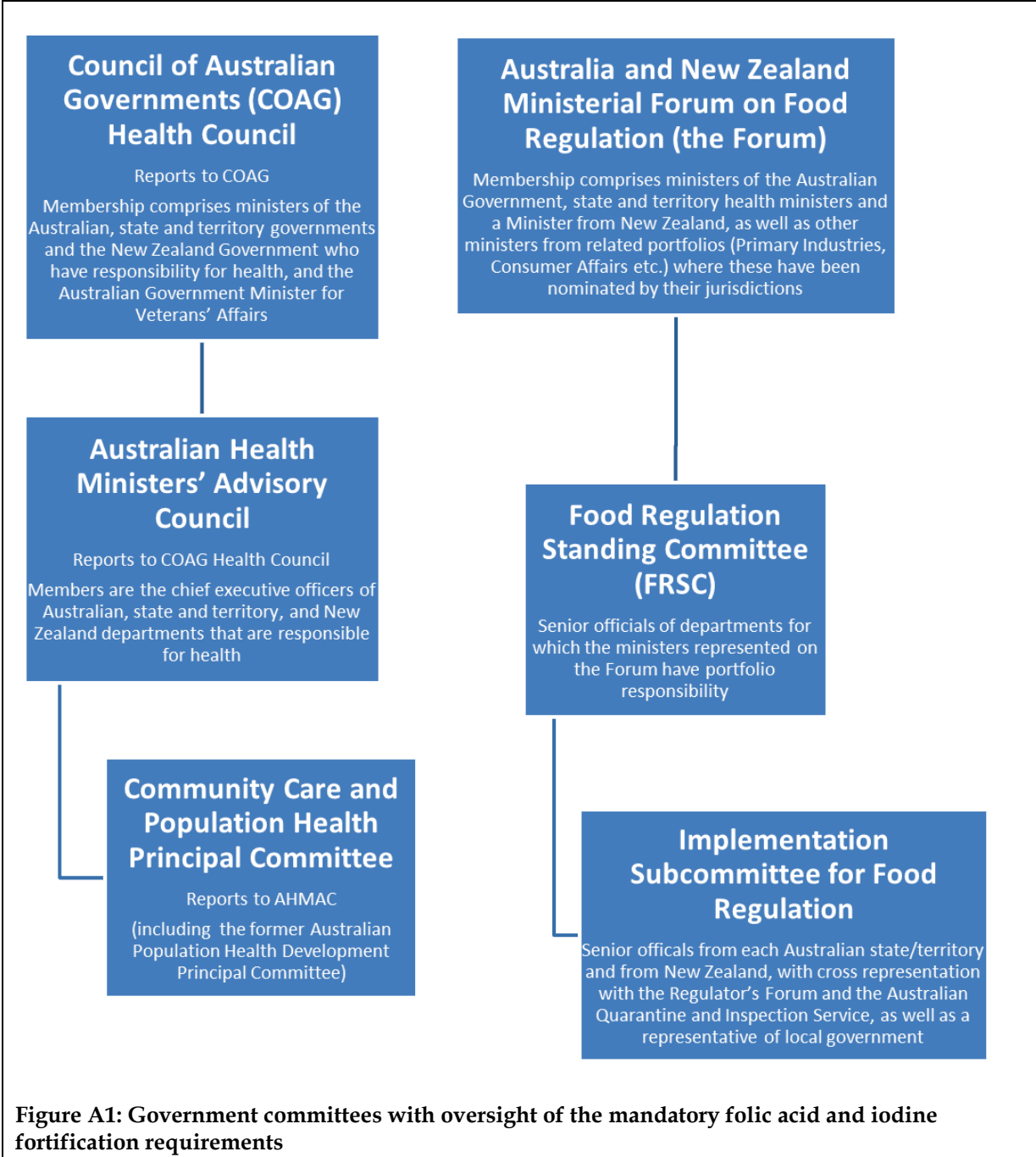
An important aspect of ongoing monitoring of mandatory folic acid fortification is continued assessment of NTDs in the population, which includes complete data collected from all states and territories, including Victoria, Tasmania and New South Wales.

**12. Ongoing monitoring of iodine status is important to assess the continued effectiveness of mandatory iodine fortification in Australia and whether there have been improvements in New Zealand.**

For Australia, periodic monitoring of iodine status will help to ensure the population maintains its current adequate iodine status. In the interim, between population monitoring, priority could be given to those states/territories and subpopulations identified as most at risk of low iodine status, such as Tasmania, and young women in their late teens and early 20s.

For New Zealand, the available evidence suggests that the iodine status of the population is still sub-optimal. Further ongoing monitoring and assessment of emerging Health Survey data is recommended to help inform the development of additional strategies to improve iodine status if warranted and to identify those most at risk.

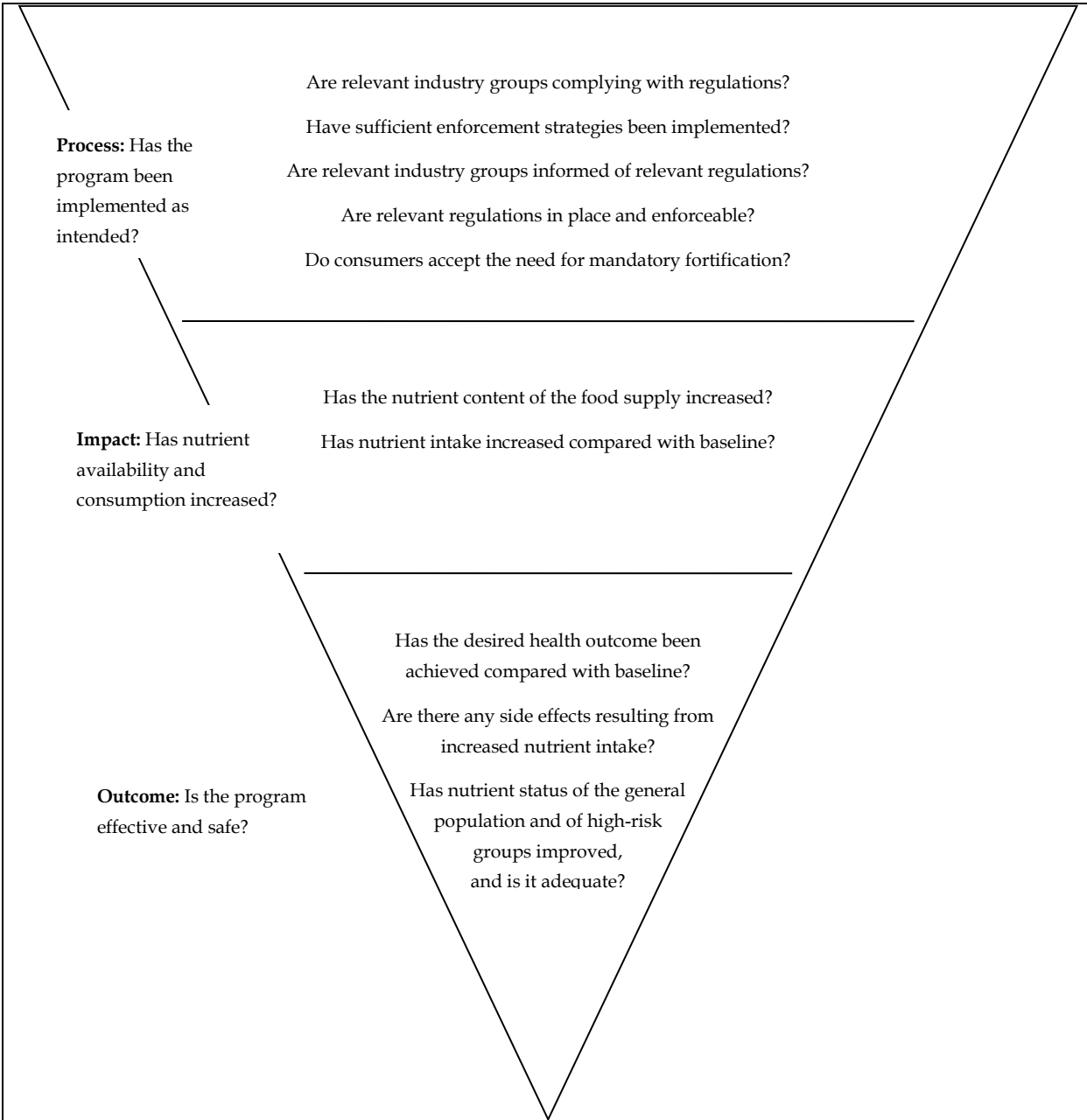
# Appendix A: Government committees with oversight of the mandatory folic acid and iodine fortification requirements





# Appendix B: Monitoring framework for mandatory fortification

The monitoring framework for mandatory folic acid and iodine fortification was developed by the Food Regulation Standing Committee (see Figure B1). This framework covers the appropriate areas that need to be monitored to assess the effects of the mandatory fortification requirements. The framework was agreed by the then Australian Population Health Development Principal Committee in August 2007, and accepted by the AHMAC in October 2007.



Source: FSANZ 2006b.

**Figure B1: Outcomes hierarchy for monitoring mandatory fortification programs**

# Appendix C: Reference values for monitoring folic acid and iodine

**Table C1: Estimated average requirements for dietary folate equivalents**

Life stage	Age (years)	Estimated average requirement (µg/day)
Children and adolescents	1–3	120
	4–8	160
	9–13	250
	14–18	330
Adults	19+	320
Pregnancy	14–50	520
Lactation	14–50	450

Source: NHMRC & NZMoH 2006.

**Table C2: Upper level of intake for folic acid**

Life stage	Age (years)	Upper level of intake (µg/day)
Children and adolescents	1–3	300
	4–8	400
	9–13	600
	14–18	800
Adults	19+	1,000

Source: NHMRC & NZMoH 2006.

**Table C3: Estimated average requirements and upper level of intake for iodine**

Life stage	Age (years)	Estimated average requirement (µg/day)	Upper level of intake (µg/day)
Children and adolescents	1–3	65	200
	4–8	65	300
	9–13	75	600
	14–18	95	900
Adults	19+	100	1100
Pregnancy	14–18	160	900
	19–50	160	1100
Lactation	14–18	190	900
	19–50	190	1100

Source: NHMRC & NZMoH 2006.

**Table C4: Epidemiological criteria for assessing iodine nutrition based on median urinary iodine concentrations of school-aged children ( $\geq 6$  years)<sup>(a)</sup>**

Median urinary iodine concentration ( $\mu\text{g/L}$ )	Iodine intake	Iodine status
<20	Insufficient	Severe iodine deficiency
20–49	Insufficient	Moderate iodine deficiency
50–99	Insufficient	Mild iodine deficiency
100–199	Adequate	Adequate iodine nutrition
200–299	Above requirement	Slight risk of more than adequate intake in the overall population
$\geq 300$	Excessive	Risk of adverse health consequences (iodine-induced hyperthyroidism, autoimmune thyroid diseases)

(a) Applies to adults, but not to pregnant and lactating women.

Source: WHO 2007.

**Table C5: Epidemiological criteria for assessing iodine nutrition based on the median urinary iodine concentrations of pregnant women<sup>(a)</sup>**

Median urinary iodine concentration ( $\mu\text{g/L}$ )	Iodine intake
<150	Insufficient
150–249	Adequate
250–499	Above requirement
$\geq 500$	Excessive

(a) For lactating women and children <2 years of age, a median urinary iodine concentration of 100  $\mu\text{g/L}$  can be used to define adequate iodine intake, but no other categories of iodine intake are defined. Although lactating women have the same requirement as pregnant women, the median urinary iodine concentration is lower because iodine is excreted in breast milk.

Source: WHO 2007.

# Appendix D: Information on selected data sources

Further information on the data sets used in this report to monitor changes pre- and post-mandatory fortification can be found in the following surveys and publications:

- Australian Health Survey
- National Health Survey
- National Nutrition and Physical Activity Survey
- National Health Measures Survey
- Australian Aboriginal And Torres Strait Islander Health Survey
- National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey
- National Aboriginal and Torres Strait Islander Health Measures Survey
- FSANZ's dietary intake assessment of folic acid
- Neural tube defects in Australia, 2007–2011 (Hilder 2016).

## Australian Health Survey

The ABS 2011–12 Australian Health Survey (AHS) collected a range of information from Australians about health-related issues, including health status, risk factors, actions, and socioeconomic circumstances. In 2011–12, the AHS collected new information on nutrition and physical activity, as well as the first national biomedical information collection. The AHS combines the previous National Health Survey (NHS) with two new components: the NNPAS and the NHMS.

People who took part in the AHS participated in either the NHS or the NNPAS. A core set of data items was common to both surveys, and information from these data items is available for all persons in the AHS (approximately 32,000). This core set of data items included household and demographic information, self-assessed health status and self-assessed body mass.

All people aged 5 and over were then invited to participate in the voluntary NHMS. Figure D1 shows the structure of the various components of the AHS.

## Scope of the Australian Health Survey

The ABS 2011–12 AHS covered approximately 25,000 private dwellings across Australia. Urban and rural areas in all states and territories were included, while *Very remote* areas of Australia and discrete Aboriginal and Torres Strait Islander communities were excluded. These exclusions are unlikely to affect national estimates, but will have an impact on prevalence estimates by remoteness.

Non-private dwellings such as institutional care facilities (including hospitals and aged care facilities), hotels, motels and short-stay caravan parks were excluded from the survey. The following groups were also excluded: certain diplomatic personnel of overseas governments, persons whose usual place of residence was outside Australia, members of non-Australian Defence forces (and their dependants) stationed in Australia, and visitors to private dwellings.

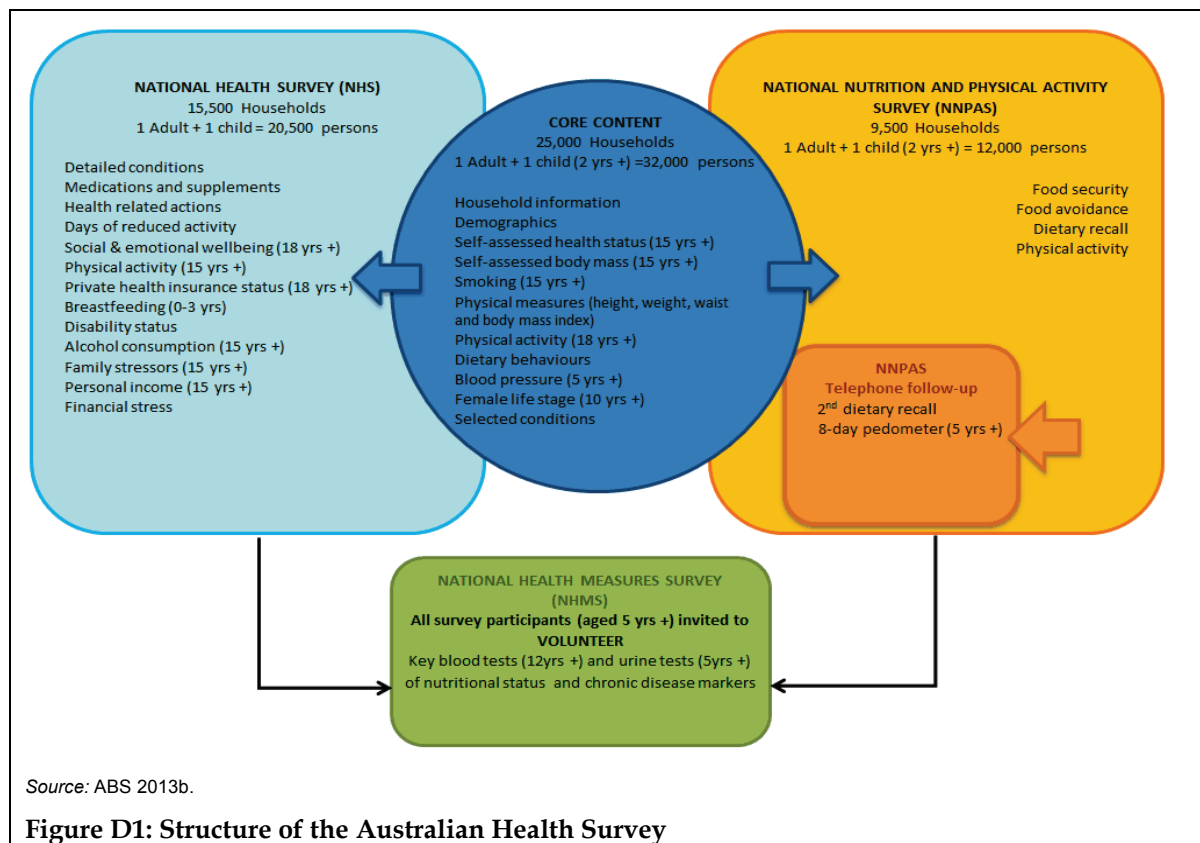


Figure D1: Structure of the Australian Health Survey

## National Health Survey

The NHS, conducted about every 3 years by the ABS, is designed to obtain national information on the health status of Australians, their use of health services and facilities, and health-related aspects of their lifestyle. The most recent survey was conducted in 2011–12, with previous surveys conducted in 2007–08, 2004–05, 2001, 1995, 1989–90, 1983 and 1977.

The 2011–12 NHS covered approximately 15,500 private dwellings across Australia and surveyed 20,500 people. As well as demographic data, the survey includes information on various long-term health conditions. The survey also collected information about health services and medicine use, and any other health-related action taken to manage these conditions. When interpreting these data, some limitations need to be considered:

- much of the data are self-reported by respondents, and therefore there is heavy reliance on the respondents knowing and providing accurate information
- the survey is community based and does not include information from people living in nursing homes or those who are otherwise institutionalised
- residents in *Very remote* areas were not included in the survey.

## National Nutrition and Physical Activity Survey

As part of the 2011–13 AHS, the 2011–12 NNPAS collected data on physical activity, foods and nutrients consumed, and selected dietary behaviours. The NNPAS sampled about 9,500 private dwellings across Australia, with urban and rural areas included, but *Very remote* areas and discrete Aboriginal and Torres Strait Islander communities excluded. These exclusions are unlikely to affect national estimates.

Trained ABS interviewers conducted personal interviews with selected residents. One person aged 18 and over in each dwelling was selected and interviewed about their own

health, including a 24-hour dietary recall and a physical activity module. An adult was then interviewed about one child (aged 2 and over) living in the household. Some children aged 15–17 were personally interviewed with parental consent. All selected persons were required to have a follow-up phone interview at least 8 days after the face-to-face interview to collect a further 24-hour dietary recall.

Of the 12,153 people in the final sample, 98% provided the first 24-hour dietary recall (Day 1), with the missing 2% of Day 1 dietary recalls being imputed. The second 24-hour dietary recall (Day 2) had 7,735 participants (64% of the total). The Day 2 24-hour dietary recall participation was slightly higher among older respondents, and sex did not appear as a factor in participation.

Like other nutrition surveys, results from the 2011–12 NNPAS indicate there has been some under-reporting of food intake by participants. It is difficult, from the available data, to accurately estimate the amount of under-reporting and therefore how much energy and nutrients are likely to be missing from the reported intakes.

### National Health Measures Survey

The 2011–13 AHS incorporated the first ABS biomedical collection: the 2011–12 NHMS. It collected voluntary samples of blood and urine from around 11,200 Australian adults and children across urban and remote areas (*Very remote* locations were excluded). Voluntary urine samples were collected from respondents aged 5 and over, and voluntary blood samples from respondents aged 12 and over.

The survey tested the samples for chronic diseases biomarkers and nutrition biomarkers, such as folate and iodine status. Further information on the specific methodologies used to determine folate and iodine status are included in Table D1.

**Table D1: Test information on folate and iodine biomarkers used in the 2011–12 National Health Measures Survey**

Test	Sample type	Assay/Method	Analyser system	Units of measure	Sonic Healthcare laboratory reference range
Serum folate	Serum	Competitive chemiluminescence	Modular E170	nmol/L	7.0–39.7
Red blood cell folate	Whole blood	Competitive chemiluminescence	Modular E170	nmol/L	776–1784
Iodine	Urine	Inductively Coupled Plasma-Mass Spectrometry	Agilent 7500ce	µg/L	Severe deficiency <20 Moderate deficiency 20–49 Mild deficiency 50–99 Optimal level 100–199 More than adequate 200–299

### Geographical structures

The Australian Statistical Geography Standard (ASGS) is a hierarchical classification system of geographical areas and consists of a number of interrelated structures. These provide a common framework for statistical geography and enable production of statistics that are comparable.

Comparisons of regions in this report use four of the ASGS remoteness areas:

- *Major cities*
- *Inner regional*
- *Outer regional*

- *Remote.*

### **Socioeconomic groups**

The ABS has constructed a number of socioeconomic indexes to classify areas on the basis of social and economic information collected in the 2011 Census of Population and Housing.

In this report, the Socio-economic Indexes for Areas (SEIFA) Index of Relative Socioeconomic Disadvantage is used (referred to as SES in this report). This is derived from social and economic characteristics of the local area such as low income, low educational attainment, high levels of public sector housing, high unemployment and jobs in relatively unskilled occupations. The SEIFA is constructed so that relatively disadvantaged areas have low index values and relatively advantaged areas have high index values.

It should be noted that the Index of Relative Socioeconomic Disadvantage relates to the average disadvantage of all people living in a statistical area, not to the level of disadvantage of a specific individual. As the population of many areas covers a broad range of socioeconomic disadvantage, these measures will generally underestimate the true effect of disadvantage on health.

### **Data quality**

Information about the data quality of the AHS can be found in *Australian Health Survey: users' guide, 2011–13* (ABS cat. no. 4363.0.55.001)

<<http://www.abs.gov.au/ausstats/abs@.nsf/PrimaryMainFeatures/4363.0.55.001?OpenDocument>>.

## **Australian Aboriginal and Torres Strait Islander Health Survey**

The ABS 2012–13 Australian Aboriginal and Torres Strait Islander Health Survey (AATSIHS) collected a range of health-related information from Aboriginal and Torres Strait Islander Australians, similar to that collected for the AHS. In 2012–13, the AHS collected new information on nutrition and physical activity, as well as biomedical information collection. The AATSIHS comprises the existing ABS National Aboriginal and Torres Strait Islander Health Survey (NATSIHS), the NATSINPAS and the NATSIHMS.

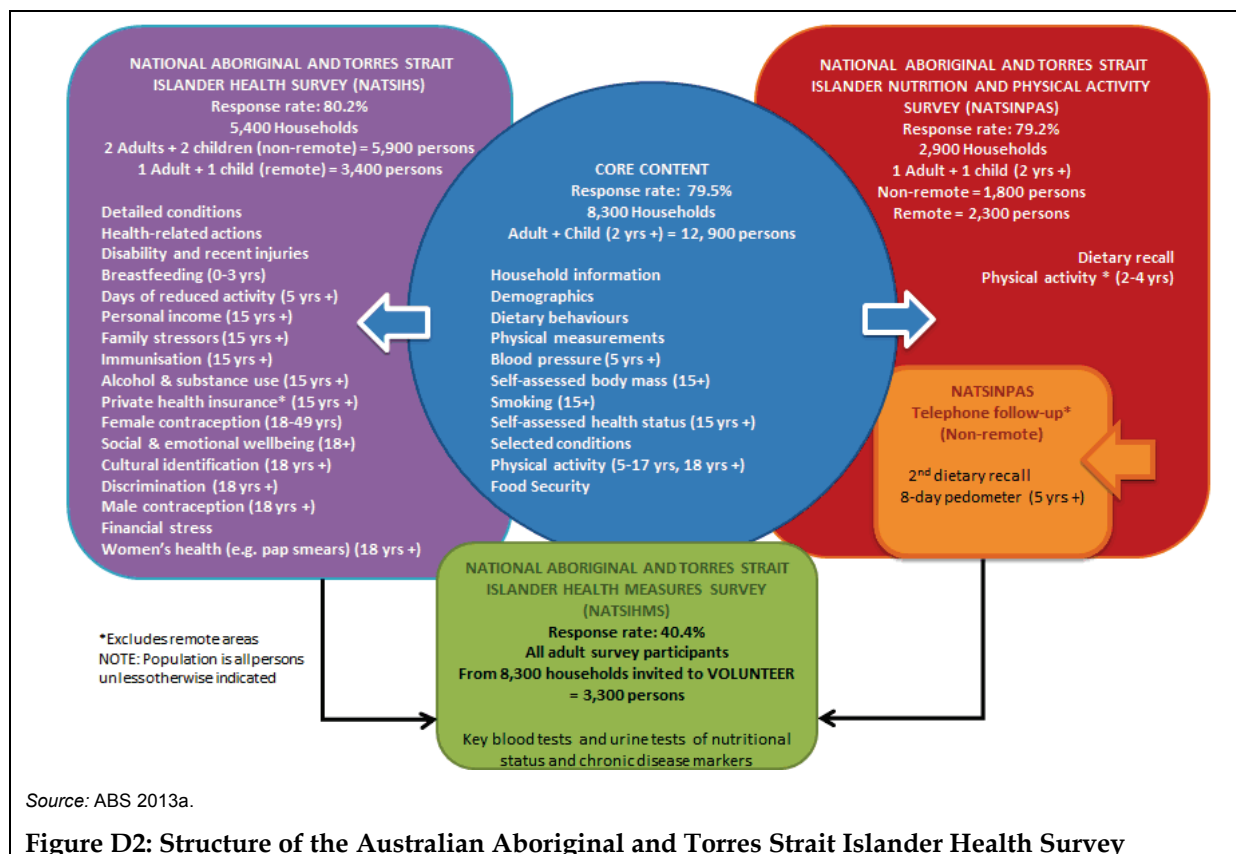
People who took part in the AATSIHS participated in either the NATSIHS or the NATSINPAS. A core set of data items was common to both surveys, and information from these data items is available for all persons in the AATSIHS (approximately 12,900).

All people aged 18 and over were then invited to participate in the voluntary NATSIHMS. Figure D2 shows the structure of the various components of the AATSIHS.

### **Scope of the Australian Aboriginal and Torres Strait Islander Health Survey**

The ABS 2012–13 AATSIHS covered approximately 8,300 private dwellings across Australia. It was conducted in non-remote and remote areas in all states and territories of Australia, including discrete Aboriginal and Torres Strait Islander communities.

Non-private dwellings such as institutional care facilities (including hospitals and aged care facilities), hotels, motels and short-stay caravan parks were excluded from the survey. The following groups were also excluded: non-Indigenous people, certain diplomatic personnel of overseas governments, persons whose usual place of residence was outside Australia, members of non-Australian Defence forces (and their dependants) stationed in Australia, and visitors to private dwellings.



**Figure D2: Structure of the Australian Aboriginal and Torres Strait Islander Health Survey**

### National Aboriginal and Torres Strait Islander Nutrition and Physical Activity Survey

The NATSINPAS contains food and nutrition data based on a 24-hour dietary recall and information on selected dietary behaviours from Aboriginal and Torres Strait Islander people. To account for possible seasonal effects on health and nutrition, the survey was conducted over a 12-month period, from August 2012 to July 2013.

All statistics from the 24-hour dietary recall are based on a single day's intake (Day 1). No adjustments have been made using the second day (Day 2) of 24-hour dietary recall information collected from respondents living in non-remote areas.

The survey is based on a sample of about 2,900 private dwellings across Australia.

### National Aboriginal and Torres Strait Islander Health Measures Survey

The NATSIHMS collected information about chronic disease biomarkers and nutrient biomarkers, such as folate and iodine from Aboriginal and Torres Strait Islander people aged 18 and over.

Of the 8,157 respondents aged 18 and over in the combined NATSIHS/NATSINPAS sample, 3,293 (40%) participated in the NATSIHMS, with a higher level of response in remote areas (56%) than in non-remote areas (28%). Participants voluntarily provided blood and urine samples, which were then analysed for specific biomarkers.



## **Food Standards Australia New Zealand's dietary intake assessment of folic acid**

FSANZ used its customised DIAMOND program to estimate the Australian population's intake of folic acid. The program was custom built by FSANZ in the mid-1990s to calculate dietary exposure to food chemicals such as food additives, pesticides, contaminants, nutrients and other food ingredients.

The weighted mean folic acid level in all breads sampled during the two phases of the FSANZ bread surveys were incorporated into its food composition database to provide updated data on folic acid levels in the food supply. These revised food composition data, together with food consumption data from the 1995 NNS and the 2007 Children's Survey, were used to determine folic acid and DFE intakes.

FSANZ used these nutrition surveys to determine baseline intake of folic acid and to predict future intakes when developing the mandatory requirement. Combined with updated folic acid data (from the 2010 and 2012 bread surveys), this provides the best available methodology for comparing the impact of mandatory folic acid fortification with pre-fortification levels.

Although more recent food consumption data are available from the NNPAS, these data were not available for analysis in DIAMOND and so could not be used in the FSANZ dietary assessment.

FSANZ incorporated data from the 2007 Children's Survey on supplement use for children aged 2–16 to model two different folic acid and DFE consumption scenarios to see what impact, if any, supplement intakes have on total nutrient intake. No data on supplement use were available for adult respondents in the 1995 NNS.

Mean folic acid data were based on the average of 2 days' food consumption data, and 10th and 90th percentile population intakes were presented to demonstrate high and low consumers of folic acid.

The average of 2 days' food consumption (24-hour food intake recall) was used to estimate folic acid intakes pre- and post-mandatory fortification. This approach was used because it was considered inappropriate to use the normal 2-day adjustment approach, due to the non-normality of the distribution of the folic acid intakes. The methodology was applied to both the 1995 NNS and the 2007 Children's Survey. In contrast, the 2-day adjustment approach was used to estimate DFE intakes.

The 1995 NNS data used to estimate folic acid intake for women of child-bearing age had consumption data for only 10% of respondents from Day 1. Although there were 3,178 women aged 16–44 in the 1995 NNS, only 328 completed both Day 1 and Day 2 food intakes. As such, this data may not be fully representative of the target population of women of child-bearing age. FSANZ undertook further validation work to investigate the issue and concluded that the data were of sufficient quality to represent this population group (FSANZ 2015b).

### ***Neural tube defects in Australia, 2007–2011***

This study by Hilder (2016) was commissioned by the Department of Health in 2014 to compare the rate of NTDs in Australia among babies conceived before and after the introduction of mandatory folic acid fortification in September 2009.

## Study data

Data on NTDs were sought from health authorities in each state or territory. New South Wales, Queensland, Western Australia, South Australia, South Australia, Tasmania and the Northern Territory agreed to provide data. Data from Victoria were not available for the whole study period and the Australian Capital Territory do not have a congenital anomaly data collection. A standardised request for NTD data was provided to the jurisdictions that agreed to provide data.

Some caution is needed when interpreting the NTD results as they may not be fully representative of the entire Australian population and due to the small numbers for specific subgroups. In addition, the relative rarity of NTDs and the short study period post-fortification need to be considered in terms of their contribution to the variability in NTD rates.

## Jurisdictional data quality

NTD rates across the study period (2007–2011) were higher in South Australia (14.3 per 10,000 births) and Western Australia (131 per 10,000 births) than in other jurisdictions. These states have congenital anomaly registers that employ active case finding and benefit from statutory collection of termination of pregnancy data. Ascertainment of NTDs is considered to be near complete in these states. Assuming that the NTD rates in these jurisdictions applied elsewhere during the same study period provided a rudimentary assessment of the expected number of NTD-affected babies.

Tasmania had the lowest jurisdictional NTD rate (5.1 per 10,000 births), which was just over a quarter (26.3%) of the number expected. Cases were obtained exclusively from birth and perinatal data collections and no NTDs were found from terminations of pregnancy before 20-weeks' gestation. The study predates decriminalisation of terminations of pregnancy in Tasmania in 2013.

The rate of NTDs in the Northern Territory were 9.8 per 10,000 births in 2007–2011, with an additional 5 NTD occurrences for residents of Northern Territory in other jurisdictions. Babies with an NTD may be lost from, or added to, jurisdictional ascertainment if women travel interstate to have their baby or to terminate their pregnancy. South Australian health services are routinely used by residents of the Northern Territory and western New South Wales. NTD-affected babies would have been lost to the study if women from participating jurisdictions travelled to Victoria to terminate their pregnancy (with data from Victoria not available for the whole study period and therefore not included).

Queensland's rate of NTDs was 10.7 per 10,000 births, which was 78.7% of that expected if the rates in South Australia and Western Australia prevailed.

New South Wales has a congenital anomalies register that includes data from termination of pregnancies and births. However, NTD ascertainment for this register relies on a passive system of notifications from health service providers. The NTD rate of 7.0 per 10,000 births in 2007–2011 was approximately half (51.4%) that of those in the states considered to have near complete ascertainment. Relative ascertainment in New South Wales in the study period was similar to that in 2004–2008 (51.2%) and 1999–2003 (53.4%). As well as the differences in data collection practices, the lower ascertainment of NTDs compared with the states considered to have near complete ascertainment of NTDs may result from the loss of data for NTD-affected babies of women travelling interstate to non-participating states and territories.

Data values to assign populations for comparison over time were substantially missing from Tasmania (18.8%) and, to a lesser extent, from the Northern Territory (5.3%) and New South Wales (2.1%).

Hilder (2016) reports that, in theory, the best estimate of NTD rates would be obtained by using data from Western Australia and South Australia. These jurisdictions, however, have relatively small populations and are more prone to random fluctuations.

### **Categorising isolated and non-isolated neural tube defects**

NTDs were classified as 'isolated' if there were no unrelated conditions present and as 'non-isolated' if there was one or more unrelated condition present. Related conditions could coexist with either isolated or non-isolated NTDs. If conditions with an uncertain relationship to NTD were present with unrelated conditions, the NTDs were also classified as 'non-isolated'. However, if these were the only other conditions present or were present with related conditions, the NTDs were classified as 'uncertain'.

### **Study strengths**

This study sought to compare NTD rates before and after the introduction of mandatory folic acid fortification. Although data collection methods varied between jurisdictions, they were consistent over the study period within each jurisdiction.

The use of pregnancy start rather than pregnancy end for both numerator (NTD-affected babies) and denominator (total births) preserves the relationship between NTD-affected babies and total births in a specified period, which allows for direct comparison of NTD rates among conceptions with NTD rates among births.

Some caution is therefore needed when interpreting the results presented here as they may not be fully representative of the entire Australian population and due to the small numbers for specific subgroups. As well, the relative rarity of NTDs and the short study period post-fortification need to be considered in terms of their contribution to the variability in NTD rates

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This report assesses the health effects of mandatory folic acid and iodine fortification, introduced to help reduce the prevalence of neural tube defects and address the re-emergence of iodine deficiency in the population. Mandatory fortification resulted in increased levels of folic acid and iodine in the food supply, increased folic acid and iodine intakes, a decreased rate of neural tube defects in Australia, and improved iodine status in the general populations in Australia and New Zealand.

