

A review of compliance with, and enforcement
impacts of the mandatory fortification of bread
with folic acid and iodine

February 2015



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Online ISBN: 978-1-76007-324-4

Publications approval number: 11961

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1 Executive Summary

In 2004, the then Australia and New Zealand Food Regulation Ministerial Council requested that Food Standards Australia New Zealand (FSANZ) consider mandatory fortification of food with folic acid. Subsequently, an amendment to Standard 2.1.1 Cereals and Cereal Products (Standard 2.1.1) came into effect in September 2009. Since that date, Australian millers must add folic acid to all wheat flour (except when the flour is represented as 'organic') for bread making. Since October 2009, Standard 2.1.1 also requires bakers to replace non-iodised salt with iodised salt in bread. Bread represented as 'organic' is also exempt, consistent with the mandatory folic acid fortification Standard. The purpose of mandatory folic acid fortification is to reduce the incidence of neural tube defects (NTDs) in the Australian population by increasing the folic acid intakes of women of child-bearing age. The purpose of mandatory iodine fortification is to address the re-emergence of iodine deficiency in Australia and New Zealand.

This review assessed the Australian milling industry's compliance with and the Government's monitoring and enforcement of mandatory folic acid fortification of wheat flour used in bread, and the compliance of the salt manufacturing and baking industries in Australia and New Zealand with the mandatory replacement of non-iodised salt with iodised salt in bread. The project also considered the cost impacts on the food industry in complying with the regulations and whether the dietary intake of folic acid and iodine had increased due to mandatory fortification.

On the basis of the information provided by 33 companies/agencies in Australia and New Zealand the review concluded that the programs have been implemented as intended. For both folic acid and iodine, the manufacturers who are tasked with the fortification have systems and documentation to ensure that they comply with Standard 2.1.1, and are able to demonstrate the same under audit. With respect to Australian wheat millers these were also the conclusions of a national compliance survey of folic acid fortification of wheat flour¹. Similarly, bakers of bread in both countries are aware of their responsibilities and have systems and documentation to ensure that they comply with the Standard, and are able to demonstrate this at audit. This was apparent for folic acid (in Australia) and iodine (in Australia and New Zealand). The enforcement agencies at state and territory level have systems for compliance and enforcement of the Standard. There was no evidence of ongoing interaction between enforcement agencies and relevant industry groups. A number of respondents advised that this was because there was confidence in the industry's self-management systems and due to a number of appropriate reasons, compliance and enforcement agencies have not seen a need to be actively working with industry groups. The disadvantage to this position is that in the absence of interaction, any examples of non-compliance and/or system failure may only be determined through audit and it may take some time before states and territories are notified.

Compliance with the Standard has meant some significant costs were incurred by industry. Millers estimated an aggregate of set up costs of over \$1 million and ongoing costs of about \$0.5 million per year. Bakers had to write off packaging at an estimated industry wide cost of \$3 million. However, ongoing costs are minimal. Salt manufacturers reported aggregate set up costs of \$666,000, although some of this reflected choices to upgrade plant. These costs, although significant, were less than the costs that were projected in the 2006² and 2007³ economic analyses that preceded the implementation of the Standard. For millers and bakers actual costs were about 50% less than those projected.

The intended outcome of the program is for an increase, from mandatory sources, of dietary intake of folic acid in the population of Australia and iodine in the populations of Australia and New Zealand.

¹ Implementation Sub Committee Co-ordinated Food Survey Plan (April 2012) National mandatory folic acid fortification of wheat flour for making bread compliance survey of flour mills producing wheat flour for making bread in October 2010-March 2011.

² FSANZ FINAL ASSESSMENT REPORT October 2006 PROPOSAL P295 Consideration of mandatory fortification with folic acid

³ Access Economics. Costs of fortifying bread and bread products with iodine: Report by Access Economics for Food Standards Australia New Zealand. Access Economics: Melbourne, 2007

For folic acid, it is clear that there is a dietary increase from mandatory sources between 2.48-2.68 tonnes folic acid per annum. This increase occurred within a short period in late 2009. The figures are in alignment with the FSANZ projected dietary increase in folic acid as a result of mandatory fortification of 2.62 tonnes per annum.

In Australia, the use of iodised salt for bread was negligible before the Standard was implemented. On the basis of the information from Australian salt manufacturers, it was estimated that around 13,000 tonnes of iodised salt equating to about 700kg iodine is added to food per annum. Taking into account the substantial portion of iodised salt that does **not** go into bread (about 4,500 tonnes salt and 245 kg iodine per annum) it is estimated that about 455 kg iodine per annum is being delivered through bread. However, from the baked goods data, it was estimated that 300 kg iodine is added to bread. Thus, in Australia the dietary intake of iodine from the mandatory use of iodised salt in bread has increased by between 300 and 455 kg iodine per annum. The FSANZ projected dietary increase for mandatory use of iodised salt in bread was 343-397 kg iodine per annum in Australia⁴. This is within the range obtained in this review.

In New Zealand, before the Standard was implemented, the use of iodised salt previously in the food supply was significant at around 65% of total salt produced. However, bakers now all use iodised salt, and an additional 115 kg iodine per annum is available via bread. The FSANZ projected additional dietary iodine from the mandatory use of iodised salt in bread was 88 kg iodine in New Zealand. The actual quantity of added iodine in New Zealand agrees reasonably with this projection.

⁴ FSANZ FINAL ASSESSMENT REPORT October 2006 PROPOSAL P230 Consideration of mandatory fortification with iodine Attachment 8

2 Overview

2.1 Scope of the project

In 2004, the then Australia and New Zealand Food Regulation Ministerial Council requested that Food Standards Australia New Zealand (FSANZ) consider mandatory fortification of food with folic acid. Subsequently, an amendment to Standard 2.1.1 Cereals and Cereal Products (Standard 2.1.1) came into effect in September 2009. Since that date, Australian millers must add folic acid to all wheat flour (except when the flour is represented as 'organic') for bread making. Since October 2009, Standard 2.1.1 also requires bakers to replace non-iodised salt with iodised salt in bread. Bread represented as 'organic' is exempt, consistent with the mandatory folic acid fortification Standard. The purpose of mandatory folic acid fortification is to reduce the incidence of neural tube defects (NTDs) in the Australian population by increasing the folic acid intakes of women of child-bearing age. The purpose of mandatory iodine fortification is to address the re-emergence of iodine deficiency in Australia and New Zealand.

The aim of this project was to review the Australian milling industry's compliance with and the Government's monitoring and enforcement of mandatory folic acid fortification of wheat flour used in bread; and the compliance of the salt manufacturing and baking industries in Australia and New Zealand with the mandatory replacement of non-iodised salt with iodised salt in bread. The project also considered the cost impacts on the food industry in complying with the regulations and whether the dietary intake of folic acid and iodine had increased due to mandatory fortification.

The overarching aim of the review was to determine if the program for fortifying wheat flour with folic acid and bread with iodised salt has been implemented as intended.

This was considered by exploring the following:

2.1.1 Compliance

- Are relevant industry groups informed of regulations for mandatory fortification?
- Are relevant industry groups complying with regulations?
- Have sufficient monitoring and enforcement strategies been implemented?
- Has enforcement action been undertaken where non-compliance has been identified?
- Are enforcement agencies working with relevant industry groups to enable and ensure compliance?

2.1.2 Cost impacts

- What have been the cost impacts on the food industry in complying with the regulations?

2.1.3 Outcome

- Has the level of folic acid and iodine in the food supply from mandatory sources been increased?

2.2 Overall approach

The overall approach was based on:

- establishing a project structure;
- prototyping the project methodology with a small and agreed sample of industry players to ensure a thorough understanding of information sources, activities and supply chain and monitoring flows. The result of the prototype was reviewed with Department of Health (Health) prior to scaling up to full industry implementation;
- developing good communications and consulting widely with key industry stakeholders using structured interview scripts developed from the pilot study;
- developing good communications with enforcement agencies to assess the effectiveness of enforcement strategies using structured interview scripts developed from the pilot study;
- monitoring project risks that may materially impact on the timeline and outcomes of the project and communicating these with Health;

- using a consistent costing methodology and creating templates to identify the cost impacts on the food industry and the levels of folic acid and iodine now in the food supply; and
- understanding and building on previous analyses of compliance with mandatory fortification e.g. those of the Implementation Sub Committee for Food Regulation (ISFR)⁵.

Mandatory folic acid fortification applies to flour millers in Australia. Bread producers are required to use folic acid fortified wheat flour at levels between a stated range.

Mandatory iodine fortification requires bread producers in Australia and New Zealand to use iodised salt, to be supplied by salt producers at a stated level and range.

In Australia, enforcement is by state and territory agencies and in New Zealand enforcement is by the Ministry for Primary Industry (MPI).

2.3 Organisations contributing to the review

Consultation was carried out with 33 organisations across Australia and New Zealand representing the following groupings:

- flour millers
- bakers of bread and baked products, either for wholesale and or retail
- salt manufacturers
- compliance and enforcement agencies.

The Australian Technical Millers Association (ATMA) is the professional association for the industry and has provided guidance about the structure of the milling industry in Australia. Whilst there are approximately 90 grain mills of varying products in Australia, preliminary investigations identified that three organisations, Manildra Milling Pty Ltd, George Weston Foods Limited and Allied Mills Pty Ltd provide approximately 80% of the wheat flour in Australia (WA Department of Agriculture and Food, 2009). These organisations also produce much of the base ingredients for the bread making industry and provide products as pre-mixes to the major supermarket chains and specialty bakeries (hot bread franchises). In addition, there are seven smaller companies in the Eastern States and Tasmania; and two companies in Western Australia. Contact details for 12 millers were obtained and approached, and six responded. The companies consulted produced between them over 95% of the fortified flour in Australia, thus providing a level of robustness in the final information.

The packaged bread industry in Australia and New Zealand is dominated by Goodman Fielder Limited (Sydney), Goodman Fielder New Zealand Limited (Auckland), and George Weston Foods Limited (Sydney). It is estimated (Australian Competition & Consumer Commission, 2008) that Coles Supermarkets Pty Ltd (Melbourne), and Woolworths Limited (Sydney) have 59% share of the bread market, with 31% sold through specialty bakeries and 10% through convenience stores (many of which are petrol stations controlled by Coles and Woolworths). In addition, there are a number of other nationwide baked bread companies. The review accessed appropriate contacts and approached eight companies, and all responded. It is estimate that over 95% of the bread market in Australia was accessed thus providing a level of robustness in the final information. In New Zealand there are a number of smaller baker's chains. The review accessed contacts for 10 of the major companies and seven responded.

The provision of salt (as an ingredient) is dominated by four organisations in Australian and New Zealand: Cheetham Salt (CK Life Sciences Int'l. (Holdings) Inc), Pacific Salt Pty Ltd (Olson Industries); Cerebos (Australia) Ltd and New Zealand-based Cerebos Gregg's Limited, trading as Dominion Salt.

For the salt production and refining industry:

⁵ National mandatory folic acid fortification of wheat flour for making bread compliance survey: of flour mills producing wheat flour for making bread in October 2010 – March 2011 Implementation Sub Committee Co-ordinated Food Survey Plan April 2012

- there are four main companies headquartered in Western Australia, with a smaller number of companies in Eastern Australia
- there is one major company in New Zealand.

The salt produced in Western Australia is mainly industrial and exported. The two main companies for food salt production in Australia were contacted and both responded.

A summary of organisations that were approached and that finally contributed to the review, by organisational types, is provided in Table 1 below.

Table 1 Summary of organisations

Organisation	Folic Acid Australia Number approached	Folic Acid Australia Number participating	Iodine Australia Number approached	Iodine Australia Number participating	Iodine New Zealand Number approached	Iodine New Zealand Number participating
Enforcement agency*	8	8	8	8	1	1
Millers	12	6	Not applicable	Not applicable	Not applicable	Not applicable
Bakers	8	8	8	8	10	7
Salt manufacturers	Not applicable	Not applicable	2	2	1	1
Total	28	22	18	18	12	9

*The nature of the enforcement agency differed in each of the state/territory jurisdictions in Australia. Seven state/territory departments of Health, and one Food Authority were interviewed.

Reasons for companies not contributing to the review were varied.

2.3.1 Millers

Of the 12 Australian millers approached, three large and three medium sized companies agreed to participate⁶. For the remainder, most of whom were smaller millers:

- Two millers were not in scope, because:
 - One did not manufacture flour for bread making,
 - One manufactured organic flour only.
- Two millers agreed to be involved, but demands on the time for staff with multiple roles meant that responses never eventuated.
- Two millers declined to be involved. One of these was because the mill was closing due to stated \$900k capital cost of dosing flour with folic acid. The other was too small and staff did not have enough time.

2.3.2 Bakers

Some bakers in New Zealand did not meet sampling targets and therefore did not participate for the following reasons:

- One baker declined to participate.
- Two bakers agreed to be involved. However, demands on the time for staff with multiple roles meant that responses never eventuated.

⁶ A large company was defined as producing more than 100,000 tonnes flour per annum.

3 Results and Discussion

The responses to the interview scripts were summarised and collated into tables and are in the Appendix. They are presented in the following lay out:

- folic acid
 - millers
 - bakers
 - compliance and enforcement for millers and bakers
- iodine
 - salt manufacturers
 - bakers
 - compliance and enforcement for salt manufacturers
 - compliance and enforcement for bakers.

3.1 Folic acid

This review assessed whether the relevant industry groups are informed of and complying with regulations for mandatory fortification of wheat flour with folic acid. Information was collected in Australia from millers, bakers and the compliance and enforcement agencies.

3.1.1 Millers and bakers compliance with regulations for mandatory fortification

In general, it was found that there was a high level of awareness of the regulations for folic acid fortification in both the milling and the baking industry.

Millers

As might be expected, the larger companies had more roles that needed to be aware of the changes compared to smaller companies with less specialisation.

The large milling companies had larger teams of people involved, including compliance staff and production staff, often across a number of locations. One company also noted that their sales staff were kept informed of folic acid fortification. In addition, millers identified a wide range of roles that were kept informed of the regulations and any changes to these including:

- product development
- quality assurance
- nutritionists
- legal services
- regulatory affairs.

In every milling business, the manager in charge of quality assurance was responsible for ensuring compliance with the fortification requirements. The smaller mills all noted that the CEO/General Manager or Managing Director held ultimate responsibility for ensuring the business complies with all regulatory requirements.

Each mill also highlighted the central role of a robust quality assurance program of documentation and systems, operating procedures, and training and updating of key staff. Verification of folic acid levels is managed through a combination of:

- production engineering practices, (e.g. auto feeders, variance alarms)
- auditing practices (e.g. per-shift, per-day, per-month reconciliations of quantity used)
- testing protocols (e.g. lab testing, mostly on a quarterly basis).

All mills, irrespective of size, had external third party audits of their systems; some also had multiple customer audits.

Bakers

All baking companies reported having a quality management system which specified requirements for the flour. The bakers identified the procurement of the folic acid fortified flour as a key control point. The supplier had contractual requirements for flour to meet specification. A certificate of analysis is required by some companies, and others test folic acid level in products as well. Typically any formulation or supplier changes are required to be signed off. In some companies all suppliers are audited. In all responses the requirements are integrated into the companies' procedures, (through one or more of the following: quality assurance system, staff training, requirement for any changes to bill of materials to be authorised by senior manager), and any legal requirement is captured in the documentation. One major baker routinely tests its final product for verification.

Bread and baked goods manufacturers supplying products to supermarkets reported being subject to third party external auditing. The other respondents were not subject to external auditing, although had internal auditing.

It was concluded that relevant industry groups are informed of the regulations and have systems in place for ensuring compliance.

3.1.2 Compliance and enforcement activities for mandatory fortification

The Ministers responsible for food regulation in Australia and New Zealand convene the Australia and New Zealand Ministerial Forum on Food Regulation (the Forum), which oversees the food regulation system for both countries. FSANZ has responsibility for the development and maintenance of the Australia New Zealand Food Standards Code (the Code), while enforcement of the Code is the responsibility of the state and territory governments in Australia. The role of local government councils in compliance monitoring and enforcement of the Code varies with each jurisdiction.

In regard to compliance and enforcement of mandatory fortification of folic acid, the review sought to ascertain the following information:

- Whether sufficient enforcement strategies are in place.
- Whether enforcement agencies are working with relevant industry groups to enable and ensure compliance.
- What enforcement action has been undertaken where non-compliance has been identified.

Are sufficient enforcement strategies in place?

It was found, through a survey process, that all state and territory agencies had well developed strategies for managing compliance and enforcement, and these are applied to millers and bakers as required.

In general, compliance monitoring is delegated to local government agencies. A case-by-case approach is taken, to investigate the cause and level of any non-compliance in conjunction with the miller/baker. An investigation through an audit and product samples for folic acid analysis may be taken. Allowance is made for the 'measurement uncertainty' inherent in any method of analysis. Depending upon the findings of the investigation, non-compliance is addressed through escalated application of accepted enforcement tools. Generally, this would involve discussions at first instance but depends on the level of risk. Continued non-compliance leads to statutory notices and eventually prosecution. The local government agency may notify the state or territory authority of any non-compliance. Some jurisdictions also have proactive programs intended to prioritise and address compliance risks. Such programs would periodically result in review of fortification compliance.

It is concluded that sufficient enforcement strategies are in place.

Are enforcement agencies working with relevant industry groups to enable and ensure compliance?

At the time of this review, no state or territory had budgeted for compliance and monitoring activities specifically for folic acid. Similarly, no state or territory has a proactive ongoing program of working with relevant industry groups in the millers or bakers sectors to enable and ensure compliance is occurring.

This was for a number of reasons provided in the interviews:

- The Implementation Sub Committee for Food Regulations Coordinated Food Survey Plan (ISFR CFSP) provides national surveillance, monitoring and evaluation activities. States and territories participate in this at a National level and are informed of any issues. This minimises the need for activities at a state or territory level.
- The above survey revealed good systems and processes including internal audit systems at the flour mill that provided confidence that mills were complying and as a result resources have been put into higher priority risk management activities⁷.
- One territory does not have any millers (and thus has not been included in this response).
- No complaints have been received about any mills or bakers.

One respondent had for the purposes of this review undertaken significant consultation with local councils and identified no issues with folic acid. Another state respondent is planning proactive work for 2014/2015 in their state.

It is concluded that due to a number of appropriate reasons (as described above), compliance and enforcement agencies have not seen a need to be actively working with industry groups.

What enforcement action has been undertaken where non-compliance has been identified?

At the time of this review, no enforcement action had been undertaken as no non-compliance has been identified.

3.1.3 Cost impacts

The review ascertained the cost impacts on the food industry in complying with the regulations for folic acid fortification.

Millers

For the millers, the initial cost of implementing folic acid fortification included:

- engineering design
- capital equipment and installation
- IT
- analysis and verification testing
- quality assurance systems, training and documentation

A simple analysis was performed for purposes of comparison only. Cost data (excluding financing, loan administration and similar) was allocated across the production throughput over three years, assuming stated capacity remains stable over that period.

On this basis the impact of up-front establishment costs generally (not linearly) reflected the scale of operations. In order of production, from the largest to the smallest miller, the cost per tonne over three years was \$0.29, \$0.58, \$0.59, \$0.74 and \$1.90. Ongoing costs for ingredients, testing and verification and quality assurance resources were estimated to be around \$1.00/tonne. These are summarised in Table 2

⁷ "Implementation Sub Committee Co-ordinated Food Survey Plan (April 2012) National mandatory folic acid fortification of wheat flour for making bread compliance survey of flour mills producing wheat flour for making bread in October 2010-March 2011

Table 2 Up front and ongoing cost for folic acid fortification for millers

Timing	Cost per tonne wheat flour*	Cost per tonne wheat flour*	Cost per tonne wheat flour*
	Low cost estimate	Average cost estimate	High cost estimate
Up front	\$0.29	\$0.82	\$1.90
Ongoing	None	\$1.00	None

*The wholesale of 1 tonne flour at November 2014 was estimated to be around AUD\$400/tonne. However, prices are commercially sensitive and vary widely primarily depending on wheat supply, demand and quality.

Half of the millers interviewed reported manufacturing inefficiencies as a result of the fortification requirement. There was no correlation with the size of the operation. The respondents who reported manufacturing inefficiencies cited a range of specific causes. These included the need to allocate specific storage silos for fortified and unfortified flour (e.g. where overseas customers specify non-fortified), requirement for additional product codes, with attendant administrative load, and double-handling due to the need to manufacture a pre-mix in order to enable effective final blending.

No identifiable benefits were reported to have arisen from mandatory fortification, apart from two respondents noting that an improvement in monitoring and record-keeping had occurred.

Bakers

For the bakers, there were one off costs incurred for changes to packaging and documentation. Most respondents managed these costs within their usual business practices during the phase-in of the new Standard. Where this was not done, total labelling-related costs ranged from \$2.7 million down to \$300,000 and \$25,000 depending upon the size of the company. Most of the companies identified no ongoing costs. However, one company pays \$82,500 annually for costs of testing finished products, although this is not mandatory.

No manufacturing inefficiencies or benefits were noted. Projected costs, in 2006⁸ compared to reported costs in 2014 from this report, are shown at an aggregated industry level in Table 3.

Table 3 Project cost for folic acid fortification for millers and bakers from 2006 vs reported cost in 2014

Cost attribution	Timing	Type	2006* projected	2014 reported
Millers	Up front	Equipment	\$264,000	Not specified
		Labelling	\$2,486,400	Not specified
		Sub total	\$2,750,400	\$1,056,000
	On going	Folic acid	\$112,000	Not specified
		Analytical	\$673,077	Not specified
		Premix	\$51,893	Not specified
		Administration	\$186,883	Not specified
		Clean out mill	\$34,739	Not specified
			Sub total	\$1,058,592
Bakers	Up front	Packaging write off	\$4,000,000	\$3,075,000*
	Ongoing	Not specified	Not specified	Minimal

*The packaging write off costs, also covered changes for the mandatory use of iodised salt. No apportionment has been attempted. Note that the 2006 figures are as actually reported and are not adjusted for CPI.

It can be seen that actual costs were less than 50% of the projected 2014 costs. This may be because not all companies were able to provide accurate and complete estimates of up-front costs, given the time that has elapsed. However, it was noted at the time in the 2006 report that the projected costs were at the high end

⁸ FSANZ FINAL ASSESSMENT REPORT October 2006 PROPOSAL P295 Consideration of mandatory fortification with folic acid

of a plausible range, being based on cost information provided by industry, and that actual costs were anticipated to be lower.

3.1.4 Outcome

The intent of the mandatory folic acid fortification in Australia was to increase the level of folic acid in the food supply. In this section the evidence for an increase is examined.

The tonnage of wheat flour per annum, wheat flour fortified with folic acid, and amount of folic acid added, as provided by the millers, is in Table 4. It was noted that a small amount of flour was fortified since mid-2005.

Table 4 Increase in folic acid fortified wheat flour used for making bread

Wheat Flour	Tonnes per annum*	Folic acid tonnes
In 2014 wheat flour milled in Australia	1,440,000	Not applicable
In 2014 wheat flour fortified with folic acid	950,000	2.54-2.74
Mid 2005 voluntary fortification	Approx. 56,000	Approx. 0.06
Increase from mandatory sources	894,000	2.48-2.68

*Although we did not receive responses from three millers, their tonnage is estimated to be very small and with no material impact on these figures.

As shown in the table, there has been an increase in dietary intake, from mandatory sources, of between 2.48-2.68 tonnes per annum of folic acid. This is in alignment with the FSANZ projected increase in dietary intake of folic acid as a result of mandatory fortification of 2.62 tonnes per annum⁹.

Extrapolating from reported results, it is estimated that an additional 4% (20,000 tonnes) of products such as pikelets and crumpets are also made with fortified flour, under *voluntary* provisions in the Code. This would deliver an additional 0.04-0.06 tonnes folic acid per annum¹⁰. Therefore, it is estimated that the total folic acid delivered per year in bread and other products made with fortified flour is between 2.52-2.74 tonnes.

Companies were asked to provide dates for when they commenced mandatory folic acid fortification of wheat flour so that dietary impact could potentially be assessed. Individual companies commenced their flour fortification between June 2009 and March 2010. The cumulative proportion of flour fortified over the transition period is shown in Table 5 below. By inference, relative proportions of folic acid track similarly.

Table 5 Phasing of commencement of folic acid fortification of wheat flour

Date	Jun 2009	Aug 2009	Oct 2009	Mar 2010
Cumulative flour proportion*	3%	69%	97%	100%

*of total flour 894,383 tonnes

3.2 Iodine

This review assessed whether the relevant industry groups are informed of and complying with regulations for mandatory fortification of iodine in the form of iodised salt in bread. Information was collected in Australia and New Zealand from salt manufacturers, bakers and the compliance and enforcement agencies.

3.2.1 Salt manufactures and bakers compliance with regulations for mandatory fortification

There was a high level of awareness of the regulations for both the salt manufacturing and the baking industry.

⁹ FSANZ FINAL ASSESSMENT REPORT October 2006 PROPOSAL P295 Consideration of mandatory fortification with folic acid

¹⁰ 20,000 tonnes at between 2 mg/kg and 3 mg/kg of folic acid

Salt Manufacturers

The salt manufacturers identified operational and plant managers, quality assurance staff and sales teams as positions that needed to be aware of the regulations for iodine fortification.

In the salt manufacturing businesses, the manager in charge of quality assurance was responsible for ensuring compliance with the fortification requirements. Iodine addition is automated and can only be changed by the Quality Manager. Iodine addition equipment is routinely calibrated, and product testing is also used. The New Zealand manufacturer has only one grade of salt for bread (i.e. specification control). In Australia the manufacturers have systems to ensure specifications meet the Standard.

All the salt manufacturing companies are audited to external standards by third parties, and iodine fortification is within this auditing scope.

Bakers

The bakers in both countries identified procurement as a key control point. In addition, they all identified a wide range of roles that need to be informed of the regulations and any changes to them including:

- product development
- quality assurance
- nutritionists
- legal services
- regulatory affairs.

In general, and as might be expected, the larger companies had more roles that needed to be aware of the changes compared to smaller companies with less specialisation.

All baking companies in Australia and New Zealand reported a quality management system which specifies requirements for the iodised salt. The supplier has contractual requirements for products to meet specification. A certificate of analysis is required by some companies, others test the iodine level in products as well. (One company noted that analysis of the iodine content of the salt and their bread produced inconsistent results.) Typically any formulation or supplier changes have to be signed off by the manager responsible for compliance. In some companies all suppliers are audited.

Bread and baked goods manufacturers supplying products to supermarkets reported being subject to external auditing. The supermarkets use internal auditing for products made in-store. Smaller companies did not appear to have third party auditing compared to the larger companies, although they did have internal auditing.

It was concluded that relevant industry groups are informed of the regulations and have systems in place, to varying degrees depending upon the size of the company, for ensuring compliance.

3.2.2 Compliance and enforcement activities for mandatory fortification

As per folic acid, the Forum oversees the food regulation system for both Australia and New Zealand; FSANZ has responsibility for the development and maintenance of the Code; and enforcement of the Code is the responsibility of the state and territory governments in Australia. The role of local government councils in compliance monitoring and enforcement of the Code varies with each jurisdiction. In

New Zealand, compliance and enforcement is the responsibility of the Ministry for Primary Industries (MPI).

In regard to compliance and enforcement of mandatory fortification with iodine, the review sought to ascertain the following information:

- Whether sufficient enforcement strategies are in place.
- Whether enforcement agencies are working with relevant industry groups to enable and ensure compliance.
- What enforcement action has been undertaken where non-compliance has been identified.

Are sufficient enforcement strategies in place?

All agencies had well developed strategies for managing compliance and enforcement, and these are applied to salt manufacturers and bakers as required.

In general, compliance monitoring is delegated to local government agencies. A case-by-case approach is taken, to investigate the cause and level of any non-compliance in conjunction with the salt manufacturer/baker. An investigation through an audit and product samples for iodine analysis may be taken. Allowance is made for the 'measurement uncertainty' inherent in any method of analysis. Depending upon the findings of the investigation, non-compliance is addressed through escalated application of accepted enforcement tools. Generally, this would involve discussions at first instance but depends on the level of risk. Continued non-compliance leads to statutory notices and eventually prosecution. The local government agency may notify the state or territory authority of any non-compliance. Some jurisdictions also have proactive programs intended to prioritise and address compliance risks. Such programs would periodically result in review of fortification compliance.

It is concluded that sufficient enforcement strategies are in place.

Are enforcement agencies working with relevant industry groups to enable and ensure compliance?

At the time of this review, no state or territory had budgeted for specific funding for an iodine monitoring strategy. Similarly, no state or territory has a proactive ongoing program of working with relevant industry groups to enable and ensure compliance. Any compliance and enforcement costs would be handled within current resources.

This was for a number of reasons provided in the interviews:

- Three states and territories do not have any salt manufacturers.
- All Australian jurisdictions have taken part in national surveys to analyse folic acid and iodine content of bread under the ISFR CFSP and one state has conducted its own additional survey.
- No perceived need for specific scrutiny, as evidence available to the agency suggested that iodine fortification has had an outcome in improving iodine intakes in children.
- Over the last three years, no complaints have been received requiring response.

It is concluded that due to a number of appropriate reasons (as described above), compliance and enforcement agencies have not seen a need to be actively working with industry groups.

However, one respondent had, for the purposes of this review, undertaken significant consultation with local councils and identified two cases in analytical investigations where iodine levels did not comply with the Standard. These will be further investigated. Another state respondent is planning proactive work for 2014/2015 in their state.

What enforcement action has been undertaken where non-compliance has been identified?

Discussions with the bakeries within the above council are ongoing.

In New Zealand, salt manufacturers and bread and bread mix manufacturers are required to have a Food Safety Program (FSP) in place, which is audited by a third party annually. If during a routine FSP audit an auditor became aware of any case in which a critical control point is either absent or ineffective they are required to immediately notify a Food Act Officer or MPI. All complaints to MPI are assessed and followed up in accordance with MPI's Food Investigation procedure. This includes entry of complaint details into a national database.

At the time of this review, no specific active monitoring and compliance strategies for iodine fortification were in place. This was, in part, because no complaints had been received either from public or third party audit agency for the salt manufacturer. New Zealand carries out regular surveys of iodine in bread and

estimates iodine intakes for children and the results have shown that iodine fortification is working effectively¹¹.

3.2.3 Cost impacts

The review ascertained the cost impacts on the food industry in complying with the regulations for iodine fortification.

Salt manufacturers

When mandatory iodisation of salt for making bread commenced, the three salt manufacturers in both countries had a number of set up costs. Costs varied by company depending on their existing manufacturing systems. One manufacturer spent \$630,000 for dosing and testing equipment, another spent around \$36,000 to upgrade the existing iodine fortification systems, while the third did not need additional equipment. All companies reported modifying systems but generally regarded these as normal business costs.

The direct ongoing costs associated with iodine fortification have been identified from the three manufacturers as including:

- direct cost of adding iodine
- additional costs of purchasing premix
- additional labour across the process
- analytical costs for determining iodine levels
- in one case, slower bagging, giving effect to lower outputs and thus increased costs.

The review was provided with three different estimates of the direct ongoing costs/tonne of salt: \$4.00, \$19.00 and \$45.00. About 25% of these costs are analytical, and about 60% are direct costs of iodine.

Mandatory iodisation generated inefficiencies in some situations. For example, existing dosing systems did not deliver uniformity and consistency, particularly where the salt was a large particle size, so that new dosing systems were required. Ongoing premixing and bagging require additional time and thus incur indirect costs. These have been absorbed by the company. However, for one company, the new iodate dosing systems improved consistency for all products; resulting in export potential for products with a tighter specification on iodine levels which may have been unachievable with the old system.

Bakers

For the baking industry in **Australia**, when mandatory iodisation of salt for making bread commenced, there were a number of set up costs. The main cost was reprinting and writing off packaging and updating documentation simultaneously for the use of iodised salt and folic acid fortified flour. Costs ranged from \$1500-\$5000 per SKU for label changes, plus administrative costs in formulation and specification update. Not all companies had access to records from that time but those that did quoted total labelling-related costs ranging from \$2.7 million down to \$25,000 depending upon the size and complexity of the company.

For the baking industry in **New Zealand**, specific set up costs were similarly incurred for reprinting and writing off packaging, and updating documentation. Costs varied between respondents, with only one respondent reporting costs of \$5000 per SKU for label changes, plus administrative costs in formulation and specification update, resulting in a total cost of around \$300,000.

¹¹ Dietary iodine intake of New Zealand children following fortification of bread with iodine MAF Technical Paper No: 2012/02

Prepared for DFR5 Monitoring Group by Julia Edmonds and Dr Terry Ryan, Science and Risk Assessment Directorate

ISBN 978-0-478-38777-3 (online) ISSN 2230-2794 (online) January 2012. An updated report for 2014 is also available.

<http://www.foodsafety.govt.nz/elibrary/industry/2014-21-Update-report-on-the-dietary-iodine-intake-of-NewZealand-children-following-fortification-of-bread-with-iodine.pdf>

For the baking industry in both countries no on-going costs were identified other than the small additional cost of iodised salt. This varied between companies, but a range of costs were identified from \$0.19-\$0.60 per tonne of bread. This equates to between \$105,000 and \$330,000 annually.

Bakers did not identify any manufacturing inefficiencies, nor any manufacturing opportunities or advantages.

Projected costs¹² in 2007, compared to reported costs in 2014 from this report, are shown at an aggregated industry level in Table 6.

Table 6 Projected cost from 2007 vs reported costs in 2014

Cost attribution	Timing	2007* projected Australia	2007* projected New Zealand	2014 reported Australia & New Zealand figures
Salt manufacturer	Up front	AUD 161,000-	NZD 303,000	AUD 666,000
Salt manufacturer	On going	AUD 314,000	NZD 20,000	Unable to determine at aggregated level
Baking	Up front	AUD 6,950,000	NZD 1,500,000	AUD25,000-2,700,000** NZD300,000
Baking	On going	AUD 30,000	NZD 30,000	Minimal*

*Iodine costs excluded

**In Australia, the packaging write off costs, also covered changes for the mandatory fortification of flour with folic acid. No apportionment has been attempted.

Note that the 2007 figures are as actually reported and are not adjusted for CPI.

For the salt manufacturers, some up-front costs were higher than projected, because the new requirement was used as an opportunity to substantially upgrade the plant, and the whole cost cannot be attributed to the cost of purchasing and adding iodine alone. Ongoing costs for salt manufacturers were not projected to be significant across the whole industry. The review was unable to obtain reliable aggregated ongoing costs for the salt manufacturers.

For the baking industry up-front costs were considerably less than a third of the 2007 projected costs, although still significant for companies. Ongoing costs, excluding iodine, were projected to be and are minimal. It was noted at the time in the 2007 reports that the projected costs were at the high end of a plausible range, being based on cost information provided by industry, and that actual costs were anticipated to be lower.

3.2.4 Outcome

The intent of the mandatory use of iodised salt in bread in Australia and New Zealand was to increase the level of iodine in the food supply. In this section the evidence for an increase is examined.

The review received estimates of iodised salt from both salt manufacturers and bakers in both countries.

Salt manufacturers

In **Australia** and from reports from salt manufacturers, in 2014, about 13,000 tonnes of iodised salt is produced per year; which at 55 mg/kg (ppm) iodine means around 700 kg iodine per annum is in the food supply. It is not clear what proportion of this salt goes into bread:

- Previously, before mandatory fortification, the largest salt manufacturer for food produced no iodised salt.
- A second salt manufacturer produced about 23% although the bread manufacturing industry is not a significant customer for them.

¹² Access Economics. Costs of fortifying bread and bread products with iodine: Report by Access Economics for Food Standards Australia New Zealand. Access Economics: Melbourne, 2007

Of this 13,000 tonnes iodised salt, a recent publication estimated approximately 4,500 tonnes of iodised table and cooking salt is used per annum in Australia¹³ equating to about 245 kg iodine. Thus, by subtraction, about 8,500 tonnes of iodised salt is being used in bread equating to a dietary supply of about 455 kg iodine per annum.

Bakers

For the baking and bread mix industry, all respondents reported 100% use of iodised salt, except for one manufacturer and retail seller of bread mixes, who advised that a proportion of their product is not iodised. The review was advised that there are >550,000 tonnes of iodised bread products sold each year. Given that bread has a 1% salt content it is estimated that 1 tonne of bread contains 550 mg iodine. Thus, from the bread products data, it is estimated that 300 kg per annum of iodine is by dietary intake from bread products. This information is summarised in Table 7.

Table 7 Increase of dietary intake of iodine from iodised salt in Australia

Iodine @55 mg/kg (ppm)	Tonnes per annum*	Iodine kg @55 mg/kg (ppm)*
In 2014 tonnage iodised salt in Australia	13,000	700
In 2014 iodised salt in bread (estimated)	Not specified	455
Iodine (@1%)	Tonnes	Iodine kg @1% salt content
In 2014 tonnage bread with iodised salt in Australia	>550,000	300

* The standard requires iodised salt to contain 25–65 mg/kg of iodine. In Australia it is added at 55 mg/kg (ppm).

It is noted that there is a difference between iodine estimates in bread from salt manufacturers at 455 kg and bakers at 300 kg. It may be that the figures provided for bread products underestimate the amount of bread consumed in Australia per annum.

Apart from a few bread bakers voluntarily using iodised salt before it was mandatory, there is no evidence of any previous use of iodised salt in bread or bread mixes. There is some reported use of iodised salt voluntarily in other baked goods, averaging around 4% of total baked volume.

It is concluded that in Australia the dietary intake of iodine from the mandatory use of iodised salt in bread has increased by between 300 and 455 kg iodine per annum. The FSANZ projected dietary intake from mandatory use of iodised salt in bread, at an assumed average input of 45ppm was 343-397 kg iodine per annum in Australia¹⁴. This is within the range obtained in this review.

Salt manufacturers

In **New Zealand** currently 2,800 tonnes of iodised salt is sold wholesale to the food industry, including for bread, and a similar amount (2,800 tonnes) into other food service and retail. At the stated salt manufacturer's fortification target content of 40 mg/kg (ppm), this equates to a total for the food supply of 220 kg per annum of iodine.

Previously, New Zealand had a significant proportion of iodised table salt compared to Australia: about 2,630 tonnes of iodised salt was sold, representing about 105 kg per annum of iodine. Thus the dietary intake of iodine in New Zealand has increased by about 115 kg per annum.

Bakers

In New Zealand, and as a validation of the information from the salt manufacturers, the dietary intake of iodine was calculated based on information from the users of iodised salt, namely the bakers. For the baking industry, advice was given that 288,549 tonnes of bread and related products such as muffins, are

¹³ Retail World Annual Report 2014 which can be located at <http://www.retailmedia.com.au/our-magazines/annual-report/>

¹⁴ FSANZ FINAL ASSESSMENT REPORT October 2006 PROPOSAL P230 Consideration of mandatory fortification with iodine Attachment 8

produced annually. Where records are available, only one respondent reported previously using iodised salt in bread or bread mixes. This usage is estimated to be 16.5% of total products.

Given that bread has a 1% salt content it is estimated that 1 tonne bread contains 400 mg iodine. From the information provided to this review of the current production of 288,549 tonnes bread in New Zealand, it is estimated that 115 kg iodine is by dietary intake from bread. This figure agrees with the figure above, estimated from the salt manufacturer. (Note, there is some reported use of iodised salt voluntarily in other baked goods, except in pastries. However, no quantitative data is available and this has not been modelled here). The information is summarised in Table 8

Table 8 Increase of dietary intake of iodine from iodised salt in New Zealand

Organisation	Tonnes per annum*	Iodine kg @40 mg/kg (ppm)*
Information from salt manufacturers		
In 2014 tonnage iodised salt in New Zealand by salt manufacturers	5,600	220 kg
Iodised salt manufactured in New Zealand before mandatory fortification	2,630	105 kg
Increase due to mandatory fortification	Not specified	115 kg
Information from bakers		
	Tonnes	Iodine kg @1% salt content
In 2014 tonnage bread with iodised salt	288,549	115 kg

* The standard requires iodised salt to contain 25 – 65 mg/kg of iodine. In New Zealand it is added at 40 mg/kg (ppm).

It is concluded that in New Zealand the dietary intake of iodine from the mandatory use of iodised salt in bread has increased by about 115 kg per annum. The FSANZ estimated additional dietary iodine, based on an assumed input of 45 mg/kg (ppm), from the mandatory use of iodised salt in bread was 88 kg iodine in New Zealand¹⁵. The 2014 calculated level of iodine in New Zealand from bread, 115 kg, agrees reasonably with this projected figure.

3.3 Other matters

The following three issues were consistently raised by industry respondents during the interviews and are reported here for completeness of the review. A response to these issues is beyond the scope of this review.

3.3.1 Accuracy of testing

Analytical protocols need to be investigated to ensure any testing is meaningful. There is a need to appreciate the statistical reality of normal "error" in any activity when setting standards. Concern was expressed about the challenge of reliably meeting the prescribed specification of the milled flour versus the fluctuations in folate content of the finished product. Folate degrades over time – the fact that it is added to bread-making flour at the prescribed level is no guarantee that it is present in the final product at the prescribed level. Variability is due to:

- instability of folic acid in flour and in bread;
- adjustments during manufacturing to water and minor ingredients due to natural variability between batches; and
- laboratory and testing method variability.

3.3.2 Legal liability

Concerns were expressed over the company's exposure to potential liability in the event of a public health problem emerging due to fortification.

¹⁵ FSANZ FINAL ASSESSMENT REPORT October 2006 PROPOSAL P230 Consideration of mandatory fortification with iodine

3.3.3 Effectiveness of fortification

It was the view of a number of respondents that Government should undertake regular surveys to determine effectiveness of fortification, and the appropriate food vehicle to achieve health outcomes.

Research in the UK published this year¹⁶ indicated that folic acid is significantly less bioavailable than natural folate and that the long term effects of folic acid are not known.

It was noted that salt intake from bread has materially declined over the past decade due to:

- almost 50% salt content reduction in bread, and
- bread intake declining from almost four slices/day to two slices/day across the population.

Companies noted that modelling the appropriate level is an important issue and questioned whether there would be a need for higher levels of iodine in salt, to ensure that adequate levels of iodine are being delivered to the population.

¹⁶ The American Journal of Clinical Nutrition 100: 593-9. 2014. Folic acid handling by the human gut: implications for food fortification and supplementation. I Patanwala et al.

4 Conclusions

On the basis of the information provided by 33 companies/agencies in Australia and New Zealand it is concluded that the programs for mandatory fortification of folic acid in wheat flour and iodine in bread have been implemented as intended. The following are noted in support of this conclusion:

1. For both folic acid and iodine, the manufacturers who are tasked with the fortification have systems and documentation to ensure that they comply with the Standard, and are able to demonstrate the same under audit.

This was the conclusion reached for folic acid in the “Implementation Sub Committee Co-ordinated Food Survey Plan (April 2012) National mandatory folic acid fortification of wheat flour for making bread compliance survey of flour mills producing wheat flour for making bread in October 2010-March 2011” and this conclusion remains valid.

Bakers of bread in both countries are aware of their responsibilities under the Standard and have systems and documentation to ensure that they comply with the Standard for both folic acid and iodine, and are able to demonstrate their compliance at audit.

2. The enforcement agencies at state and territory level have systems in place for compliance and enforcement of the Standard. However, there was no evidence of ongoing interaction between enforcement agencies and relevant industry groups. A number of respondents advised that this was because there was confidence in the industry’s self-management systems and for a number of appropriate reasons, compliance and enforcement agencies have not seen a need to be actively working with industry groups. The disadvantage to this position is that in the absence of interaction any examples of non-compliance and/or system failure will be picked up in an audit but it may take a while for states and territories to be notified. In New Zealand MPI is notified of absent or ineffective critical control points by third parties. Some jurisdictions also have proactive programs intended to prioritise and address compliance risks. Such programs would periodically result in review of fortification compliance.
3. Compliance with the Standard has meant costs were incurred by industry. Manufacturing companies in particular identified some significant set up costs, particularly for millers fortifying with folic acid. However, these costs were significantly less than the costs that were projected in the 2006 and 2007 economic analyses that preceded the implementation of the Standard.
4. The intended outcome of the program is for an increase, from mandatory sources, of dietary intake of folic acid in the population of Australia and iodine in the populations of Australia and New Zealand.

For folic acid, it is clear that the dietary intake from mandatory sources increased between 2.48-2.68 tonnes per annum folic acid. This commenced within a short period in late 2009. This is in alignment with the FSANZ projected increase in folic acid from dietary sources as a result of mandatory fortification of 2.62 tonnes per annum.

In Australia, the use of iodised salt for bread was negligible before the Standard was implemented. On the basis of the information from Australian salt manufacturers, it was estimated that around 13,000 tonnes iodised salt equating to about 700kg iodine is added to food per annum. Taking into account the substantial portion of iodised salt that does **not** go into bread (about 4,500 tonnes salt and 245 kg iodine per annum) it is estimated that about 455 kg iodine per annum is being delivered through bread.

However, from the baked goods data, it was estimated that 300 kg iodine is added to bread. It is concluded that in Australia the dietary intake of iodine from the mandatory use of iodised salt in bread has increased by between 300 and 455 kg iodine per annum. The FSANZ projected dietary

increase from mandatory use of iodised salt in bread was 343-397 kg iodine per annum in Australia¹⁷. This is within the range obtained in this review.

In New Zealand, the use of iodised salt previously by dietary intake was significant at around 65% of total salt produced. However, bakers all now use iodised salt, and it is concluded that in New Zealand the dietary intake of iodine in the food supply from the mandatory use of iodised salt in bread has increased by about 115 kg per annum. The FSANZ projected additional dietary iodine through mandatory use of iodised salt in bread was 88kg iodine in New Zealand. The actual level of iodine in New Zealand agrees reasonably with this figure.

5. Despite the overall successful implementation of the program, companies expressed a number of concerns about accuracy of testing, legal liability and effectiveness of fortification.

¹⁷ FSANZ FINAL ASSESSMENT REPORT October 2006 PROPOSAL P230 Consideration of mandatory fortification with iodine Attachment 8

5 Appendix

5.1 Folic acid

5.1.1 Collated responses from millers

Table 9 Folic acid fortification of flour used for making bread – Millers

Has the level of folic acid in the food supply increased from mandatory sources?

Numbered survey questions	Collated response
1a How much flour for human consumption do you produce per year on average? (tonnes)	In total, they mill 1.44 million tonnes of flour for the food industry. Three smaller millers also contributed with their combined output of 80,000 tonnes.
1b What proportion of this flour is now fortified with folic acid?	Per individual miller, the proportion of flour for the food industry that is fortified ranges from 60% to 88%. For the total milled product the total volume fortified is 950,000t or 66%. A relatively higher proportion of flour from the three smaller millers is produced for end-users such as bakers, where fortification is required.
2 How much folic acid is now being added to fortified flour you produce? (kg 'pure' folic acid, not premix)	For each respondent, 2 - 3mg folic acid is added per 1kg of flour, as mandated. This is equivalent to a total of 1.9t to 2.85t folic acid total per annum.
3 Before mandatory fortification with folic acid was prescribed, how much was being added to flour you produced (use the same quantification measures)?	Only one miller had previously added folic acid to some of its product, although this product was for export. Thus for Australia the answer is zero.
4 What month and year did you commence adding folic acid to wheat flour?	The bulk of Australian bread flour (i.e. from the three large millers) was fortified according to the new requirement from August, September and October 2009. The smaller millers commenced fortification in June and August 2009 and in March 2010.

Are all relevant industry groups aware of the relevant regulations?

Numbered survey questions	Collated response
5 Who in your company needs to be aware of the mandatory folic acid fortification requirement for flour used in making bread? (Standard 2.1.1)	In every milling business, the manager in charge of QA was responsible for ensuring compliance with the fortification requirements. The smaller millers all noted that the CEO/General Manager or Managing Director held ultimate responsibility for ensuring the business complies with all regulatory

Numbered survey questions	Collated response
	requirements. The larger millers had larger teams of people involved, including compliance staff and production staff, often across a number of locations. One company also noted that its sales staff were kept informed of folic acid fortification.
6 How do you ensure the relevant people are/continue to be made aware of the requirement?	The millers typically identified the role of QA documentation and systems, operating procedures, and training and updating of key staff. In some cases a follow-up question was posed: "what would it take for folic acid fortification to be inadvertently dropped out of the production requirements?" This again pointed back to the control systems in place, including the requirement for several layers of managers to sign off on any change in a Bill of Materials.

Is the food industry complying with the mandatory fortification standards?

Numbered survey questions	Collated response
7 Please describe your company's plan and processes to meet the requirements for mandatory folic acid fortification of flour used for making bread.	Every miller highlighted the central role of a robust QA program. This is necessary in order to satisfy customers that every aspect of product safety and quality is being managed, not only folic acid fortification. In some responses, great detail was provided about the production systems used to manage the challenging requirement to add a very small proportion of folic acid to bread flour and ensure that it is evenly blended. This relates also to issues of verification (Q8) and the capital/testing costs of compliance. (Q9)
8 How does your company verify meeting the Standard? For instance, measure use of folic acid per shift and/or laboratory testing.	Verification is managed through a combination of production engineering practices, (e.g. auto-feeders, variance alarms); auditing practices (e.g. per-shift, per-day, per-month reconciliations of quantity used); and testing protocols (e.g. lab testing, mostly on a quarterly basis). Note later comments regarding concerns expressed about the accuracy/reproducibility of the lab tests employed.
9 Is your company subject to external auditing that includes folic acid fortification in its scope? (This might be by a quality systems audit for ISO 9000 or a supermarket, or by a government representative.)	In every case, the millers are subject to extensive external auditing procedures in order to satisfy customer requirements. Generally, every major customer will have its own specific food safety and quality system, generally falling within a HACCP and/or ISO9001 framework. This covers all aspects of the product and folic acid automatically falls within these checks when it becomes part of the product ingredients.

What have been the cost impacts on the food industry in complying with the mandatory fortification standards?

Numbered survey questions	Collated response
<p>10 When mandatory fortification of flour for making bread with folic acid commenced, what were the initial costs to your company to comply? Please estimate and itemise total costs. (These are likely to have been capital (e.g. new or improved vitamin premix system); modifying operating and QA systems and documents; and initial verification, for example laboratory testing.)</p>	<p>Each of the respondents was able to give a more or less precise breakdown of the initial costs of implementing fortification. As anticipated, these costs included: engineering design; capital equipment and installation, including IT costs; analysis and verification testing; training and documentation, including QA systems; packaging redesign and wastage.</p> <p>A simple analysis was performed for purposes of comparison only. This was based on the cost data provided which excludes financing, loan administration and similar. It allocates the initial costs to the production throughput over three years, assuming stated capacity remains stable over that period.</p> <p>One large mill is excluded from the analysis because it was already set up to produce fortified flour and so had minimal establishment costs – only some extra testing costs to ensure compliance.</p> <p>For the other mills, as may be expected, the impact of establishment costs generally (not linearly) reflected the scale of operations. In order of production, from the largest the smallest miller, the cost per tonne over three years was 29c, 58c, 59c, 74c and \$1.90.</p> <p>It should be noted that one miller declined to participate, stating that the capital cost attached to undertaking fortification had been a major factor in their imminent announcement of closure of their mill.</p>
<p>11 Following the establishment of the new systems above, please identify the direct ongoing costs associated with folic acid fortification. Please estimate and itemise, and report as cost per tonne of flour. (These might include the cost of vitamin premix, specific equipment maintenance, and. specific QA requirements.)</p>	<p>The estimates from two large and two smaller millers were around \$1/tonne (93c, \$1, \$1.40 and 90c). These responses contain a detailed breakdown by ingredients, testing and verification and QA resources. The two other mills responding had estimates very significantly higher than the other four.</p>
<p>12a Did the establishment of the new systems above result in manufacturing inefficiencies?</p>	<p>50% of respondents said that manufacturing inefficiencies resulted from the new systems established to enable fortification. The other 50% said they did not.</p>
<p>12b If so please specify, and identify any subsequent action taken.</p>	<p>The respondents who reported manufacturing inefficiencies provided a range of causes. These included the need to allocate specific storage silos for fortified and unfortified flour (e.g. where overseas customers specify non-fortified),</p>

Numbered survey questions	Collated response
	requirement for additional product codes, with attendant administrative load, double-handling due to the need to manufacture a pre-mix in order to enable effective final blending.
13 Did the establishment of the new systems above result in new manufacturing opportunities or advantages, such as better blending, better records, or potential to manufacture new products? If so please specify.	No identifiable benefits were reported to have arisen from mandatory fortification, apart from two respondents noting that an improvement in monitoring and record-keeping had occurred.

Other Comments

Accuracy of testing

Concerned about very precise range regulated for fortification at time of milling, given the nine-month shelf-life of flour and the reported instability of folic acid in flour and in bread. Reiterating the challenge of reliably meeting the prescribed spec. Need to appreciate the statistical reality of normal "error" in any activity when setting standards. Folate degrades over time – the fact that it is added to bread-making flour at the prescribed level is no guarantee that it is present in the final product at the prescribed level. Folate degrades quicker in some flours than others (e.g wholegrain versus white).

Legal liability

Concerns over the company's exposure to potential liability in the event of a public health problem emerging due to fortification.

Ethics of population based medication

Government should undertake regular surveys to determine effectiveness of fortification to achieve health outcomes. Key concern around the science that supports medicating 23 million people on a daily basis with a substance where the long-term effects are unknown. Using bread as the method of delivery of the medication given that the link between reducing NTD and folate in bread is not adequately established.

Consumer views

Very little negative feedback from consumers to compulsory fortification, but some turning to organics.

5.1.2 Collated response from bakers

Table 10 Folic Acid Fortification of Flour used for Making Bread – Wholesale supplier of packaged baked goods or bread mixes

Has the level of folic acid in the food supply increased from mandatory sources?

Numbered survey questions	Collated response
1 What is the average yearly quantity of bread or bread mix that you sell, and what proportion (ideally on a weight basis) use flour fortified with folic acid?	Between them the reporting companies produce 520,000 tonnes of bread. 0.6% does NOT contain folic acid. These products are either organic or gluten free.
2 Before mandatory folic acid fortification, what proportion of these products contained it voluntarily?	One company (producing about 11% of reported bread tonnage) commenced using folic acid fortified flour voluntarily in all their products in mid-2005. Apart from this there is no reported voluntary fortification.
3 How much other products do you make (e.g. pizza bases, crumpets) that now also contain folic acid voluntarily due to the use of fortified flour?	Extrapolating based on reported results, we estimate that an additional 4% (20,000 tonnes) of products such as pikelets and crumpets are also fortified.

Are all relevant industry groups aware of the relevant regulations?

Numbered survey questions	Collated response
4 Who in your company needs to be aware of the mandatory folic acid fortification requirement for flour used in making bread? (Standard 2.1.1)	While companies identified a number of functions needing to be aware of the Standard, most identified the control through purchasing specifications and formulations. Roles specifically identified included procurement, product development, QA, legal services, regulatory affairs and nutritionists. In general, the larger companies had more roles that needed to be aware of the changes compared to smaller companies with less specialisation.
5 How do you ensure the relevant people are/continue to be made aware of the requirement?	In all responses the requirement was integrated into the companies' procedures, such one or more of the following: QA system, staff training, any changes of bill of materials have to be authorised by senior manager, any legal requirement is captured in the documentation.

Is the food industry complying with the mandatory fortification standards?

Numbered survey questions	Collated response
6 Please describe your company's plan and processes to meet the mandatory folic acid fortification of flour used for making bread.	All companies reported a quality management system which specifies requirements for the flour. Supplier has contractual requirements for flour to meet specification. A certificate of analysis is required by some companies, others test folic acid level in product also. Typically any

Numbered survey questions	Collated response
	formulation or supplier changes have to be signed off. In some companies all suppliers are audited.
7 How does your company verify meeting the Standard? For instance, raw material control, only purchasing fortified flour or pre-mixes, or testing your final product.	Most companies rely on purchase specifications and manufacturing QA systems. One major baker routinely tests their final product for verification.
8 Is your company subject to external auditing that includes folic acid fortification in its scope? (This might be by a quality systems audit for ISO 9000 or a supermarket, or by a government representative).	Manufacturers supplying product to supermarkets reported being subject to external auditing. The other respondents are not subject to external auditing.

What have been the cost impacts on the food industry in complying with the mandatory fortification standards?

Numbered survey questions	Collated response
9 When mandatory fortification of flour for making bread with folic acid commenced, what were the initial costs to your company to comply? Please estimate and itemise total costs. (These may have included capital (e.g. additional flour storage) and modifying operating and QA systems and documents. The lead-in period was intended to allow no product or packaging write-offs or immediate need for new packaging).	There was a wide range of responses to this question. The two main costs, where they were incurred were packaging and changes to documentation. Most respondents said that they managed these costs within their usual business practices. Where this was not done, reported costs were in the range \$1500-\$5000 per SKU for label changes, plus administrative costs in formulation and specification update. Total labelling-related costs reported ranged from \$2.7 million down to \$300,000 and \$25,000.
10 Following the establishment of the new systems above, please identify the direct ongoing costs associated with folic acid fortification. Please estimate and itemise, and report as cost per tonne of bread or bread mix.	Most of the companies identified no ongoing cost apart from the extra cost of folic acid in the flour, estimated by one respondent as 50c/tonne of flour. One company pays \$82,500 annually for testing in finished products.
11a Did the establishment of the new systems above result in manufacturing inefficiencies?	No.
11b If so please specify, and identify any subsequent action taken.	Not applicable.
12 Did the establishment of the new plant or systems above result in new manufacturing opportunities or advantages, such as potential to manufacture new products? If so please specify.	No.

Other Comments

Accuracy of levels

Fluctuations in folate content of the finished product are inevitable due to: folate stability varies with flour type (white vs wholemeal vs wholegrain); adjustments during manufacturing to water and minor ingredients due to natural variability between batches; bagged flour vs direct from silo; laboratory and testing method variability; humidity and temperature also effect the rate of proving.

Effectiveness of folic acid

Has folic acid reduced the incidence of NTDs? Is bread the right vehicle? Should it be folate or folic acid? Which is the most bioavailable and stable? These are questions that the company call centre gets regularly. Research in the UK and published this year indicated that folic acid is significantly less bioavailable than natural folate and that the long term effects of folic acid are not known.

Legal liability

Concerns over company exposure to liability in the event of a public health problem emerging due to fortification.

5.1.3 Collated response from compliance and enforcement

Table 11 Folic Acid Fortification of Flour used for Making Bread

Have sufficient enforcement strategies been implemented and what are the impacts on enforcement agencies in ensuring industry compliance?

Numbered survey questions	Collated response with respect to millers	Collated response with respect to bakers
<p>1 Does your agency (or state or territory) have an ongoing monitoring or compliance strategy for millers/ for bakers or bread mix manufacturers with respect to folic acid fortification of flour for making bread? If so, please describe.</p>	<p>One territory does not have any millers and thus has not been included in this response. No other state or territory has an active ongoing monitoring and compliance strategy for folic acid in wheat flour. In 6 jurisdictions, Health has administrative responsibility for the Food Standards Code, but local government councils are the primary enforcement agency, and include flour millers as part of their food industry compliance programs. Some jurisdictions also have proactive programs intended to prioritise and address compliance risks. Such programs would periodically result in review of fortification compliance.</p>	<p>One territory does not have any wholesale suppliers and thus has not been included in this response. No other state or territory currently has an active ongoing monitoring and compliance strategy for folic acid in bread made from wheat flour. One state proposes to have ongoing surveillance. Where monitoring and compliance occur by the councils/local government agencies there is generally no specific requirement on such agencies to inform the state or territory agency. Some jurisdictions also have proactive programs intended to prioritise and address compliance risks. Such programs would periodically result in review of fortification compliance.</p>
<p>2 How many folate compliance investigations have been carried out in the past three years (by year)?</p>	<p>Nil reactive or proactive action.</p>	<p>Nil reactive or proactive action.</p>
<p>3 If there have not been any, please provide the reason.</p>	<p>The 2010 survey revealed good systems and processes, and internal audit system at the flour mill, which provided confidence that mills were complying. As a result resources have been put into higher priority risk management activities. No complaints have been received. Proactive work for 2014/2015 is being planned in one state.</p>	<p>The 2010 survey revealed good systems and processes, and internal audit system at the flour mill, which provided confidence that mills were complying. As a result resources have been put into higher priority risk management activities. No complaints have been received.</p>
<p>4 How many of these investigations resulted in Enforcement Actions? (by year)</p>	<p>Not applicable.</p>	<p>Not applicable.</p>

Numbered survey questions	Collated response with respect to millers	Collated response with respect to bakers
<p>5 The strategy presumably has a cost associated with it. What is the estimated annual cost, and how is this justified?</p>	<p>No state or territory had budgeted for specific compliance and monitoring activities for folic acid. One state estimated that it would cost between \$350 and \$600 per inspection, and this was not justified when there is no evidence of non-conformance.</p>	<p>Specific funding is not allocated, which is appropriate because a specific compliance program would incur significant costs and there is no evidence of non-conformance from local government or other sources.</p>

Has enforcement action been taken where non-compliance has been identified?

Numbered survey questions	Collated response with respect to millers	Collated response with respect to bakers
<p>6a What is the policy and strategy with respect to non-compliance?</p>	<p>The Food Standards Code is enforced by local government agencies which may notify the state or territory authority of any non-compliance In general all states/territory indicated that they would take a case-by-case approach, to investigate the cause and level of non-compliance in conjunction with the miller and proportional regulatory action taken depending upon findings of investigation.</p>	<p>The Food Standards Code is enforced by local government agencies which may notify the state or territory authority of any non-compliance. In general all states/territories indicated that they would take a case-by-case approach, to investigate the cause and level of non-compliance in conjunction with the miller and proportional regulatory action taken depending upon findings of investigation.</p>
<p>6b If non-compliance is identified or reported, what is the protocol?</p>	<p>Investigation, initially through audit. Samples may be taken. Allowance is made for the 'measurement uncertainty' inherent in any method of analysis. Non-compliance is addressed through escalated application of enforcement tools. Generally this will involve discussions at first instance. Continued non-compliance leads to statutory notices and eventually prosecution.</p>	<p>Investigation, initially through audit. Samples may be taken. Allowance is made for the 'measurement uncertainty' inherent in any method of analysis. Non-compliance is addressed through escalated application of enforcement tools. Generally this will involve discussions at first instance. Continued non-compliance leads to statutory notices and eventually prosecution.</p>

Numbered survey questions	Collated response with respect to millers	Collated response with respect to bakers
7a Has enforcement action been taken with respect to mandatory folic acid fortification of wheat flour for making bread since implementation?	No.	No.
7b If it has been, how was the enforcement action's effectiveness verified?	Not applicable.	Not applicable.
8 Please enumerate the type and level of these enforcement actions (by year).	None.	None.

Are enforcement agencies working with relevant industry groups to enable and ensure compliance?

Numbered survey questions	Collated response with respect to millers	Collated response with respect to bakers
9a In your jurisdiction, does a government agency have an ongoing program of working with the milling/baking industry with respect to mandatory folic acid fortification?	In general no ongoing program at state and territory level, although these authorities would become involved if needed. Local government involvement on an individual basis.	In general no ongoing program at state and territory level, although these authorities would become involved if needed. Local government involvement on an individual basis.

Numbered survey questions	Collated response with respect to millers	Collated response with respect to bakers
<p>9b If so, describe the scope of the program, including the parties involved (e.g. individual businesses or peak bodies), its objective, and its activities.</p>	<p>In one state where a new mill opened, the council was conducting analyses of bread making flour within the next 6 months. Other councils had engaged with millers to provide information when the new Standard was first implemented.</p>	<p>Not applicable.</p>

Other Comments

Collated response with respect to millers

Flour is a commodity product that is distributed nationally and therefore monitoring of industry compliance is ideally addressed nationally in a coordinated approach. There is general confidence in the mills' QA programs.

Collated response with respect to bakers

The compliance focus is at the flour mill level.

5.2 Iodine

5.2.1 Collated Response from Salt Manufacturers

Table 12 Iodine Fortification of Salt used for Making Bread

Has the level of iodine in the food supply increased from mandatory sources?

Numbered survey questions	Collated response for Australia and New Zealand
1 How much iodine is now being added to salt you produce for human consumption, in a gross sense? i.e. quantity of salt made per year, proportion of iodised salt, and quantity of iodine used per year.	Overall: In NZ 2,800 tonnes of iodised salt sold wholesale to the food industry annually, including for bread, and about a similar amount into other food service and retail, i.e. total 5600 tonnes iodised salt. The target content is 40 ppm iodine. Total iodine addition is 220 kg pa. In Australia the largest manufacturer produces about 13,000 tonnes of iodised salt per year, which uses around 700 kg pa iodine. It is not clear what proportion of this salt goes into bread. For the other major salt manufacturer, the bread manufacturing industry is not a significant customer.
2 Before mandatory use of iodised salt for making bread was prescribed, how much iodine was being added to salt you produced (same measures)?	In NZ before the mandatory use about 30 tonnes of iodised salt was sold to the wholesale food market and 2600 tonnes was sold into retail and food service, a total of around 115 kg iodine. In Australia the largest salt manufacturer produced no iodised salt. The other major salt manufacturer produced about 23%, but the bread manufacturing industry is not a significant customer.
3 Before mandatory fortification, what proportion of retail salt products contained iodine? Has this changed following mandatory fortification?	In NZ there appears to be a slight increase in the proportion of table salt that is iodised (from 65-70% up to 75%) In Australia no change was reported.

Are all relevant industry groups aware of the relevant regulations?

Numbered survey questions	Collated response for Australia and New Zealand
4 Who in your company needs to be aware of the mandatory iodised salt requirement for bread?	Companies identified a similar range of positions: operational and plant managers, QA staff and sales teams.
5 How do you ensure the relevant people are/continue to be made aware of the requirement?	The NZ manufacturer has only one grade of salt for bread (i.e. specification control). In Australia the manufacturers have systems to ensure specifications meet the FSANZ Standard.

Is the food industry complying with the mandatory fortification standards?

Numbered survey questions	Collated response for Australia and New Zealand
6 Please describe your company's plan and processes to meet the mandatory Standard for iodised salt.	In both countries iodine is delivered automatically according to customer and regulatory standards.
7 How does your company verify meeting the Standard? For instance, measure use of iodine per shift and/or laboratory testing.	Salt addition is automated and only changeable by the Quality Manager. Salt addition equipment is routinely calibrated, and product testing is also used.
8 Is your company subject to external auditing that includes iodine fortification in its scope? (This might be by a quality systems audit for ISO 9000 or a supermarket, or by a government representative.)	All the companies are audited to external standards by third parties, and iodine fortification is within this auditing.

What have been the cost impacts on the food industry in complying with the mandatory fortification standards for iodine?

Numbered survey questions	Collated response for Australia and New Zealand
9 When mandatory iodisation of salt for making bread commenced, what were the initial costs to your company to comply? Please estimate and itemise total costs. (These may have been capital (e.g. new or improved iodine dosing system); modifying QA systems and documents; and initial verification, for example laboratory testing.)	Costs varied company by company depending on their existing manufacturing systems. For example one manufacturer spent \$630,000 for iodising and testing equipment, another spent around \$36,000 to upgrade the existing iodine fortification systems, the other did not need additional equipment. All companies reported modifying systems but generally regarded these as usual business costs.
10 Following the establishment of any new systems above, please identify the direct ongoing costs associated with iodine fortification. Please estimate and itemise, and report as cost per tonne of iodised salt. (These might include the cost of iodine (perhaps as a diluted premix), specific equipment maintenance, and specific QA requirements.)	Identified costs included cost of iodine, additional labour, premixing costs, analytical costs, and in one case slower bagging. We received three different estimates of the additional costs/tonne: \$4, 19 and 45.
11a Did the new requirement result in manufacturing inefficiencies?	In some cases.
11b If so please specify, and identify any subsequent action taken.	For the companies concerned, their existing dosing systems did not deliver uniformity, particularly where the salt was a large particle size. In both cases the additional mixing stage and equipment introduces some inefficiencies. At start up one company identified that new dosing systems were required to achieve consistency of iodine within the salt. Ongoing premixing and bagging require additional time and thus indirect costs. These have been absorbed by the company.
12 Did the establishment of the new systems, if any, result in new manufacturing opportunities or advantages, such as potential to manufacture new products?	One company identified that the new iodate dosing systems improved consistency for all products; resulting in export potential for products with a tighter specification on iodine levels which may have been unachievable

Numbered survey questions	Collated response for Australia and New Zealand
If so please specify.	with old system.
Other Comments	Nil.

5.2.2 Collated response from bakers

Table 13 Iodine Fortification of Salt used for Making Bread

Has the level of iodine in the food supply increased from mandatory sources?

Numbered survey questions	Collated Response Australia	Collated response New Zealand
1 What proportion of bread or bread mix that you sell (ideally on a weight basis) use iodised salt?	>550,000 tonnes sold, All respondents reported 100% use of iodised salt, except for one manufacturer and retail seller of bread mixes advised that a proportion of their product is not iodised.	288,549 tonnes bread products and identified. All manufacturers reported 100% use of iodised salt in bread and mixes.
2 Before the mandatory use of iodised salt in bread, what proportion of these products contained iodised salt voluntarily?	Apart from a few bread bakers voluntarily using iodised salt before it was mandatory, there is no evidence of any use of iodised salt in bread or bread mixes.	Where records are available, only one respondent reported using iodised salt in bread or bread mixes. We estimate this to be 16.5% of total products. Note that there is a proportion of products for which the information is not available.
3 What proportion of baked products, not required to contain iodised salt, now contain iodised salt voluntarily compared to before the fortification requirement?	There is some reported use of iodised salt voluntarily in other baked goods, averaging around 4% of total baked volume.	There is some reported use of iodised salt voluntarily in other baked goods, except pastries. No quantitative data.

Are all relevant industry groups aware of the relevant regulations?

Numbered survey questions	Collated Response Australia	Collated response New Zealand
4 Who in your company needs to be aware of the mandatory iodised salt requirement for bread? (Standard 2.1.1)	While companies identified a number and range of functions needing to be aware of the Standard, most identified the control through purchasing specifications and formulations. Roles specifically identified procurement, product development, QA, legal services, regulatory affairs and nutritionists. In general, and as might be expected, the larger companies had more roles that needed to be aware of the changes compared to smaller companies with less specialisation.	While companies identified a number of functions needing to be aware of the Standard, most identified the control through purchasing specifications and formulations. Roles specifically identified procurement, product development, QA, legal services, regulatory affairs and nutritionists. In general, and as might be expected, the larger companies had more roles that needed to be aware of the changes compared to smaller companies with less specialisation.
5 How do you ensure the relevant people	In all responses the requirement was integrated	In all responses the requirement was integrated

Numbered survey questions	Collated Response Australia	Collated response New Zealand
are/continue to be made aware of the requirement?	into the companies' procedures, such one or more of the following: QA system, staff training, any changes to bill of materials has to be authorised by senior manager, any legal requirement is captured in the documentation.	into the companies' procedures, such one or more of the following: QA system, staff training, any changes to bill of materials has to be authorised by senior manager, any legal requirement is captured in the documentation.

Is the food industry complying with the mandatory fortification standards?

Numbered survey questions	Collated Response Australia	Collated response New Zealand
6 Please describe your company's plan and processes to meet the mandatory requirement to use iodised salt when making bread.	All companies reported a quality management system which specifies requirements for the salt. Supplier has contractual requirements for product to meet specification. A certificate of analysis is required by some companies, others test iodine level in product as well. Typically any formulation or supplier changes have to be signed off. In some companies all suppliers are audited.	All companies reported a quality management system which specifies requirements for the salt. Supplier has contractual requirements for product to meet specification. A certificate of analysis is required by some companies, others test iodine level in product as well. Typically any formulation or supplier changes have to be signed off. In some companies all suppliers are audited.
7 How does your company verify meeting the Standard? For instance, raw material control, only purchasing iodised salt, or testing bread or bread mixes.	Most companies rely on purchase specifications and manufacturing QA systems. One company noted that analysis of the iodine content of the salt and their bread produced inconsistent results.	Most companies rely on purchase specifications and manufacturing QA systems.
8 Is your company subject to external auditing that includes the iodised salt requirement in its scope? (This might be by a quality systems audit for ISO 9000 or a supermarket, or by a government representative.)	Manufacturers supplying product to supermarkets reported being subject to external auditing. The supermarkets use internal auditing for products made in-store. Smaller companies did not appear to have third party auditing compared to the larger companies.	Manufacturers supplying product to supermarkets reported being subject to external auditing. The supermarkets use internal auditing for products made in-store. Smaller companies did not appear to have third party auditing compared to the larger companies.

What have been the cost impacts on the food industry in complying with the mandatory fortification standards for iodine?

Numbered survey questions	Collated Response Australia	Collated response New Zealand
<p>9 When mandatory iodisation of salt for making bread commenced, what were the initial costs to your company to comply? Please estimate and itemise total costs. (These may have included capital (e.g. additional salt storage) and modifying operating and QA systems and documents. The lead-in period was intended to allow no product or packaging write-offs or immediate need for new packaging.)</p>	<p>Not all companies had access to records from that time. For those that did, the main cost was reprinting packaging and updating documentation simultaneously for the use of iodised salt and folic acid fortified flour. Costs were very variable, but were in the range \$1500-\$5000 per SKU for label changes, plus administrative costs in formulation and specification update. Total labelling-related costs reported ranged from \$2.7 million down to \$25,000 depending upon the size and complexity of the company.</p>	<p>Where companies incurred specific costs they were for reprinting and writing off packaging, and updating documentation. Costs were very variable, with only one respondent reporting large costs (\$5000 per SKU for label changes, plus administrative costs in formulation and specification update, resulting in a total cost of around \$300,000).</p>
<p>10 Following the establishment of any new systems above, please identify the direct ongoing costs associated with the use of iodised salt. Please estimate and itemise, and report as cost per tonne of finished product.</p>	<p>None other than small additional cost of iodised salt. This will vary between companies, with the additional cost reported as 19c, 25c and 60c/tonne of finished product.</p>	<p>None other than small additional cost of iodised salt, estimated to be 45c per tonne of bread.</p>
<p>11a Did the new requirement result in manufacturing inefficiencies?</p>	<p>No.</p>	<p>No manufacturing inefficiencies were noted, but one company identified that it constrained how product was able to be marketed, since the label "all natural" cannot be used.</p>
<p>11b If so please specify, and identify any subsequent action taken.</p>	<p>Not applicable.</p>	<p>Not applicable.</p>
<p>12 Did the establishment of the new systems, if any, result in new manufacturing opportunities or advantages, such as potential to manufacture new products? If so please specify.</p>	<p>No.</p>	<p>No.</p>

Other Comments

Some common issues were raised trans-Tasman.

Testing accuracy

Concern about inaccuracy in testing results, and what this means for the program.
Analytical protocols need to be investigated to ensure any testing is meaningful.

Legal liability

Concerns over the company's exposure to potential liability in the event of a public health problem emerging due to fortification.

Very little negative feedback reported from consumers, although some consumers desire products to be "e-free", and additives are not reported this way in Australia (see below).

Salt reduction in bread has been material. Note that over past decade salt addition to bread has roughly halved. Similarly bread intake has declined almost four slices/day to two slices/day across the population.

There could be a need for higher levels of iodine in salt, to ensure that adequate levels of iodine are being delivered to the population. Modelling the appropriate level is an important issue. Government should undertake regular surveys to determine effectiveness of fortification to achieve health outcomes

e-numbers

Ambiguity regarding e-numbers. Iodine has an e-number in Europe but not in Australia, where it is reported as "iodine". This causes communication difficulties for manufacturers and for consumers seeking "e-free" foodstuffs (who find this confusing and potentially misleading).

5.2.3 Collated response from compliance and enforcement for salt manufacturers

Table 14 Iodine Fortification of Salt used for Making Bread

Have sufficient enforcement strategies been implemented?

Numbered survey questions	Collated response Australia	Collated response NZ
1 Does your agency (or state or territory) have an ongoing monitoring or compliance strategy for salt manufacturers with respect to iodised salt? If so, please describe.	No specific enforcement strategies are in place, but where iodised salt is manufactured or imported it is within the scope of the overall compliance regime. All state and territory agencies take part in coordinated national coordinated surveys. . Some jurisdictions also have proactive programs intended to prioritise and address compliance risks. Such programs would periodically result in review of fortification compliance. Note that three states/territories do not have any salt manufacturers.	No specific active monitoring and compliance strategies are in place. Salt manufacturers are required to have a FSP in place, which is audited by a third party annually.
2 How many Iodine compliance investigations have been carried out in the past three years (by year)?	None.	Nil.
3 If there have not been any, please provide the reason.	No perceived need for specific scrutiny: available evidence suggests that iodine fortification has had an outcome in improving iodine intakes in children; no complaints received requiring reactive response.	No complaints received either from public or third party audit agency.
4 How many of these investigations resulted in Enforcement Actions (by year)?	Not applicable.	Not applicable.
5 The strategy presumably has a cost associated with it. What is the estimated annual cost, and how is this justified?	No specific funding has been associated with an iodine monitoring strategy. Any compliance and enforcement costs would be handled within current business.	The agency has no budget associated with monitoring and compliance.'

Has enforcement action been taken where non-compliance has been identified?

Numbered survey questions	Collated response Australia	Collated response NZ
6a What is the policy and strategy with respect to non-compliance by salt manufacturers?	As with other issues, this would be the subject of a risk based, graduated, proportionate response.	All food manufacturers must comply with all regulatory requirements for the sale of food

Numbered survey questions	Collated response Australia	Collated response NZ
	<p>Compliance is usually assessed at the point of production. If found/suspected, non-compliances would be dealt with as per the powers granted under the food legislation and in proportion with the seriousness of the issue.</p>	<p>including the labelling and compositional requirements of the ANZ Food Standards Code. If during a routine FSP audit an auditor became aware of any case in which a critical control point is either absent or ineffective, thus causing a potential risk to public health, they are required to immediately notify the regulatory authority granting the exemption. They can notify Compliance by contacting a Food Act Officer or by emailing MPI. If there are ongoing non-conformance issues the auditor can notify the regulatory authority in writing outlining their concerns, providing a time frame of when concerns were raised and any response received from the exemption holder. Notification for these issues is to MPI Approvals. Auditors can include recommendations to increase audit frequency for businesses who are failing to address the identified corrective actions in the mutually agreed time frames.</p>
<p>6b If non-compliance is identified or reported, what is the protocol?</p>	<p>Alleged non-compliance is investigated by the relevant Authority. Enforcement action is taken where the requirements set out in the Code are not met. Allowance is made for the 'measurement uncertainty' inherent in any method of analysis. Non-compliance is addressed through escalated application of enforcement tools. Generally this will involve discussions at first instance. Continued non-compliance leads to statutory notices and eventually prosecution.</p>	<p>The type of follow up depends on the risk categorisation of the non-compliance and how it is identified. All complaints to MPI are assessed and followed up in accordance with MPI's Food Investigation procedure. This includes entry of complaint details into a national database. Non-compliances can also be identified during routine audits and followed up with the manufacturer using an agreed corrective action procedure.</p>
<p>7a Has enforcement action been taken with a salt manufacturer in respect to failure to meet the Standard for iodised salt?</p>	<p>No.</p>	<p>No.</p>
<p>7b If it has been, how was the enforcement</p>	<p>Not applicable.</p>	<p>Not applicable.</p>

Numbered survey questions	Collated response Australia	Collated response NZ
action's effectiveness verified?		
8 Please enumerate the type and level of these enforcement actions (by year).	Not applicable.	Not applicable.

5.2.4 Collated response from compliance and enforcement for bakers using salt

Table 15 Iodine Fortification of Salt used for Making Bread

Have sufficient enforcement strategies been implemented?

Numbered survey questions	Collated response Australia	Collated response NZ
1 Does your agency (or state or territory) have an ongoing monitoring or compliance strategy for bakers or bread mix manufacturers with respect to the use of iodised salt in bread making? If so, please describe	Some jurisdictions reported that they had no compliance and enforcement activities planned or undertaken. Others noted that these products are within the scope of their normal programs. All Australian jurisdictions have taken part in national bread surveys, one state has conducted its own additional survey.	NZ jurisdiction carries out regular surveys of iodine in bread and iodine intakes for children. Bread and bread mix manufacturers are required to have an FSP which includes use of iodine fortified salt. There are no specific monitoring and compliance surveys in place.
2 How many iodine compliance investigations have been carried out in the past three years (by year)?	None.	None.
3 If there have not been any, please provide the reason.	There has been no reactive action because no complaints have been received. The health outcomes are perceived to be working well.	No complaints received.
4 How many of these investigations resulted in Enforcement Actions (by year)?	Not applicable.	Not applicable.
5 The strategy presumably has a cost associated with it. What is the estimated annual cost, and how is this justified?	Because the health impacts are being achieved and there have been no complaints, there is no justification for a specific program.	Iodine surveys are estimated to cost about \$50,000 each.

Has enforcement action been taken where non-compliance has been identified?

Numbered survey questions	Collated response Australia	Collated response NZ
6a What is the policy and strategy with respect to non-compliance by bakers or bread mix manufacturers?	As with other foods, a risk-based, graduated, proportionate response. Compliance is usually assessed at the point of production. If found/suspected, non-compliances would be dealt with as per the powers granted under the food legislation and in proportion with the seriousness of the issue.	Iodised salt manufacturers are treated in the same manner as other food producers.

Numbered survey questions	Collated response Australia	Collated response NZ
6b If non-compliance is identified or reported, what is the protocol?	Alleged non-compliance is investigated by the appropriate Authority. Enforcement action is taken where the requirements set out in the Code are not met. Allowance is made for the 'measurement uncertainty' inherent in any method of analysis. Non-compliance is addressed through escalated application of enforcement tools. Generally this will involve discussions at first instance. Continued non-compliance leads to statutory notices and eventually prosecution.	The type of follow up depends on the risk categorisation of the non-compliance and how it is identified. All complaints to MPI are assessed and followed up in accordance with MPI's Food Investigation procedure. This includes entry of complaint details into a national database. Non-compliances can also be identified during routine audits and followed up with the manufacturer using an agreed corrective action procedure.
7a Has enforcement action been taken with a salt manufacturer in respect to failure to meet the Standard for iodised salt?	No.	No.
7b If it has been, how was the enforcement action's effectiveness verified?	Not applicable.	Not applicable.
8 Please enumerate the type and level of these enforcement actions (by year).	Not applicable.	Not applicable.

Are enforcement agencies working with relevant industry groups to enable and ensure compliance?

Numbered survey questions	Collated response Australia	Collated response NZ
9a In your jurisdiction, does a government agency have an ongoing program of working with the baking industry with respect to the mandatory use of iodised salt in bread baking?	There were no specific ongoing programs, but the jurisdictions have ongoing relations with industry groups.	No.
9b If so, describe the scope of the program, including the parties involved (e.g. individual businesses or peak bodies), its objectives, and its activities.	No specific compliance and enforcement ongoing programs.	N/A.

Other Comments:

[from Australia] It is considered that health outcomes for iodine have been achieved and mandatory fortification is working well.