

[7-08]
22 April 2008

PROPOSAL P1003 MANDATORY IODINE FORTIFICATION FOR AUSTRALIA ASSESSMENT REPORT

Executive Summary

This Assessment Report considers mandatory fortification with iodine as a means of addressing the re-emergence of iodine deficiency in Australia. Iodine deficiency, as reported in Australia, can have a negative impact on mental and nervous system development in children, and increases the risk of some forms of hyperthyroidism, especially in the elderly.

In May 2004, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested that Food Standards Australia New Zealand (FSANZ) give priority consideration to mandatory fortification with iodine. In response, FSANZ prepared Proposal P230 – Consideration of Mandatory Fortification with Iodine.

Initially, Proposal P230 was intended to address iodine deficiency in both Australia and New Zealand. However, prior to completing Proposal P230, FSANZ was asked to defer its consideration of mandatory iodine fortification for Australia while Australian Health Ministers re-evaluated the evidence on the prevalence and severity of iodine deficiency in Australia. In the interim, in recognition of the magnitude and severity of iodine deficiency in New Zealand, Proposal P230 was finalised as a separate Standard for New Zealand.

In March 2008, FSANZ received advice from the Australian Health Ministers' Advisory Council (AHMAC) confirming that iodine deficiency is prevalent and severe enough to warrant intervention in Australia and that mandatory fortification is considered the most cost-effective strategy to redress this (see SD1¹ and 2²). The Australian Health Ministers' Conference subsequently endorsed this advice.

¹ SD1: Australian Population Health Development Principal Committee (APHDPC) (2007) *The Prevalence and Severity of Iodine Deficiency in Australia*. Report commissioned by AHMAC.

² SD2: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of alternative strategies to redress iodine deficiency in Australia*. Report commissioned by the Department of Health and Ageing.

On the basis of the AHMAC advice, FSANZ has prepared Proposal P1003 – Mandatory Iodine Fortification for Australia. A new Proposal is necessary because the finalisation of Proposal P230 as a New Zealand only Standard precludes any further work being undertaken to address the Australian situation under Proposal P230.

As Proposal P230 was originally intended as a joint Standard for Australia and New Zealand, considerable work and consultation has already been undertaken for both Australia and New Zealand. Consequently, this new Proposal draws heavily on this existing work. FSANZ is proposing that a mandatory iodine fortification standard for Australia be the same as the New Zealand Standard, with the same food vehicle (iodised salt in bread) and the same salt iodisation range. The objective of this new Proposal therefore is to amend the New Zealand only Standard to become a joint Standard for both Australia and New Zealand.

The Preferred Approach

The preferred approach is to amend the New Zealand only mandatory iodine fortification Standard so it becomes a joint Standard for both Australia and New Zealand.

The joint Standard will require the mandatory replacement of non-iodised salt with iodised salt in bread. The salt iodisation level is to be in the range of 25-65 mg of iodine per kg of salt. Bread represented as organic will be exempt from this requirement.

The voluntary permission for iodine in iodised salt and reduced salt will be retained at the current range of 25-65 mg per kg, to be consistent with the mandatory requirement.

Reasons for the Preferred Approach

- FSANZ received advice from AHMAC, endorsed by Health Ministers, confirming that iodine deficiency is prevalent and severe enough to warrant intervention in Australia and that mandatory fortification is considered the most cost-effective strategy to redress this deficiency.
- Replacement of non-iodised salt with iodised salt in bread will address iodine deficiency across much of the Australian population, and prevent it from becoming more serious in the future.
- Replacement of non-iodised salt with iodised salt in bread is technologically feasible and well tested internationally.
- Use of iodised salt to reduce the prevalence of iodine deficiency is consistent with international guidance and experience.

- The Tasmanian voluntary program using iodised salt in bread, at an average of 45 mg iodine per kg salt, led to an improvement in the iodine status of a mildly deficient population.
- Based on the available evidence, including overseas experience with mandatory fortification, the proposed level of fortification does not pose a risk to general public health and safety. The level has been set to minimise any potential health risks. In groups that are generally more sensitive to increases in iodine intake, e.g. individuals with existing thyroid conditions, the risk of a negative impact on health is still considered to be very low.
- The Proposal delivers net-benefits to Australia. These benefits compare well with a small ongoing cost of fortification of around two cents per person each year.
- FSANZ commissioned the Centre for Health Economics Research and Evaluation (CHERE) to assess the cost-effectiveness of mandatory fortification with iodine (see SD3³). CHERE concluded that in terms of cost-effectiveness ratios, the cost of reducing the risk of iodine deficiency disorders appears small compared with the potential benefits associated with improved health, reduced health care costs and/or gains in productivity and Gross Domestic Product (GDP).
- The Proposal is consistent with Ministerial policy guidance on mandatory fortification.

Monitoring is considered an essential component of implementing this Proposal, consistent with Ministerial policy guidance. It will ensure the ongoing effectiveness and safety of this strategy to sustain reductions in the prevalence of iodine deficiency in Australia.

Consultation

FSANZ will undertake one round of public consultation on this new Proposal. As the preferred approach is the same as Proposal P230, FSANZ has drawn heavily on previous consultations to inform the development of this new Proposal.

During the development of Proposal P230, FSANZ undertook extensive consultation with a wide range of stakeholders. FSANZ released an Initial Assessment in 2005, a Draft Assessment in 2006 and an Issues Paper in May 2007 for public consultation.

Issues identified from the above public submissions and consultations formed the basis of further targeted consultation with key stakeholder groups. FSANZ commissioned a number of consultants and experts to consult with industry to help address issues raised. FSANZ involved the Fortification Standards Development Advisory Committee (SDAC) to also help identify key views and issues.

³ SD3: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of iodine fortification in Australia and New Zealand*. Report commissioned by FSANZ. (Note this is different from the DoHA report – see SD2.)

An Iodine Scientific Advisory Group (ISAG) was established, prior to Draft Assessment, to advise on scientific and medical matters.

FSANZ commissioned an independent economic consultancy organisation, Access Economics, to undertake a cost benefit analysis of Proposal P230 (see SD4⁴ and 5⁵) and also commissioned the CHERE, to undertake further work on the cost-effectiveness of the mandatory fortification with iodine (see SD3⁶).

The majority of government stakeholders, public health professionals and consumer groups indicated support for Proposal P230. There was general acknowledgement of the inability of the Proposal to fully meet the substantially increased iodine requirements of pregnant and breastfeeding women without exceeding the Upper Level (UL) for iodine in young children. Overall, submitters considered that the small manageable risks associated with mandatory fortification were outweighed by the public benefit. The majority of industry submitters opposed mandatory fortification, preferring a voluntary approach. The need for effective monitoring and education/health promotion strategies was generally acknowledged.

⁴ SD4: Access Economics (2006) *Cost benefit analysis of fortifying the food supply with iodine*. Report commissioned by FSANZ.

⁵ SD5: Access Economics (2007) *Costs of fortifying bread and bread products with iodine*. Report commissioned by FSANZ.

⁶ SD3: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of iodine fortification in Australia and New Zealand*. Report commissioned by FSANZ.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material. Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 20 May 2008

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942**

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SUPPORTING DOCUMENTS

The following materials, which were used in the preparation of this Assessment Report, are available on the FSANZ website at

<http://www.foodstandards.gov.au/standardsdevelopment/proposals/proposalp1003mandato3882.cfm>:

- SD1: Australian Population Health Development Principal Committee (APHDPC) (2007) *The Prevalence and Severity of Iodine Deficiency in Australia*. Report commissioned by AHMAC.
- SD2: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of alternative strategies to redress iodine deficiency in Australia*. Report commissioned by the Department of Health and Ageing.
- SD3: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of iodine fortification in Australia and New Zealand*. Report commissioned by FSANZ.
- SD4: Access Economics (2006) *Cost benefit analysis of fortifying the food supply with iodine*. Report commissioned by FSANZ.
- SD5: Access Economics (2007) *Costs of fortifying bread and bread products with iodine*. Report commissioned by FSANZ.
- SD6: FSANZ (2007) *International experience with iodine fortification programs*.
- SD7: The Australia and New Zealand Food Regulation Ministerial Council Policy Guideline Policy Guideline *Fortification of Food with Vitamins and Minerals*.
- SD8: FSANZ (2008) *Nutrition Assessment Report*.
- SD9: FSANZ (2007) *Safety Assessment and Risk Characterisation Report*.
- SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report*.
- SD11: FSANZ (2007) *Food Technology Report*.

- SD12: Winger, R. J. (2007) *Technological issues with salt brine addition of iodine to foods*. Report commissioned by FSANZ.
- SD13: FSANZ (2008) *Communication and Education Strategy*.
- SD14: Brooke-Taylor & Co Pty Ltd. (2006) *Report on the logistics and labelling changes related to the introduction of mandatory fortification of bread and breakfast cereals with iodised salt (and the impact of a preceding requirement for mandatory fortification of bread with folic acid)*. Report prepared for FSANZ P295 Final Assessment Report, Appendix 1.
- SD15: FSANZ (2007) Summary of Submitter Comments to Draft Assessment Report for Proposal P230.
- SD16: FSANZ (2007) Summary of Submitter Comments to Issues Paper for Proposal P230.

INTRODUCTION

This Assessment Report considers mandatory fortification with iodine as a means of addressing the re-emergence of iodine deficiency in Australia.

Some parts of Australia have a history of iodine deficiency; most notably Tasmania, and parts of Victoria and New South Wales. Widespread use of iodised salt and the unintentional contamination of milk with iodine from iodine-containing cleaning agents are believed to be the main reasons why iodine deficiency was no longer a problem during the 1960s-1980s. However, mild iodine deficiency has re-emerged over the last 10-15 years.

Internationally iodine deficiency is considered the leading cause of preventable mental impairment in children. Australia is a signatory to the 1990 United Nations sponsored *Declaration for the Survival, Protection and Development of Children* which states 'every child has the right to an adequate supply of iodine to ensure its normal development' (United Nations, 1990).

In May 2004, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) adopted a Policy Guideline on the *Fortification of Food with Vitamins and Minerals*. Ministers also requested that Food Standards Australia New Zealand (FSANZ) give priority consideration to mandatory fortification with iodine in Australia and New Zealand. In response, FSANZ raised Proposal P230 – Consideration of Mandatory Fortification with Iodine.

Initially, Proposal P230 was intended to address iodine deficiency in both Australia and New Zealand. However, prior to completing the Proposal, the then Chair of the Ministerial Council asked FSANZ to defer its consideration of mandatory iodine fortification for Australia so that Health Ministers could finalise advice regarding the prevalence and severity of iodine deficiency in Australia.

In the interim, in recognition of the magnitude and severity of iodine deficiency in New Zealand, Proposal P230 was finalised as a separate Standard for New Zealand. This Standard, gazetted on 13 March 2008, requires the mandatory replacement of salt with iodised salt in bread for New Zealand and provides a transition period until September 2009.

To further consider the prevalence and severity of iodine deficiency in Australia, a working group was established by the Australian Population Health Development Principal Committee (APHDPC). This group reported their findings at the APHDPC meeting in February 2008 and provided formal advice to AHMAC in March 2008. Based on these findings, AHMAC advised FSANZ that:

- *Mild iodine deficiency is prevalent in south eastern Australia which is the most densely populated area of Australia;*
- *The iodine intake of pregnant women in south eastern Australia is particularly inadequate and iodine intake in pregnant women is likely to be inadequate across Australia;*

- *There is supportive evidence for mandatory fortification of the food supply with iodine in Australia; and*
- *In regards to the cost effectiveness of strategies to redress iodine deficiency, in terms of reducing the number of people no longer at risk of iodine deficiency, mandatory fortification is the most cost effective intervention to redress iodine deficiency.*

In April 2008, the Australian Health Ministers' Conference endorsed AHMAC's advice noting that the prevalence and severity of iodine deficiency in Australia is significant and warrants intervention; and acknowledged that mandatory iodine fortification is the most cost-effective strategy to redress this. On the basis of AHMAC's advice, FSANZ has prepared this Proposal to consider mandatory iodine fortification for Australia. A new Proposal is necessary because the finalisation of Proposal P230 as a New Zealand only Standard precludes any further work being undertaken to address the Australian situation under Proposal P230.

FSANZ has already undertaken considerable work and consultation in progressing Proposal P230 for both Australia and New Zealand. It is the intention of this new Proposal to amend the mandatory iodine fortification Standard for New Zealand to create a joint Standard for both Australia and New Zealand.

This Assessment Report provides a description of the current iodine status of Australians and the resulting implications for health and mental performance. It includes the dietary intake assessment conducted to establish the impact of mandatory fortification, and describes the benefits of improving Australian's iodine status through safe mandatory fortification. The Report also details the cost of the proposed mandatory fortification and includes a cost-effectiveness analysis of options and an overall cost benefit analysis. Details of communication, education, monitoring, and implementation issues are also included. Issues arising from public submissions and targeted stakeholder consultation in response to Proposal P230 have been addressed where possible in appropriate sections of the Report.

Scope of this Proposal

The Proposal is seeking to amend the mandatory iodine fortification Standard for New Zealand to create a joint Standard for both Australia and New Zealand. The Proposal reflects advice that iodine deficiency in Australia is prevalent, warrants intervention and mandatory fortification is considered the most cost-effective strategy.

1. Background

1.1 Sources of Iodine

Iodine is not normally found in its elemental state in nature; instead it occurs bound to other elements to form various iodates and iodides (Freake, 2000). The concentration of iodine in the soil determines the concentration in plants, which affects what is available to livestock. As iodine is essential for animal health, livestock feeds, water, and/or salt licks may be fortified with iodine.

The iodine content of animal products may also be increased due to small amounts of iodine contamination from iodine-based drenches, teat sprays and sanitisers.

Iodised salt, dairy products, seafood, fruits, vegetables, eggs, meat and cereals all contribute to total dietary iodine. Of these, certain seafood and kelp can contain very high levels of iodine. Iodine containing supplements and medicines can also be major contributors to iodine intake for some people.

1.2 Nutritional Role of Iodine

Iodine is essential for the healthy function of the thyroid, which stores and uses iodine to produce the iodine containing hormones thyroxine and triiodothyronine (thyronine) (Freake, 2000; Gibson, 2005). These hormones play a key role in regulating metabolism, metabolic rate, and body temperature. They are also essential for brain and nervous system development in the foetus and young child. The foetus is totally dependent on the mother for iodine and somewhat dependent for thyroid hormones; therefore pregnant women need substantially more iodine than adults generally (Delange, 2000). An exclusively breastfed infant is completely dependent on breast milk for iodine, which means breastfeeding women also need more iodine than other adults; as shown in Table 1.

Greater than 97% of all iodine consumed is absorbed from the gastrointestinal tract, generally as iodide (Gibson, 2005). Absorbed iodide enters the circulation where most of it is taken up by the thyroid. The uptake of iodide by the thyroid is regulated by thyroid-stimulating hormone, which is sensitive to dietary iodine intake. At low intakes consistent with iodine deficiency, uptake of iodide into the thyroid is enhanced whereas at very high intakes, iodide uptake into the thyroid decreases. When replete, the body stores 15-20 mg of iodine, the bulk of which is in the thyroid, whereas a very deficient individual may store only around 3 mg.

1.2.1 Nutrient Reference Values for Australia and New Zealand for Iodine

The recommendations for iodine intakes are set out in the *Nutrient Reference Values for Australia and New Zealand*⁷. A range of nutrient reference values (NRV) exist for iodine including the estimated average requirement (EAR⁸), the recommended dietary intake (RDI⁹) and the upper level of intake (UL¹⁰). In the absence of sufficient data to determine an EAR and RDI, an adequate intake (AI¹¹) was established for infants aged less than one year instead of an EAR and RDI.

⁷ This document is available online at <http://www.nhmrc.gov.au/publications/synopses/n35syn.htm>.

⁸ A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.

⁹ The average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all (97-98%) healthy individuals in a particular life stage and gender group.

¹⁰ The highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population. As intake increases above the UL, the potential risk of adverse effects increases.

¹¹ The average daily nutrient intake level based on observed or experimentally-determined approximations or estimates of nutrient intake a group (or groups) of apparently healthy people that are assumed to be adequate. For infants aged less than 6 months, the AI is based on the average intake of breastfed infants.

The most recent NRVs, released in May 2006, are higher than previous recommendations, especially during pregnancy and lactation, and ULs have been established for the first time. The NRVs for iodine are given in Table 1 arranged by age, gender and physiological state.

Table 1: Australian and New Zealand Nutrient Reference Values for Iodine

	Age	AI	EAR	RDI	UL
		(µg per day)			
Infants	0-6 months	90	-	-	-
	7-12 months	110	-	-	-
Children & Adolescents	1-3 years	-	65	90	200
	4-8 years	-	65	90	300
	9-13 years	-	75	120	600
	14-18 years	-	95	150	900
Adults	19+ years	-	100	150	1100
Pregnancy	14-18 years	-	160	220	900
	19-50 years	-	160	220	1100
Lactation	14-18 years	-	190	270	900
	19-50 years	-	190	270	1100

Source: NHMRC, 2006

1.2.1.1 Basis for the Upper Level of Intake for Iodine

The UL is based on the underproduction of thyroid hormone i.e. hypothyroidism, observed in supplementation studies in adults given 1700-1800 µg of iodine per day. An uncertainty factor of 1.5 has been applied to give a margin of safety to yield an adult UL of 1100 µg of iodine per day. ULs for children and adolescents were extrapolated from the adult recommendation on a metabolic body weight basis. The adult UL was also used for pregnancy and lactation, as there was no evidence of increased sensitivity associated with those physiological states. Individuals with thyroid disorders or a long history of iodine deficiency may respond adversely at levels of intake below the UL. Further explanation of iodine-induced hypothyroidism is provided in Section 7.2.1.

1.3 Assessment of Iodine Status

The iodine content of foods is dependent on the iodine content of the environment, particularly soil, in which it is produced. Soil iodine varies considerably as iodine is not evenly distributed in the Earth's crust and tends to be low in mountainous regions, flood plains, and areas affected by erosions (FAO/WHO, 2002). Where the same foods have very diverse iodine content across regions, constructing appropriately representative food composition databases may not be possible. Further, goitrogens i.e. substances that inhibit absorption or utilisation of iodine by the thyroid can influence iodine status independent of the iodine content of foods (Gibson, 2005). It is therefore considered more appropriate to assess population iodine status by measuring urinary iodine concentration in children and adults, and blood thyroid-stimulating hormone concentration in neonates, rather than relying on dietary intake data (Gibson, 2005, ICCIDD *et al.*, 2001).

Thyroid volume increases in response to prolonged iodine deficiency and can therefore be used to determine long-term iodine status (ICCIDD *et al.*, 2001). Increased thyroid volume is also known as goitre, which can range in size from being detectable only by ultrasound to being clearly visible.

Current international classification defines an enlarged thyroid as being a goitre only once a certain size is reached relative to the size of the person (Gibson, 2005).

Although goitrogens inhibit iodine uptake, this only occurs when their intake is unusually high, e.g. where the diet is very high in cassava, vegetables from the brassicae family, or drinking water is very high in naturally-occurring fluoride (Delange and Hetzel, 2005; BEST, 2006). The general agreement of urinary iodine concentrations and dietary iodine intake data described in Sections 2 and 9 respectively indicate that goitrogens are not major contributors to iodine deficiency in Australia.

1.3.1 *WHO, ICCIDD Guidelines for the Assessment and Classification of Iodine Status*

Median urinary iodine concentration is the preferred measure of population iodine status of the International Council for the Control of Iodine Deficiency Disorders (ICCIDD) and World Health Organization (WHO). This measure closely reflects iodine intake in dietary amounts and is a sensitive indicator of recent changes in iodine intake in children and adults, but not necessarily pregnant women (Gibson, 2005). Surveys using single urine samples from several participants are suitable for assessing population iodine status rather than individual iodine status (Gibson, 2005, ICCIDD *et al.*, 2001). However, because an individual's iodine intake, and therefore excretion, can be highly variable from day-to-day, spot samples are not suitable for assessing individual iodine status (Gibson, 2005).

The WHO and ICCIDD have developed a system of classifying populations into categories of iodine status based on their median urinary iodine concentration (MUIC) (see Table 2). For the purposes of population-based surveys, the WHO and ICCIDD recommend school-aged children as the most suitable group in which to measure iodine status indicative of the overall population status (ICCIDD *et al.*, 2001). The WHO and ICCIDD state that a: *MUIC of 100 µg/L and above define a population which has no deficiency. In addition not more than 20% of samples should be below 50 µg/L. A MUIC less than 50 µg/L is indicative of overall moderate iodine deficiency in a population.*

Table 2: Epidemiological Criteria for Assessing Population Iodine Status Based on Median Urinary Iodine Concentrations in School-Aged Children

Median urinary iodine concentration ($\mu\text{g/L}$)	Iodine intake	Iodine status
< 20	Insufficient	Severe iodine deficiency
20 – 49	Insufficient	Moderate iodine deficiency
50 – 99	Insufficient	Mild iodine deficiency
100 – 199	Adequate	Optimal
200 – 299	More than adequate	Risk of iodine-induced hyperthyroidism in susceptible groups [†]
>300	Excessive	Risk of adverse health consequences

[†]In populations characterised by longstanding iodine deficiency and rapid increment in iodine intake, median value(s) for urinary iodine above 200 $\mu\text{g/L}$ are not recommended because of the risk of iodine-induced hyperthyroidism (see Section 7.2.2.).

Source: ICCIDD *et al.*, 2001

The latest guidelines from the ICCIDD state that in populations of children less than two years old and breastfeeding women, a MUIC below 100 $\mu\text{g/L}$ indicates an *insufficient* iodine intake (ICCIDD, 2007). In pregnant women, who have higher iodine requirements than children or other adults, a population MUIC below 150 $\mu\text{g/L}$ indicates an *insufficient* iodine intake. Evidence from Australia and elsewhere suggests that women of childbearing age have poorer iodine status than school children (Burgess *et al.*, 2007, Chan *et al.*, 2003; Gunton *et al.*, 1999; Hamrosi *et al.*, 2003; Hamrosi *et al.*, 2005; McElduff *et al.*, 2002; Travers *et al.*, 2006).

1.4 Iodine Deficiency Disorders

Iodine deficiency can lead to a wide range of problems collectively known as iodine deficiency disorders (Hetzel, 2000). The nature and severity of these disorders are closely related to the severity and duration of the deficiency (Delange and Hetzel, 2005). As the iodine status of a population deteriorates, the health impact across the population worsens. Further, the lower the iodine status of the group, the greater the risk of there being individuals with very low iodine status. The population health impact of different levels of iodine deficiency is detailed in Section 2.2.

1.5 History of Iodine Deficiency in Australia

Levels of iodine in the Tasmanian soil are lower than in other parts of Australia (Thomson, 2003), leaving the Tasmanian population at risk of an inadequate iodine intake. In 1949, the Tasmanian Health Department began to monitor goitre rates and urinary iodine excretion in school children (Gibson, 1995). Evidence of poor iodine status resulted in a State-wide iodine supplementation program for the prevention of goitre in school children commencing in 1950 (Clements, 1986). This program had limited success and was discontinued in the 1960s.

In 1966, potassium iodate began to be used in bread improvers, but this practice was discontinued in 1976 due to unacceptably high rates of iodine-induced hyperthyroidism, particularly in the elderly with a lifelong history of iodine deficiency.

The increased incidence of iodine-induced hyperthyroidism has been attributed to unanticipated increases in the iodine content of the food supply additional to those from fortification (Clements, 1986). Contributing factors included iodine contamination of dairy food from iodine containing sanitisers used by the dairy industry, and increased sourcing of food higher in iodine from mainland Australia.

In mainland Australia, endemic goitre has been recognised in certain regions since the middle of last century; specifically in the Atherton Tablelands in Queensland and along the Great Dividing Range extending through New South Wales into Victoria (Clements, 1986). Goitre has also been recorded in the Canberra region, the township of West Wyalong in New South Wales and in the Gippsland region of Victoria.

In 1947, in response to identified iodine deficiency, the Australian government provided funding for iodine tablets as part of a goitre prevention program. In 1953 the recommendation to add iodised salt to bread was adopted in the ACT and continued until the 1980s.

From the 1960s a major source of iodine, if not the prime source in the Australian food supply, was obtained from milk as a result of iodine contamination from the use of iodine-based disinfectants by the dairy industry (Li *et al.*, 2006).

1.6 Recent Tasmanian Experience with Iodine Fortification

In the late 1980s, the Tasmanian population was considered iodine-sufficient. However, a series of investigations in the late 1990s concluded that Tasmanians had become mildly iodine deficient. In response, the Tasmanian Government introduced an interim, State-based voluntary iodine fortification intervention in October 2001 (Seal, 2007) while urging consideration of a bi-national approach. Bakeries were asked to use iodised salt in place of regular salt and a Memorandum of Understanding (MoU) was established between the Tasmanian Government and those in the baking industry willing to participate; approximately 80% of the industry. Salt manufacturers also signed a MoU agreeing to supply the baking industry in Tasmania with iodised salt at an average concentration of around 45 mg of iodine per kg salt. An integral component of this strategy was the employment of a government officer to ensure the ongoing effectiveness of the MoU.

Initially, several food vehicles for fortification were considered; however, bread was decided as the most appropriate because it was widely consumed and produced locally, supported by both bread and salt industries and did not require any legislative change. A monitoring program was established to assess the iodine content of bread, the iodine status of the Tasmanian population and to determine any adverse effects of the fortification program. The monitoring program concluded that iodine status improved in Tasmanian schoolchildren and to some extent in pregnant women (Hynes *et al.*, 2004; Seal *et al.*, 2007; Burgess *et al.*, 2007).

However, the results for pregnant women were based on convenience samples and may not be representative of the change in iodine status across pregnant women generally or the broader population. In addition, the incremental increase in urinary iodine is not directly related to the incremental increase in dietary iodine intake in pregnant women (Laurberg *et al.*, 2007).

The interim Tasmanian fortification intervention demonstrates:

- the suitability of replacing salt with iodised salt in bread as a means to successfully increase the iodine status of a mildly deficient population;
- that it is technologically feasible to add iodised salt to bread;
- no evidence of any adverse effects due to an increase in iodine intakes from fortification;
- a broad acceptance by the general public of this public health intervention; and
- the importance of establishing an effective monitoring system and the key components of such a system.

While acknowledging the positive attributes of the intervention, the following limitations were noted (Seal *et al.*, 2007; Burgess *et al.*, 2007):

- the inability to meet the increased requirements of pregnant and breastfeeding women;
- the inability to deliver sufficient iodine to those who consume little or no bread;
- concerns regarding the long term sustainability, reach and ongoing costs of a voluntary program; and
- the complexity of adequately monitoring and enforcing a voluntary intervention.

1.7 International Experience in Addressing Iodine Deficiency

One third of the world's populations still live in areas at risk of iodine deficiency (de Benoist, 2004). Universal Salt Iodisation, or USI¹², is the recommended strategy for the control of global iodine deficiency (WHO and UNICEF, 2004). Since the 1990s, the WHO/UNICEF iodine supplementation programs have successfully eliminated or reduced the risk of iodine deficiency disorders in many developing countries (de Benoist, 2004).

USI, as defined, is rarely achieved and most countries practise a modified version of USI, where either all household salt is iodised and/or particular manufactured foods contain iodised salt. Mandatory iodisation of household salt is the most common strategy for iodine fortification.

¹² Universal Salt Iodisation (USI) – the iodisation of all salt used for human and animal consumption.

It is particularly effective in developing countries because table salt is the major dietary source of salt, in contrast to developed countries like Australia, where manufactured foods provide 75-80% of dietary salt (James *et al.*, 1987; Mattes and Donnelly, 1991).

Countries with complex food systems, such as the United States, Canada, Switzerland, Belgium, the Netherlands, Denmark and Germany, have not adopted universal salt iodisation as defined by the ICCIDD *et al.* (2001). Instead, these countries have introduced legislation allowing, and in some cases mandating, the iodisation of cooking and table salt and/or use of iodised salt in some processed foods. All the aforementioned countries have adopted salt as the delivery vehicle for iodine.

As not all of these countries have introduced regular monitoring, the *relative* impact of these initiatives is unclear although there has been a documented overall improvement in iodine status following the implementation of the various approaches to iodine fortification. For further details of iodine fortification programs in selected countries, refer to SD6¹³.

1.8 Ministerial Council's Policy Guideline on Fortification

The Ministerial Council's Policy Guideline on *Fortification of Food with Vitamins and Minerals* (the Policy Guideline, see SD7¹⁴) provides guidance on the addition of vitamins and minerals to food for both mandatory and voluntary fortification. In considering mandatory fortification as a possible regulatory measure, FSANZ must have regard to the Policy Guideline.

The Policy Guideline provides 'High Order' Policy Principles as well as 'Specific Order' Policy Principles and additional guidance for mandatory fortification. The 'High Order' Policy Principles reflect FSANZ's statutory objectives (see Section 4) and therefore take precedence over the 'Specific Order' Policy Principles.

The five 'Specific Order' Policy Principles state that mandatory fortification should:

1. be only in response to a demonstrated significant population health need taking into account the severity and prevalence of the health problem;
2. be assessed as the most effective public health strategy to address the public health problem;
3. be consistent, as far as possible, with national nutrition policies and guidelines;
4. not result in detrimental dietary excesses or imbalances of vitamins and minerals; and

¹³ SD6: FSANZ (2007) *International experience with iodine fortification programs*.

¹⁴ SD7: The Australia and New Zealand Food Regulation Ministerial Council Policy Guideline Policy Guideline Fortification of Food with Vitamins and Minerals.

5. deliver effective amounts of added vitamins or minerals to the target group to meet the health objective.

Consistent with the Policy Guideline, AHMAC has considered 'Specific Order' Policy Principles one and two in relation to the prevalence and severity of iodine deficiency in Australia and the cost-effectiveness of strategies to redress iodine deficiency. On 6 March 2008, AHMAC advised that iodine deficiency is prevalent and severe enough to warrant intervention in Australia and that mandatory fortification is considered the most cost-effective strategy. On the basis of this advice, FSANZ has prepared this Proposal for mandatory fortification of iodine in Australia.

1.9 Codex Alimentarius

The Codex Alimentarius does not mandate the addition of nutrients to foods other than to some special purpose foods and iodine to salt in deficient areas. Section 3.4 – Iodisation of food grade salt of the Codex Standard for Food Grade Salt (CODEX STAN 150-2001) states: 'in iodine deficient areas, food grade salt shall be iodised to prevent iodine deficiency disorders for public health reasons. Levels of iodisation should be established by national authorities in light of the local iodine deficiency problem.'

For generally consumed foods, the *General Principles for the Addition of Essential Nutrients to Foods*¹⁵ state that essential nutrients may be added to foods for the purposes of restoration, nutritional equivalence of substitute foods, fortification¹⁶, or ensuring the appropriate nutrient composition of a special purpose food.

2. Description of Current Situation

The following sections outline the current iodine deficiency in Australia and the negative implication for population health and performance. A more detailed description of the iodine status of Australians and the potential consequences is in SD8¹⁷. The sections also include information on relevant Standards in the Code relating to iodine and salt.

2.1 Iodine Status of the Australian Population

The recent APHDPC report *The Prevalence and Severity of Iodine Deficiency in Australia* concluded that '*mild iodine deficiency is prevalent in south eastern Australia*' (see SD1¹⁸). The evidence on which this conclusion was based is presented below. The studies identified have assessed iodine status by comparing median urinary iodine excretion with the WHO guidelines described in section 1.3.1.

¹⁵ Codex Alimentarius Commission, 1991.

¹⁶ 'Fortification' or 'enrichment' means the addition of one or more essential nutrients to a food for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups.

¹⁷ SD8: FSANZ (2008) *Nutrition Assessment Report*.

¹⁸ SD1: Australian Population Health Development Principal Committee (APHDPC) (2007) *The Prevalence and Severity of Iodine Deficiency in Australia*. Report commissioned by AHMAC.

The results of the Australian National Iodine Nutrition Study (NINS) conducted during 2003-2004 in school-aged children in all jurisdictions except Tasmania and the Northern Territory are shown in Table 3 (Li *et al.*, 2006). As discussed in Section 1.6, the situation in Tasmania is unique in Australia as a state government sponsored voluntary fortification was introduced in 2001.

Table 3: Australian NINS Median Urinary Iodine Concentration Data

State	Median Urinary Iodine Concentration ($\mu\text{g/L}$) ¹⁹	Interquartile Ranges	Iodine Status
New South Wales	89	65.0-123.5	Mild deficiency
Victoria	73.5	53.0-104.3	Mild deficiency
South Australia	101	74.0-130.0	Borderline deficiency
Western Australia	142.5	103.5-214.0	Adequate
Queensland	136.5	104.0-183.8	Adequate
Weighted Total	98		Mild Deficiency

Source: Li *et al.*, 2006; SD¹⁸

The data from the NINS show that nearly 73% of the children in Victoria, 60% of children in NSW and 48% of children in SA had urinary concentrations <100 $\mu\text{g/L}$, indicating inadequate iodine nutrition. Overall 46% of children tested had some degree of iodine deficiency with nearly 10% being moderately deficient.

The results of the NINS were consistent with an earlier study in NSW school children that also indicated a state of mild deficiency (Guttikonda *et al.*, 2003). Other studies conducted in recent years indicate various degrees of iodine deficiency amongst pregnant women in Melbourne and Sydney, and mild iodine deficiency amongst school children in Melbourne and NSW (Chan *et al.*, 2003; Gunton *et al.*, 1999; Guttikonda *et al.*, 2003; Hamrosi *et al.*, 2005; Li *et al.*, 2001; Travers *et al.*, 2006). Two out of three studies also suggest iodine deficiency amongst neonates in NSW (Chan *et al.*, 2003; McElduff *et al.*, 2002; Travers *et al.*, 2006). The latest study, conducted in adults living in the Riverina, reported mild deficiency with a clear trend for increased iodine deficiency in older vs. younger adults (Uren *et al.*, 2008). The same study also reported that although women had a similar MUIC than men, more women fell into the category of moderate deficiency.

In 1998-99, prior to intervention, children in Tasmania were mildly iodine deficient (Hynes *et al.*, 2004). In 2000-01, also prior to intervention, the proportion of children below the cut-off for moderate deficiency had increased, despite no apparent change in MUIC. This suggests a continuing downward trend in iodine status during this time.

2.2 Potential Impact of Iodine Deficiency

The most well known consequence of iodine deficiency is a swelling of the thyroid usually referred to as goitre. This swelling represents an adaptation by the thyroid to increase its ability to absorb iodine and produce thyroid hormones.

¹⁹ According to the WHO and ICCIDD, an MUIC of 50-99 $\mu\text{g/L}$ indicates mild iodine deficiency in a population.

A brief summary of the consequences of mild and moderate iodine deficiency follows; a more comprehensive summary can be found in SD8²⁰.

2.2.1 *Mild and Moderate Iodine Deficiency and Thyroid Health*

The impact of iodine deficiency is affected by the severity and duration of the deficiency and where it occurs in the life cycle. Adverse impacts on cognitive performance, hearing and reaction time have been reported in moderately, and to a lesser extent, mildly deficient populations.

Impairments occurring during early brain and nervous system development i.e. before the age of two-to-three years cannot be reversed by an adequate supply of iodine later in life (Hetzel, 2000; Hetzel, 1994). However, those impairments resulting from iodine deficiency experienced in later childhood may be largely reversed by the provision of adequate iodine in childhood or early adolescence (van den Briel *et al.*, 2000; Zimmermann *et al.*, 2006). It is unclear if providing adequate iodine in adolescence or adulthood would result in similar improvements as this has not been studied. Thus iodine deficiency is of greatest concern in the foetus, infant and young child to three years of age, and therefore also in pregnant and breastfeeding women.

The most common form of thyroid disease in populations that have been mildly or moderately iodine deficient for decades is multinodular toxic goitre (Delange and Hetzel, 2005). This condition can lead to spontaneous or iodine-induced hyperthyroidism, especially in the elderly (Aghini-Lombardi *et al.*, 1999; Laurberg *et al.*, 2000; Pedersen *et al.*, 2003). The risk of multinodular toxic goitre is higher in moderately than in mildly deficient populations. This problem is most commonly seen in areas where deficiency has been a problem for decades (Hetzel and Clugston, 1998) (see SD9²¹).

2.2.2 *Consequences of Mild and Moderate Iodine Deficiency during Pregnancy and Early Childhood*

The cognitive and motor skill impacts in the offspring of iodine deficient pregnant and breastfeeding women in Australia have not been specifically researched. However, in overseas populations, suboptimal thyroid hormone production resulting from iodine deficiency or other causes, has been shown to result in impaired mental function in the offspring of affected mothers. Functions sensitive to mild-to-moderate iodine deficiency include verbal, perceptual, mental and motor skills, and intelligence quotient (IQ) (Galan *et al.*, 2005; Haddow *et al.*, 1999). Infants with iodine deficiency have poorer information processing skills (Choudhury and Gorman, 2003). Such children may also be at substantially increased risk of attention-deficit and hyperactivity disorders (ADHD) (Alvarez-Pedrerol *et al.* 2007; Hauser *et al.*, 1993; Vermiglio *et al.*, 2004).

²⁰ SD8: FSANZ (2008) *Nutrition Assessment Report*.

²¹ SD9: FSANZ (2007) *Safety Assessment and Risk Characterisation Report*.

Moderately iodine deficient children perform more poorly than mildly deficient or non-deficient children in tasks such as rapid target marking, symbol search, rapid object naming, and visual problem solving (Zimmermann *et al.*, 2006). Iodine deficiency can impair abstract reasoning and verbal fluency (van den Briel *et al.*, 2000). Children with moderate iodine deficiency also have poorer reading, spelling and mathematical skills as well as poorer general cognition when compared with mildly deficient children (Huda *et al.*, 1999). Mildly iodine deficient children have slower reaction times than those with adequate iodine intakes (Delange, 2001).

Iodine deficiency may also result in impaired hearing at both high and normal speech frequencies. Elevation of the auditory threshold²² has been reported in mild and moderate iodine deficiency, and has been shown to track closely with poorer performance in both verbal and non-verbal tests of mental function as well as poorer fine motor control (Valeix *et al.*, 1994; Soriguer *et al.*, 2000; van den Briel *et al.*, 2001).

The thyroid contains a small store of iodine that may be accessed during periods of inadequate intake. Thus if a woman is iodine replete before pregnancy, she will have some capacity to draw on these stores to compensate for a suboptimal intake during pregnancy. However, if the mother is deficient before pregnancy, there is a greater risk the child will be iodine deficient and as a result experience poorer neural development.

2.3 Relevant Standards in the Code

Standard 2.1.1 – Cereals and Cereal Products requires the mandatory replacement of non-iodised salt with iodised salt in bread for New Zealand only. This requirement does not apply to bread represented as organic.

Current provisions in Standard 2.10.2 – Salt and Salt Products permit the voluntary addition of potassium iodate or iodide, or sodium iodate or iodide to all salt and reduced sodium salt mixtures to provide 25-65 mg iodine/kg. Furthermore, by virtue of subclause 10(3) of Standard 1.1.1., the use of iodised salt in mixed foods is permitted providing those foods are appropriately labelled. Permitted forms of iodine may be added to dairy substitutes such as soy beverages but in smaller amounts as specified in Standard 1.3.2 – Vitamins and Minerals. Standard 2.9.1 – Infant Formula Products specifies the minimum and maximum amounts of iodine and the permitted forms that may be added to infant formulas and follow-on formulas.

2.4 Current Availability and Use of Iodised Salt

Information from industry indicates that approximately 15-20% of salt sold as table and cooking salt is iodised in Australia. Currently there is minimal use of iodised salt in commercially produced food.

²² The volume below which a given frequency of sound can no longer be heard.

3. The Health Issue

In order to establish the regulatory response, the health issue under consideration needs to be clearly summarised.

There has been a recent re-emergence of mild iodine deficiency in Australia. Iodine deficiency is associated with a wide range of adverse health effects; with the most detrimental involving the developing brain, especially during foetal growth and infancy. Hence the iodine status of pregnant and breastfeeding women is of particular importance.

As substantial brain and nervous system development continues into the first 2-3 years of life, this period is also critical with respect to iodine nutrition. In adults, long periods of iodine deficiency increase the risk of thyroid dysfunction, predominantly hyperthyroidism and associated serious health consequences in later life. Further, both adults and children are at risk of developing goitre from iodine deficiency. Thus, iodine deficiency represents a significant threat to the health and wellbeing of the Australian community now and in the future.

Internationally a number of countries have successfully reduced the risk from iodine deficiency through food fortification programs involving the use of iodised salt. Therefore increasing the iodine content of the Australian food supply is important to reduce the prevalence of iodine deficiency and the resulting adverse effects on population health.

4. Objectives

The specific purpose of the regulatory measures outlined in this Proposal is to reduce the prevalence of iodine deficiency in Australia, especially in children, to the maximum extent possible so as to reduce the risk of physical and mental impairment, and thyroid disease across all age groups. The most vulnerable population groups, the developing foetus and young children up to three years of age, are a particular focus. The primary approach for achieving a reduction in this risk will be to increase the iodine content of the food supply.

In developing or varying a food standard, FSANZ is required by its legislation to meet three objectives which are set out in Subsection 18(1) of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

Subsection 18(2) of the FSANZ Act also requires FSANZ to have regard for:

- the need for standards to be based on risk analysis using the best available scientific evidence;

- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

5. Consideration of Options for Addressing Iodine Deficiency in Australia

FSANZ has considered a range of four options, in addition to the status quo, that potentially could achieve the objective of reducing the prevalence of iodine deficiency in the Australian population. The four options, in addition to the status quo, are:

- A high profile education program, to encourage the population to increase its intake of dietary iodine.
- An iodine supplementation program to increase the intake of iodine in pregnant women.
- Mandatory fortification of bread with iodised salt, implemented to coincide with the fortification of bread with folic acid (with cost savings on relabelling and labelling write-offs).
- Voluntary fortification of bread with iodised salt, implemented to coincide with the fortification of bread with folic acid (with cost savings on relabelling and labelling write-offs).

In the initial consideration of these options, FSANZ drew on a substantive cost effectiveness analysis undertaken by the Centre for Health Economics Research and Evaluation (CHERE) (see SD2²³). This report was commissioned by the Australian Government Department of Health and Ageing, and access to it is acknowledged and appreciated. CHERE estimated the costs of each option for Australia in terms of the net present value over 10 years (see Table 4).

²³ SD2: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of alternative strategies to redress iodine deficiency in Australia*. Report commissioned by the Department of Health and Ageing.

Table 4: Costs of each Option (Net Present Value over 10 Years)

		Australia (\$AUD)
1	High profile education program	12,108,000
2	Supplementation program for pregnant women	73,320,000
3	Mandatory fortification of bread, with implementation coinciding with that for folic acid	3,101,000
4	Voluntary fortification of bread, with implementation coinciding with that for folic acid	2,639,000

Source: SD2²³

The CHERE team also identified a range of indicators of effectiveness in addressing dietary iodine deficiency. A key indicator was the number of people that would no longer be severely iodine deficient (urinary iodine below 50 ug/l). CHERE then estimated the effectiveness of each option and compared this with its 10 year net present value costs, to produce a cost-effectiveness ratio (see Table 5). The option with the lowest cost-effectiveness ratio can more effectively and efficiently achieve the objective of the intervention.

However, the CHERE team noted that it was not possible to compare the cost-effectiveness ratios for the fortification options with the education and supplementation options which is why they are excluded from Table 5.

Table 5: Cost-effectiveness Ratio for Fortification Options

		Australia (\$AUD/person)
1	Mandatory fortification of bread, with implementation coinciding with that for folic acid	24.32
2	Voluntary fortification of bread, with implementation coinciding with that for folic acid	25.82

The CHERE Report concludes that mandatory fortification is the most cost-effective option. Comparing the voluntary and mandatory fortification programs, the lower level of fortification coverage under a voluntary scheme will not automatically translate into a proportional reduction in costs, because both options involve variable and fixed costs. A voluntary fortification process would also be subject to additional uncertainty.

The CHERE Report also noted that mandatory fortification is superior to supplementation programs targeting pregnant women, principally because the population of pregnant women with severe iodine deficiency (urinary iodine below 50ug/l) is small. Mandatory fortification is also superior to a high profile education program.

5.1 Feasibility of Voluntary Fortification

The analysis undertaken by CHERE indicates that mandatory fortification would be more cost-effective than voluntary fortification. This section examines whether voluntary fortification could still be considered a feasible option.

As noted in Section 1.5, a voluntary fortification scheme has been used in Tasmania since 2001. This scheme did achieve some population objectives in reducing iodine deficiency, particularly in young children. To ensure the ongoing effectiveness of the voluntary fortification scheme, it was necessary to employ a government officer to initiate and oversee the scheme. Eighty per cent of bakeries participated in the scheme whereby iodised salt was used in place of salt in bread-making. However, the Tasmanian Government raised concerns about the variability of iodised salt usage by some bakeries and limitations in the coverage of products and reach to the population. CHERE have used the Tasmanian experience as the basis for its benchmark for coverage of 80% in its modelling of the voluntary fortification option.

FSANZ has previously consulted extensively with a wide range of stakeholders on iodine fortification, including industry. During these consultations, the food industry suggested a voluntary approach be included in FSANZ's assessment of options to address iodine deficiency. FSANZ worked collaboratively with industry to model their suggestions. The foods proposed by industry included certain breads, breakfast cereals and biscuits. Data on the proportion of the market likely to be voluntarily fortified under such a scheme and the level of salt in these foods were provided by industry. The nominated foods represented 15-30% of each market segment.

FSANZ undertook a dietary intake assessment to estimate the level of iodine intake under the suggested voluntary fortification scheme. As detailed in SD10²⁴, the estimated mean dietary iodine intakes for Australians increased minimally: for 2-3 year old children (+10 µg/day), women aged 16-44 years (+12 µg/day) and the population aged 2 years and above (+15 µg/day). In contrast, the mandatory fortification option increased the mean dietary iodine intake by +37 µg/day, +46 µg/day and +54 µg/day for children aged 2-3 years, 16-44 years (female) and 2 years and above, respectively.

FSANZ has considered the outcome of the dietary intake estimates and concludes that iodine intakes under the suggested voluntary approach would be inadequate and would not substantially address iodine deficiency in the Australian population.

FSANZ notes that CHERE relied on the Tasmanian experience in modelling the cost-effectiveness of a voluntary approach and in particular adopted the 80% coverage. Information provided by the food industry indicates coverage of only 15 - 30%. FSANZ considers there would be a high risk that voluntary fortification would fall well short of the 80% coverage and could easily be less than 50%. This low level of coverage could not address population health objectives and therefore FSANZ considers the voluntary approach would not be a feasible option.

Mandatory fortification is considered the most cost-effective measure to address iodine deficiency in Australia. On this basis FSANZ has focussed further detailed assessment to achieve the objective of addressing iodine deficiency in Australia, on the option of mandatory fortification.

5.2 Options

The options for further assessment are:

²⁴ SD10: FSANZ (2008) *Dietary Intake Assessment Report* – Main Report.

5.2.1 *Option 1: Current approach – the status quo*

Maintenance of the *status quo* would see the continuation of the existing permissions for the voluntary addition of iodine to salt, and the use of iodised salt as an ingredient in food. The Code currently permits the addition of iodine to all salt and reduced sodium salt mixtures to provide 25-65 mg iodine per kg.

5.2.2 *Option 2: The mandatory replacement of salt with iodised salt in bread*

This option proposes to amend the New Zealand only mandatory iodine fortification Standard so it becomes a joint Standard for both Australia and New Zealand. This option requires the mandatory replacement of non-iodised salt with iodised salt in the manufacture of bread, with a salt iodisation range from 25-65 mg iodine per kg salt. This concentration will address the mild iodine deficiency in Australia. The current level of salt iodisation (from 25-65 mg/kg) would be retained, as would the current voluntary permission.

RISK/BENEFIT ASSESSMENT OF MANDATORY FORTIFICATION

6. Key Risk Assessment Questions

The risk assessment questions addressed include:

- What are the potential health benefits and risks associated with increasing iodine intakes?
- What are appropriate food vehicles to deliver additional iodine to the target populations?
- How much additional iodine needs to be added to the food supply to meet the specific objective of the Proposal?
- What is the efficacy and safety of the preferred fortification scenario?

7. Potential Health Benefits and Risks of Increased Iodine Intakes

This section outlines benefits and risks of increased iodine intakes following fortification programs that have been implemented internationally. For a discussion of benefits and risks associated with the proposed mandatory iodine fortification in Australia see Section 10.

7.1 Potential Health Benefits

7.1.1 Alleviation of Existing Iodine Deficiency Disorders

Studies examining the impact of improving iodine status in mildly-to-moderately deficient children have reported substantial improvements within a year of supplementation or fortification.

Children whose iodine status was improved from moderate deficiency to adequate status performed better on tests of hand eye coordination, visual recognition and problem solving, and rapid object naming (van den Briel *et al.*, 2000; Zimmermann *et al.*, 2006). The relative improvement in status, at least in primary school children, may be more important than absolute status for improvements in mental function (van den Briel *et al.*, 2000).

Recent data from China show improvements in the IQ and psychomotor development in children in regions of severe and moderate iodine deficiency following salt iodisation programs (Tang *et al.*, 2007). The younger the child at the introduction of salt iodisation, the greater the average relative improvement in IQ and psychomotor scores. Further, giving mothers living in severely iodine deficient areas adequate iodine supplementation resulted in their children having only marginally lower intelligence quotients (IQ) than children born in areas of sufficient iodine intake (Qian *et al.*, 2005). The same held true for children born in areas traditionally iodine deficient but now receiving iodised salt.

These findings illustrate the ability of iodine fortification to prevent mental impairment caused by iodine deficiency. The impact on mental function, if any, of alleviating iodine deficiency in adults, has not been characterised.

7.1.2 *Reduction of Future Risk of Iodine Deficiency Disorders*

Based on the information outlined above, iodine fortification would be expected to reduce the risk of children born with, or later developing, impaired cognitive function (Qian *et al.*, 2005). Fortification would also reduce the risk of goitre in children and adults, thereby reducing the risk of thyroid dysfunction, e.g. hyper or hypothyroidism (Delange and Hetzel, 2005).

7.2 **Potential Health Risks**

A number of potential health risks have been associated with increased iodine intakes (JECFA, 1989; Delange and Hetzel, 2005). The most relevant of these is the potential for disturbance of normal thyroid activity. The effects produced, i.e. iodine-induced hypothyroidism or iodine-induced hyperthyroidism, depend on the current and previous iodine status of the individual and any current or previous thyroid dysfunction. See SD9²⁵ for a review of the potential consequences of excess iodine and tolerable levels of iodine in both healthy and sensitised populations.

7.2.1 *Iodine-Induced Hypothyroidism*

Iodine-induced hypothyroidism, in some cases resulting in goitre, refers to an underproduction of thyroid hormones in response to: 1) sudden substantial increases in iodine intake, or 2) chronically very high iodine intakes (JECFA, 1989; ATSDR, 2004; Delange and Hetzel 2005, Teng *et al.*, 2006). It is the endpoint on which the UL for iodine is based.

²⁵ SD9: FSANZ (2007) *Safety Assessment and Risk Characterisation Report*.

Hypothyroidism can be clinical or subclinical with the health impact of the former being greater and better defined than that of the latter. Iodine-induced hypothyroidism is generally subclinical and transient. Even in the event that it does not clear spontaneously, it is easily treated by either removing the source of excess iodine and/or providing thyroid hormone (ATSDR 2004).

Individuals who are particularly susceptible include those with Graves' disease previously treated with iodine; women who have post-partum thyroiditis; or those who have subacute thyroiditis. However, globally, iodine deficiency, not excess iodine, is the more common cause of hypothyroidism (Delange and Hetzel, 2005).

7.2.2 Iodine-Induced Hyperthyroidism

Iodine-induced hyperthyroidism is an overproduction of thyroid hormones in response to an increased intake of iodine (Delange and Hetzel, 2005). Prolonged iodine deficiency can lead to physical changes in the thyroid that predispose individuals to the development of iodine-induced hyperthyroidism following an increase in iodine intake.

These changes develop over a long period with those over 40 years of age who have experienced a lifetime of iodine deficiency at greatest risk (Hetzel and Clugston, 1998). Some increase in iodine-induced hyperthyroidism has been observed following some, but not all fortification programs (Delange and Hetzel, 2005). The relationship between iodine deficiency and iodine-induced hyperthyroidism is discussed further in Section 10.2.3.

8 Food Vehicle Selection

FSANZ has drawn on international experience in identifying appropriate food vehicles for considering mandatory iodine fortification. The WHO, ICCIDD, and the United Nations Children's Fund (UNICEF) recommend iodisation of all salt as the main strategy for the control of global iodine deficiency (ICCIDD *et al.*, 2001). Iodisation of some or all food salt is common in many countries as the main or sole measure to address iodine deficiency (de Benoist, 2004). Iodised salt has been found to be a suitable substitute for non-iodised salt in the majority of foods tested with minimal impact on taste and appearance (West *et al.*, 1995). In contrast, there is a paucity of evidence as to the impact of the addition of iodine to food other than via salt (Winger *et al.*, 2005). Further details on the food technology aspects of iodine fortification are provided in SD11²⁶.

Guidance on the suitability of potential food vehicles for fortification is also provided by published international criteria (Codex Alimentarius Commission, 1991; Nutrivit, 2000; Darnton-Hill, 1998). These criteria include the need for the selected vehicle(s) to:

- be regularly consumed by the population at risk in stable, predictable amounts (upper and lower intake levels known);

²⁶ SD11: FSANZ (2007) *Food Technology Report*.

- supply optimal amounts of micronutrient without risk of excessive consumption or toxic effects;
- be available to the target population regardless of socio-economic status;
- retain high level stability and bioavailability of the added micronutrient under standard local conditions of storage and use;
- be economically feasible;
- be centrally processed so quality control can be effectively implemented; and
- not interact with the fortificant or undergo changes to taste, colour or appearance as a result of fortification.

These criteria were considered in the selection of an appropriate food vehicle and will be addressed in the sections below.

8.1 Refinement of Food Vehicle

In western countries approximately 75-85% of dietary salt is estimated to come from processed foods (James *et al.*, 1987; Mattes and Donnelley, 1991).

Dietary intake estimates indicate that approximately 50% of salt in processed foods come from cereals, cereal products²⁷, and cereal-based products and dishes²⁸. The option of replacing salt with iodised salt in cereal products was therefore explored and compared with replacing salt with iodised salt in all processed foods. Both approaches were similar in efficacy but fortification of cereal products was preferable in terms of minimising industry costs, trade impacts, enforcement issues, potential technological difficulties and consumer concerns. Therefore the Preferred Option in the Draft Assessment of Proposal P230 was the mandatory replacement of salt with iodised salt in bread, breakfast cereals and biscuits.

Trade and technical issues resulted in a further refinement to the food vehicle such that the mandatory replacement of salt with iodised salt is being recommended in bread only. Further explanation of this refinement is provided in Section 12.1.

8.1.1 Selection of Bread

FSANZ's dietary intake estimates indicate that 88% of Australians aged 2 years and over consume bread daily. Similarly, 88% of children aged 2-3 years consume bread (see SD10²⁹). Bread is a nutritious food that is typically made domestically for the local market; concerns related to its importation and exportation are therefore reduced relative to foods with a large import and/or export component.

²⁷ Includes grains, cereal flours and starch powders, breads and rolls, breakfast cereals, English-style muffins, crumpets, tortillas, pastas, noodles and rice.

²⁸ Includes biscuits (sweet and savoury), cakes, buns, muffins (cake style), scones, slices, pastries and pastry products (sweet and savoury), pizzas, sandwiches, filled rolls and hamburgers, taco and tortilla-based dishes, savoury pasta and sauce dishes, dim sims, spring rolls, savoury rice-based dishes, pancakes, crepes, pikelets and doughnuts.

²⁹ SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report*.

Bread has a short shelf life and so is less likely to be affected by nutrient loss than products with longer shelf lives. Both national and international research shows iodised salt can successfully be added to bread. In practice, the salt, and hence iodine content, of commonly consumed bread is not as variable as in breakfast cereals and biscuits.

By increasing the iodine concentration in salt (to the proposed concentration level), a similar outcome can be achieved by mandating the use of iodised salt in bread only, as that previously predicted for fortification of bread, breakfast cereals and biscuits. The amount of iodine added to the food supply is ultimately constrained by the desire to limit the proportion of young children who might exceed the UL.

8.2 Alternative Food Vehicles

8.2.1 Universal Salt Iodisation

As noted in Section 1.7, USI is recommended by the WHO to address iodine deficiency internationally. In submissions to Proposal P230, several public health stakeholders stated a preference for USI, believing it would deliver higher iodine intakes for pregnant and breastfeeding women.

As part of the Draft Assessment for Proposal P230, the impact of replacing salt with iodised salt in *all processed foods*, assuming all discretionary salt was also iodised, was explored.

The Draft Assessment indicated that a similar outcome was achievable by mandating the use of iodised salt in a smaller range of foods. Regardless of the food vehicle, the amount of iodine that can be added to the food supply is constrained by the desire to limit the proportion of young children who might exceed the UL. Therefore, if USI were adopted, the mandated concentration of iodine in salt would be much lower. Hence pregnant and breastfeeding women would not receive substantially more iodine than mandating a higher concentration of iodine for salt in bread.

Further, FSANZ's investigation of USI as an option identified the following issues:

- the iodisation of salt that has a very small or relatively large granule size is not currently technically feasible;
- significant export and import issues would result, including increased costs, enforcement issues and trade restrictions that could potentially result in World Trade Organization (WTO) challenges;
- greatly increased industry costs resulting from the many hundreds of labelling changes that would be required;
- inconsistency with the Council of Australian Governments (COAG) requirement to ensure minimum effective regulation; and
- iodising all or even most of the salt in the food supply would result in minimal choice for consumers.

8.2.2 *Direct Addition*

There is a paucity of evidence as to the impact of the addition of iodine to food other than via salt (Winger *et al.*, 2005). Before such an option could be considered viable more data on the behaviour of iodine added to selected food vehicles would need to become available.

8.2.3 *Milk*

The re-emergence of iodine deficiency broadly correlates with changes to dairy industry cleaning processes. During the 1960s and 1970s, the uncontrolled use of iodophor-containing sanitisers inadvertently raised iodine levels in milk. Tighter controls introduced in the early 1970s produced changes to dairy industry practices. As a result, the iodine content of milk has decreased. While iodophors continue to be used as effective sanitisers in some sections of the dairy industry, their use today is more controlled and measured. Alternatives, such as the cheaper chlorhexidine-based sanitisers, are predominantly used for cleaning processing equipment. Despite this decline, dairy foods still remain an important source of dietary iodine.

During consultations, it was suggested that the dairy industry re-establish their previous cleaning practices using iodophor-containing sanitisers to boost iodine levels in the food supply. However, it would be inappropriate to rely on unpredictable accidental contamination as a strategy to address the re-emergence of iodine deficiency.

8.2.4 *Voluntary MoU Proposal*

Several industry submissions state their opposition to mandatory fortification. In its place industry advocate a voluntary system. They argue that many countries have successfully adopted a voluntary approach to address iodine deficiency. Many countries with voluntary fortification e.g. Switzerland and the USA, that originally were successful in improving iodine status, now find changes in food habits, manufacturing practice and imports/exports, have resulted in decreases in dietary iodine supply.

In response to the Draft Assessment for Proposal P230, the food industry proposed a voluntary iodine fortification scheme. Certain food manufacturers proposed signing a MoU to fortify a range of foods using iodised salt. The foods proposed for the MoU were specific brands of bread, breakfast cereals and biscuits; similar food groups to those selected for mandatory fortification in the Draft Assessment of Proposal P230. However, the nominated foods represented only 15-30% of each market. FSANZ has undertaken dietary intake estimates to assess the level of iodine intake under this voluntary fortification scheme. Assuming iodisation of salt at the current average concentration, this voluntary fortification would be significantly less effective in increasing iodine intakes than the proposed mandatory fortification. Further details can be found at SD10³⁰.

³⁰ SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report*.

9. Dietary Intake Assessment

Although standard international practice calls for population iodine status to be assessed by measuring urinary iodine excretion, for the purposes of this Proposal it was necessary to also assess dietary intakes to: (1) determine potential food vehicles; and (2) establish an appropriate level of fortification. The relationship between dietary intake and urinary iodine concentration is usually linear such that an increase in dietary intake results in an increase in urinary excretion of the same magnitude (Gibson, 2005). Based on the current iodine status of the Australian population as outlined in Section 2.1, a two-to-three-fold increase in MUIC and hence similar increase in mean iodine intake would be consistent with ensuring an adequate intake throughout the general population.

The complete dietary intake assessment, first undertaken as part of Proposal P230, includes New Zealand as well as Australian data. This section of the Report, however, focuses on Australia.

A detailed description of the dietary intake assessment methodology and results can be found in: SD10³¹ – Dietary Intake Assessment Report – Main; SD10 Attachment 1 – Dietary Intake Assessment Methodology; SD10 Attachment 2 – Summary of Fortification Scenarios Considered; SD10 Attachment 3 – Breads and Breakfast Cereals; SD10 Attachment 4 – Universal Salt Iodisation; and SD10 Attachment 5 – Alternative Approaches.

9.1 Sources of Food Consumption Data

Several sources of data were used to estimate the impact of mandatory iodine fortification with iodine in different sections of the Australian population. The food consumption data sources used in the dietary intake assessment are summarised in Table 6. As food consumption survey data for children aged below 2 years were not available for Australia a theoretical diet was established for this group. It is important to include this age group in the assessment because they generally have the smallest range of intakes between the reference points for inadequacy and possible excess and also have high levels of food consumption relative to body weight.

³¹ SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report*.

Table 6: Key Sources of Food Consumption Data Used to Conduct the Dietary Intake Assessment for Australia

Data Source	Data Type	Data Details
1995 Australian National Nutrition Survey	Food consumption data for the general population aged 2 years and over	Second-day adjusted [†] . Specifically considered data for 2-3 year old children.
Theoretical Diet	Children aged 1 year	Average diet for one day. Used in the absence of survey data. Does not provide a distribution of dietary intake.

[†]A second day of dietary intake data can be used to more accurately calculate usual intake. The absence of second day adjustment leads to a broader and less accurate distribution of dietary intakes.

Pregnant and breastfeeding women are an important target group for iodine fortification. There were not enough pregnant and breastfeeding women surveyed in the 1995 Australian National Nutrition Survey (NNS) to allow these two groups to be considered on their own. FSANZ has therefore compared the intakes of all women aged 16-44 years in the NNS, as a proxy for women of child-bearing age, with the reference standards for pregnant and for breastfeeding women. This does not allow for the higher energy, and hence food consumption, recommended during pregnancy and lactation. In particular, it does not include the impact of the general recommendations for extra serves of dairy foods, which are sources of iodine, and the proposed food vehicle bread. However, pregnant women are also advised to avoid certain types of fish (rich in iodine) and other dietary changes may happen. Hence, it is not possible to accurately estimate baseline intakes or predict iodine intakes following fortification for these specific population groups using the NNS data.

The Australian Longitudinal Study of Women's Health collected dietary information from women aged 25-30 years using a food frequency questionnaire. Comparison of pregnant and post-partum women with non-pregnant/not postpartum women showed that pregnant and post-partum women reported eating more bread and had higher estimated iodine intakes. It was also estimated that, after fortification, iodine intakes would continue to be higher in these groups than in the general adult female population (Mackerras *et al*, personal communication, 2008).

9.2 Food Composition Data

Although food consumption data were sourced from the 1995 NNS, the salt and iodine content of foods have been determined using recent data from the following four major sources:

- total diet studies for Australia and New Zealand;
- analytical data for foods sampled in Australia and New Zealand from 2000 to 2005;
- overseas analytical data; and
- recipe calculations.

These data include the most recent food composition data available at the time of the dietary intake assessment. Thus, the dietary intake assessment takes into account both the current natural iodine content and amount of salt added during processing.

9.3 Assessment of Dietary Inadequacy

The proportions of the population groups with dietary iodine intakes below the EAR were assessed and used as an estimation of the prevalence of inadequate iodine intakes.

The prevalence of inadequate nutrient intake can best be assessed by applying the Probability Method to the distribution of usual intakes in the population (NRC, 1986). This method essentially compares the distribution of intakes for a nutrient with the distribution of requirements to yield an estimate of the proportion of the population that has an inadequate intake. An alternative method of assessing inadequate intakes in the population is the EAR Cut-Point Method. This method involves simply calculating the proportion of the population with intakes below the EAR. It is a good estimator of the results of the more complex full Probability Method, if certain conditions are met (Health Canada, 2006) (see SD10³² Attachment 1 for more details). The EAR Cut-Point Method has been used to estimate the prevalence of inadequate intakes in the current document.

The RDI was not used to assess dietary inadequacy because it should not be used to assess intakes of populations (NHMRC, 2006).

The EARs used in this assessment were from the NRVs released in 2006 for Australia and New Zealand (NHMRC, 2006), noting that the EARs for iodine for women who are pregnant and lactating are much higher than for other women of the same age.

9.4 Key Uncertainties in the Dietary Intake Assessment

A full list of the assumptions and limitations inherent in dietary intake assessment can be found at SD10³³ Attachment 1. This section addresses the uncertainties that are specific to this Proposal.

9.4.1 Uncertainties in Relation to Discretionary Salt

There were insufficient quantitative data on discretionary salt use (i.e. table and cooking salt) in the Australian 1995 NNS to enable this to be included in the dietary intake assessment. Therefore, two sources have been used to estimate discretionary salt use based on the amount of salt consumed in processed food. Mattes and Donnelly (1991) reported that 77% of sodium intake in the United States came from sodium added during processing; 11.6% from sodium found naturally in foods; 6.2% from salt added at the table, and 5.1% from salt added in cooking.

³² SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report*.

³³ SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report*.

From these data, it can be calculated that 87% of salt (sodium chloride) came from processed foods and 13% from discretionary uses. More recently, the Food Safety Authority of Ireland (2005) estimated that 65-70% of dietary sodium intake was from manufactured foods; 15% from sodium found naturally in foods; and 15-20% from discretionary salt. Therefore 76-82% of salt (sodium chloride) was derived from processed foods and 18-24% from discretionary uses.

Therefore, in Proposal P230, FSANZ estimated salt intakes using a figure of 18% of total salt coming from discretionary uses and 82% from processed foods. As the quantity from processed food is known for each survey respondent, the quantity from discretionary uses could be calculated. In general, the new approach predicted discretionary salt use of approximately 1 g/day in Australia, with some variation around this value for different age/gender groups.

9.5 Approaches to Dietary Intake Assessment

Two approaches were used when estimating the mean intake and the proportion of people with an inadequate intake of iodine.

9.5.1 Market Weighted Model

The Australian 1995 NNS did not ascertain whether respondents used iodised or non-iodised salt; therefore, this approach factors in the proportion of discretionary salt consumed (as estimated as described in section 9.4.1 above) that is iodised based on sales data. In Australia ~20% of table salt sales are for iodised salt, and this was used to derive a weighted average concentration of iodine in discretionary salt.

9.5.2 Consumer Behaviour Model

The availability of both iodised and non-iodised discretionary salt allows the buyer to choose one or the other. To reflect the potential differences in individual consumer behaviour, two options for discretionary salt were investigated:

- where it was assumed that individuals always select non-iodised salt; and
- where it was assumed that individuals always select iodised salt.

In the dietary intake assessments, 62% of Australians aged 2 years and above were assumed to be consumers of discretionary salt (whether iodised or non-iodised) based on responses to questions in the 1995 NNS. Thirty six per cent of children aged 2-3 years consumed discretionary salt.

The consumer behaviour models assessed iodine intakes for groups of individuals only. Where mean dietary iodine intakes have been presented as a range, the lower number in the range represents where individuals always avoid iodised salt and the upper number in the range represents where individuals always select iodised salt.

A limitation of this model type is that it is not a population estimate but rather gives the upper and lower ends of a range of possible intakes for a group of individuals.

Therefore the market-weighted results lie between the results projected for those who would never choose iodised salt and those who always choose iodised discretionary salt (i.e. the consumer behaviour models). For example, for Australian teenagers aged 14-18 years at baseline, the estimated market-weighted mean intake of iodine is 121 µg/day compared to 114 µg/day and 149 µg/day for those who never and always choose iodised discretionary salt respectively.

9.6 Results of Dietary Intake Assessment

The preferred option is to mandate the use of iodised salt in bread, with salt iodised to an average level of 45 mg iodine per kg of salt, but with no particular quantity of salt to be added to bread specified. This is consistent with the New Zealand Standard. For the dietary intake assessments, iodised salt containing 45 mg iodine per kg of salt was used in breads, assuming 40 mg of iodine per kg of salt remained in the salt of iodine-fortified bread after baking. The iodine concentration in iodised discretionary salt was assumed to be 45 mg iodine per kg salt. For complete results from the dietary intake assessment see SD10³⁴.

9.6.1 Australians Aged Two Years and Over

Currently, just over 40% of Australians aged two years and over are estimated to have inadequate iodine intakes; following fortification this is estimated to drop below 10%.

Current (baseline) mean iodine intakes range between 94 µg/day and 121 µg/day, depending on the population group. Following fortification of bread the estimated mean intakes range between 133 µg/day and 179 µg/day; increasing between 38 µg/day and 58 µg/day depending on the population group.

No-one aged nine years and over is expected to exceed the UL currently or following fortification. Currently, no 4-8 year olds and less than 1% than of 2-3 year olds are estimated to exceed the UL for iodine. Following fortification less 1% of 4-8 year olds, and 6% of 2-3 year olds would exceed the UL for iodine.

Tables 7 and 8 present the proportion of Australians aged two years and over with inadequate iodine intakes and mean intakes respectively.

³⁴ SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report*.

Table 7: Estimated Proportion of Australians' Aged 2 Years and Over with Inadequate Dietary Iodine Intakes at Baseline and Following the Proposed Fortification

Population Group	Proportion of Population with Inadequate Iodine Intakes (%)			
	Market Weighted Model		Consumer Behaviour Model*	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread
2-3 years	16	1	18 – 12	2 – <1
4-8 years	18	1	22 – 12	1 – <1
9-13 years	21	<1	29 – 14	2 – <1
14-18 years	35	4	41 – 16	6 – 3
19-29 years	41	6	47 – 22	9 – 4
30-49 years	47	5	54 – 23	8 – 3
50-69 years	53	5	61 – 22	8 – 2
70 years & above	63	6	72 – 26	9 – 2

* In the consumer behaviour model, the left-hand number in the range is for consumers who never choose iodised discretionary salt and the right-hand number in the range is for consumers who always choose iodised discretionary salt, i.e. salt with a mean iodine concentration of 45 mg iodine/kg salt.

Table 8: Estimated Mean Iodine Intakes at Baseline and Following the Proposed Fortification in Australians Aged 2 Years and Over

Population Group	Mean Intake of Iodine ($\mu\text{g}/\text{day}$)			
	Market Weighted Model		Consumer Behaviour Model*	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread
2-3 years	95	133	93 – 105	130 – 143
4-8 years	94	139	91 – 109	135 – 154
9-13 years	108	160	103 – 128	155 – 180
14-18 years	121	179	114 – 149	172 – 207
19-29 years	119	177	113 – 145	171 – 203
30-49 years	110	166	104 – 133	161 – 189
50-69 years	105	158	98 – 129	152 – 182
70 years & above	96	147	90 – 120	141 – 171

* In the consumer behaviour model, the left-hand number in the range is for consumers who never choose iodised discretionary salt and the right-hand number in the range is for consumers who always choose iodised discretionary salt, i.e. salt with a mean iodine concentration of 45 mg iodine/kg salt.

9.6.2 Women of Child-bearing Age

For the purposes of the dietary intake assessment, women of child-bearing age are assumed to be 16-44 years of age. Results of the assessment are shown in Table 9.

As explained in Section 9.1, it was not feasible to perform a dietary intake assessment based on food consumption survey data from pregnant and breastfeeding women.

Therefore, the intakes of the general population of women aged 16-44 years were compared to the EAR and UL for pregnant and breastfeeding women respectively. Despite these uncertainties, it is clear that the majority of Australian women are unlikely to meet their iodine requirements during pregnancy or lactation. However, following the proposed fortification most women would enter pregnancy after a period of adequate intake, and therefore with iodine stores intact.

At present, 65% of non-pregnant non-breastfeeding Australian women who do not use iodised salt are estimated to have inadequate intakes and would therefore be expected to enter pregnancy in a deficient state.

No women of childbearing age are predicted to exceed the relevant UL for iodine either at baseline or when bread is fortified with iodised salt.

Table 9: Estimate of Inadequate and Mean Dietary Iodine Intakes in Australian Women of Childbearing Age at Baseline and Following Fortification

Population Group	Proportion of Population with Inadequate Iodine Intakes (%)			
	Market Weighted Model		Consumer Behaviour Model*	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread
Women Aged 16-44 years	59	9	65 – 31	13 – 6
Compared to EAR for Pregnant Women	93	71	95 – 82	75 – 45
Compared to EAR for Breastfeeding Women	97	88	98 – 93	90 – 71
Mean Intake of Iodine ($\mu\text{g}/\text{day}$)				
Women Aged 16-44 years	100	146	94 – 122	140 – 169

* In the consumer behaviour model, the left-hand number in the range is for consumers who never choose iodised discretionary salt and the right-hand number in the range is for consumers who always choose iodised discretionary salt, i.e. salt with a mean iodine concentration of 45 mg iodine/kg salt.

9.6.3 Children Aged One Year

The available dietary survey from Australia did not include children aged less than two years. Therefore a theoretical diet was used to estimate iodine intakes for Australian children aged one year.

The theoretical diet did not include any discretionary salt but was analysed with, and without, inclusion of one 226 g serve of Formulated Supplementary Foods for Young Children (FSFYC); commonly known as toddler milk. As the theoretical diet was based on a single consumption value for each food, there is no distribution of intakes. The 95th centile was estimated, by using a simple equation based on the mean intake, as an indication of how high iodine intakes might be in some children (see Table 10 for details). There is a substantial improvement in mean intake with fortification, although the impact on the proportion of the population group with inadequate intakes cannot be quantified. However, the UL for children this age is 200 µg/day, suggesting that some children may have intakes above the UL.

Table 10: Estimated Mean and 95th centile Dietary Iodine Intakes of Australian Children Aged 1 Year Based on a Theoretical Diet

Population Group	Mean Intake of Iodine (mg/day)		95 th Percentile of Iodine Intake	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread*
Without FSFYC*	79	95	198	238
With FSFYC	92	107	230	268

Note: no discretionary salt, iodised or otherwise, is included in the above models

* Formulated Supplementary Foods for Young Children

9.7 Dietary Intake Assessment Conclusions

In the general population aged 2 years and older, the proposed fortification is predicted to reduce the prevalence of inadequate intakes from 43% to less than 5% overall. Following fortification the proportion of children aged 2-13 years with inadequate intakes is estimated to drop below 1%.

Although the proposed mandatory fortification will increase the iodine intakes of pregnant and breastfeeding women by an important and useful amount, it is likely that a high proportion of these groups will still have inadequate intakes.

The concentration of iodine in salt is constrained by the desire to limit the potential for intakes to exceed the UL, especially in young children. Increasing the concentration of iodine in salt further to reduce the prevalence of inadequate intakes in the population generally will increase the proportion of young children who exceed the UL.

10. Assessment of the Health Outcomes from Mandatory Iodine Fortification

This section outlines the anticipated improvement in health and performance of the Australian population following the proposed mandatory fortification of the food supply with iodine. It addresses the reduction in iodine deficiency-related mental impairment in children and thyroid disease in the adult populations. The section also addresses the implications of a small proportion of young children exceeding the UL.

10.1 Expected Reductions in Iodine Deficiency and Impact on Health

10.1.1 Children and Adolescents

Following mandatory fortification, the iodine intake of Australian children aged 2-13 years is predicted to be below the EAR in less than 1% of children. One year-olds are also likely to have an adequate iodine intake. As a result the risk of children having impaired hearing, fine motor control, reaction times, visual problem solving, abstract reasoning, verbal fluency, reading proficiency, spelling, mathematical skills, or general cognition due to poor iodine status during childhood will be substantially reduced. Where one or more of these impairments are already present and caused by iodine deficiency a substantial improvement would be expected within several weeks to several months of fortification.

This is assuming that the impairment(s) arose due to iodine deficiency after the age of 2-3 years. Those impairments that arose earlier will not be reversed, but will be prevented in future generations.

In those aged 14-18 years approximately 4%, predominantly female, would fall below the EAR for iodine intake. The specific impact of iodine deficiency and the outcome of alleviating it in this age group are largely unknown. The positive outcome predicted is a reduction in the risk of goitre and other negative changes to the thyroid predisposing to thyroid disease later in life.

10.1.2 Women of Child-bearing Age

The proposed fortification would substantially decrease the proportion of 16-44 year old women with inadequate iodine intakes. The health implications for this include a reduction in the risk of iodine deficiency-related goitre and future thyroid problems.

During pregnancy the majority of women would still not achieve iodine intakes consistent with the elevated NRV requirements. However, the anticipated increase in iodine intakes raises the likelihood of iodine stores being replete before pregnancy, allowing a portion of the added iodine requirement during pregnancy to be met by iodine stores. Though the situation would still not be ideal, it would reduce the risk of neurological impairment in children born after introduction of mandatory fortification.

10.1.3 General Adult Population

The proposed fortification would eliminate iodine deficiency throughout most of the adult population. A reduction in the risk of adverse changes in the thyroid predisposing to thyroid disease would be the main expected outcome. Addressing iodine deficiency now rather than later would reduce risk of iodine-induced hyperthyroidism, which increases with duration of deficiency, following any future increases to iodine intake. An improvement in the prognosis of thyroid cancer is also anticipated.

10.2 Potential Adverse Effects of Raising Population Iodine Intake in Australia

Following Draft Assessment of Proposal P230, FSANZ reconvened the Iodine Scientific Advisory Group³⁵ to assist in addressing specific concerns raised in submissions. This group consists of experts in thyroid disease, including thyroid cancer treatment, as well as specialists in iodine deficiency disorders and iodine nutrition. We also conducted extensive reviews of available scientific and medical literature and guidelines to assess the safety concerns of increasing the iodine content of the food supply. The relevant findings are provided below. More detail is provided in SD8³⁶ and 9³⁷.

10.2.1 International Experience Following Fortification

Denmark has recently shifted from voluntary iodine fortification of salt to mandatory fortification of household and commercial bread making salt (Pedersen *et al.*, 2006). Cases of hyperthyroidism were systematically recorded in two areas, one originally mildly deficient the other moderately deficient, prior to and during voluntary and subsequent mandatory fortification. There was an initial rise in the incidence of hyperthyroidism after voluntary fortification from 1.028-1.228/1000/year, a further rise to 1.407/1000/year following mandatory fortification, and a small decline to 1.387/1000/year 3-4 years following the introduction of mandatory fortification. The region with moderate iodine deficiency accounted for the bulk of the increase in hyperthyroidism.

In 1990 Austria doubled its level of table salt iodisation from 7.5 to 15 mg/kg to address persistent mild iodine deficiency (Mostbeck *et al.*, 1998). Extensive monitoring revealed an initial increase in the incidence of hyperthyroidism. After five years, annual incidence had declined but was still above baseline.

Switzerland has voluntary iodisation of salt with the bulk of salt used in local food manufacture being iodised (Zimmerman *et al.*, 2005). Following an increase in the iodisation concentration from 7.5 mg iodine/kg salt to 15 mg/kg, this shifted the surveyed population from mild deficiency to adequate intake (Baltisberger *et al.*, 1995).

³⁵ For a list of members refer to:

<http://www.foodstandards.gov.au/foodmatters/fortification/iodinescientificadvi3251.cfm>

³⁶ SD8: FSANZ (2008) *Nutrition Assessment Report*.

³⁷ SD9: FSANZ (2007) *Safety Assessment and Risk Characterisation Report*.

There was an initial 27% rise in the incidence of hyperthyroidism followed by a steady decline, with the incidence of hyperthyroidism eight years after increased iodisation being 44% lower than the incidence before iodisation.

Though international experience varies with respect to length of monitoring, the findings indicate that:

- dealing with iodine deficiency when it is still mild results in smaller increases in cases of hyperthyroidism than addressing iodine deficiency when it is moderate;
- initial increases in cases of thyroid disorders are followed by a decline; and
- addressing iodine deficiency with fortification is likely to result in long-term positive outcomes for population thyroid health.

10.2.2 Upper Levels of Intake for Children

Following introduction of mandatory iodine fortification, it is estimated that a small percentage of young children may exceed the UL for iodine. The magnitude of the exceedance depends on the amount of discretionary iodised salt in the diet. The level of exceedance is greatest for 2-3 year old children, especially if iodised discretionary salt is consumed, but disappears in later childhood. No other age groups are estimated to exceed the UL.

In considering if the estimated intakes for young children are likely to represent a health and safety risk, it is important to remember age-specific ULs are based on findings in adults and are extrapolated to children based on relative metabolic body weights. They are not absolute thresholds for toxicity but rather represent intake limits incorporating a comfortable margin of safety. Exceeding the UL, although not desirable, does not automatically lead to an adverse outcome. The maximum estimated intake, approximately 300 µg per day, still remains within the one-and-a-half fold margin of safety given the UL for 1-3 year olds is 200 µg per day.

The adverse endpoint on which the UL for iodine is based is sub-clinical hypothyroidism. In most individuals, a state of sub-clinical hypothyroidism represents a transient, adaptive response to increased levels of iodine. Usually, this state does not persist, even if the excess intake continues. It is worth noting that iodine intakes as high as 1350 µg per day in toddlers have been reported without apparent harm (Park *et al.*, 1981); this is over four times the highest predicted intake following mandatory fortification. Thus it is unlikely that those children exceeding the UL would be adversely affected.

10.2.3 Impact of Iodine Fortification on those with Existing Thyroid Conditions

10.2.3.1 Thyroid Cancer Patients

Patients with thyroid cancer may be advised to consume a low iodine diet a few weeks prior to treatment with radioiodine (Cooper *et al.*, 2006; Royal College of Physicians and British Thyroid Association, 2002). This restriction of dietary iodine is to maximise the uptake of radioiodine by the thyroid. Similar advice may be given to patients prior to receiving a thyroid scan utilising radioiodine containing contrast media.

Not all clinicians will advise patients to restrict iodine prior to treatment or scans, as clinical practices vary. The decision to restrict iodine is likely to be dependent on the patients' iodine status. To be compliant with any advice to restrict iodine intake, patients may need to avoid iodised medication, foods naturally high in iodine and iodine fortified products for the period of restriction, typically 2-3 weeks prior to being given radioiodine.

10.2.3.2 Individuals with existing Hyperthyroidism including Graves' Disease

Those individuals with existing hyperthyroidism, including Graves' disease, are more likely to be sensitive to increases in iodine intake than the rest of the population (AAACE Thyroid Taskforce, 2002, Topliss *et al.*, 2004). These groups are often advised to avoid medication, supplements and foods high in iodine such as Lugol's iodine, some cough medicine, iodine containing contrast media, kelp supplements, seafood and kelp/seaweed. A single dose or serve of these products usually contains hundreds of micrograms to several milligrams of iodine. The proposed mandatory fortification on the other hand is estimated to lead to an average increase in iodine intake of approximately 45-66 µg per day; an amount comparable to that found in approximately one oyster, or three eggs. A slice of bread would contain approximately 10-25 µg of iodine, depending on the size of the slice and the amount of iodised salt added.

Those with thyroid disease are likely to be under medical care for their condition. Further, the proposed increase to iodine intake is modest and therefore unlikely to cause harm even in the majority of sensitive individuals.

10.2.3.3 Individuals with Thyroiditis

For individuals with thyroiditis e.g. Hashimoto's disease, high intakes of iodine may exacerbate the condition, producing either sub-clinical or clinical hypothyroidism (Akamizu *et al.*, 2007; Wiersinga, 2004). The effect is usually transient once the high iodine intake is discontinued, although some individuals may require transient thyroxine replacement therapy.

Although the impact of iodine supplementation programmes on the occurrence of clinically significant iodine-induced thyroiditis has not been extensively studied, it appears that such effects are typically associated with iodine intakes of 500 µg/day or greater (Wiersinga, 2004). Given the proposed modest increase in iodine intakes through mandatory fortification, a significant increase in the incidence of iodine-induced thyroiditis among the Australian population is considered unlikely.

11. Risk Assessment Summary

There is strong evidence, from studies and surveys measuring urinary iodine excretion, showing widespread re-emergence of mild iodine deficiency in south eastern Australia. As south eastern Australia is the most densely populated region in Australia a high proportion of the population is at risk of iodine deficiency.

The WHO, ICCIDD, and UNICEF recommend iodisation of food salt as the primary means of addressing widespread iodine deficiency. Internationally various legislative approaches to increasing iodine content of the food supply using iodised salt have been used with a good degree of success and safety.

The proposed mandatory fortification with iodine would reduce the risk of children having neurological impairments³⁸. In adults, fortification would reduce the risk of goitre and iodine-induced hyperthyroidism.

The iodine intake following fortification would still not be sufficient for the majority of women during pregnancy or lactation. However, following the proposed fortification most women would enter pregnancy after a period of adequate intake, and therefore with iodine stores intact. These stores could then contribute towards iodine requirements during pregnancy and lactation.

A small proportion of children aged 1-3 years and an even smaller proportion of those aged 4-8 years may exceed the UL. Although it is generally not desirable to exceed the UL, in this case the estimated worst-case iodine intakes for young children are calculated to be below a level at which adverse effects may be observed. This, and the reversible nature of the endpoint on which the UL is based, means such intakes are unlikely to represent a health and safety risk to young children, though a reduced margin of safety exists.

Mandatory iodine fortification would contribute considerably to alleviating the consequences of existing deficiency, and prevent it from becoming even more widespread and serious in the future. Perhaps most importantly it would prevent mothers from becoming progressively more iodine deficient through successive pregnancies, further increasing the risk of children being born with serious impairment from iodine deficiency.

RISK MANAGEMENT

12. Identification of Risk Management Issues

The following section identifies risks, other than the public health and safety risks outlined in the Risk Assessment Section, and discusses issues relevant to mandating the replacement of non-iodised salt with iodised salt in bread for Australia. These issues include social, technical and economic considerations. FSANZ will consider the totality of the identified risks and issues when developing appropriate risk management strategies which are outlined in Section 15.

³⁸ Including poorer verbal and information processing skills, lower scores of perceptual, mental and motor assessment, and potentially attention deficit and hyperactivity disorders resulting from iodine deficiency in mothers. Mandatory fortification would also reduce the risk of deficits in fine motor control, visual problem solving, and abstract reasoning as well as reading, spelling and mathematical skills resulting from iodine deficiency in later childhood.

12.1 Food Vehicle Selection

12.1.1 *Removal of Biscuits as a Food Vehicle for Iodine Fortification*

Bread, biscuits and breakfast cereals were initially selected as food vehicles for iodine fortification because approximately 95 % of salt intake from cereal-based foods is derived from these three food categories. However, of these three categories, biscuits contributed the least to increasing the population's iodine intake, but posed the greatest impost on trade with respect to both imports and exports.

The removal of biscuits as a food vehicle from Proposal P230 eliminated nearly all trade related costs, and therefore resulted in considerable cost savings. It also significantly reduced upfront costs and ongoing costs for industry, such as those for machinery, testing and labelling.

In deciding to omit biscuits as a food vehicle for iodine fortification, FSANZ also considered:

- the variable salt content of different biscuit categories;
- concerns that fortification would legitimise biscuits as being a 'health' food;
- reducing the regulatory burden with respect to the number of products to monitor; and
- uncertainty surrounding the definition of 'biscuit'.

12.1.2 *Removal of Breakfast Cereals as a Food Vehicle for Iodine Fortification*

During the development of Proposal P230, FSANZ was alerted to a potential technical difficulty for one of Australia's leading breakfast cereal manufacturers. This manufacturer indicated that their particular salt addition method, involving a brine system, may deliver inconsistent amounts of iodine to their products. Subsequent testing confirmed this technical difficulty and it became apparent that considerable time would be needed to resolve this issue.

As a consequence, FSANZ elected to remove breakfast cereals as a food vehicle for iodine fortification. If monitoring reveals insufficient iodine in the food supply following mandatory fortification of bread, FSANZ will reconsider breakfast cereals as an additional food vehicle.

As part of any future consideration, the possibility of directly adding iodine to breakfast cereals could be explored, providing appropriate technical data were available for consideration. Direct addition is a novel approach, not having been extensively tested, and so it will require significant research and development time prior to implementation. If feasible, direct addition would be independent of the amount of salt added to a given breakfast cereal, and allows a more consistent and predictable amount of iodine to be added across products.

In the interim, it was preferable to commence an iodisation program using bread in the first instance. To compensate for the removal of biscuits and breakfast cereals as food vehicles, the level of iodine required in salt was increased from that initially proposed; giving comparable dietary intake estimates.

12.1.3 Selection of Bread as a Food Vehicle for Iodine Fortification

FSANZ's dietary intake estimates indicate that 88% of Australians aged two years and above, consume bread.

Bread is a nutritious food that is typically made domestically for the local market, so it is little affected by special concerns about imports and exports. Bread has a short shelf life and so is less likely to be affected by technological issues. Both national and international research shows iodised salt can successfully be added to bread. In practice, the salt content, and hence the iodine content, does not vary significantly across the market leaders in bread. In contrast, the salt content of different biscuits and breakfast cereal categories varies considerably.

12.1.4 Definition of Bread

It is intended that non-iodised salt will be replaced with iodised salt in bread. Bread is defined in Standard 2.1.1 – Cereals and Cereal Products as:

the product made by baking a yeast-leavened dough prepared from one or more cereal flours or meals and water.

This definition encompasses yeast-leavened bread made from all cereals flours, not solely wheat flour. It includes foods such as bread, bread rolls, buns, English muffins, fruit bread, yeast-leavened flatbread, and breadcrumbs and stuffing made from yeast-leavened bread.

Yeast-free 'breads' will not be required to replace salt with iodised salt, as these 'breads' do not meet the above definition. However, iodised salt can be added to any food by virtue of the voluntary permissions that exist in the Code. Manufacturers of yeast-free 'breads' may choose to use iodised salt.

During consultations on Proposal P230, the issue was raised as to whether all salt added to bread needed to be iodised, including coarse salt added as toppings and seasonings to bread, such as focaccia. Technical difficulties for ensuring even iodine distribution in coarse crystallised rock structures were noted.

It is the intention of this Proposal that only bread dough will be required to contain iodised salt in place of non-iodised salt, unless the bread dough is represented as 'organic'. Salt used as a topping on bread will not be required to be iodised.

12.1.4.1 Frozen Dough

A recent development in bread production is the growth in the frozen dough and par-baked products market.

Whereas par-baked products are partially cooked bread products, frozen dough is on sold in a frozen state for subsequent proofing and baking by the purchaser. Frozen dough is produced for both domestic and export markets. It is widely used in fast food outlets providing bread 'baked on the premises' and also used in some in-store supermarkets. Although frozen dough does not meet the definition of bread, dough destined for the Australian market will be required to use iodised salt as it will be sold and consumed as bread.

FSANZ will prepare an User Guide to provide further clarification as to the scope of bread included in the fortification scenario.

12.2 Appropriateness of Replacing Non-iodised Salt with Iodised Salt in Bread

As outlined in Section 8, the suitability of using iodised salt as the food vehicle has been assessed against international criteria. The Risk Assessment concludes that the proposed fortification presents minimal risk of excessive iodine consumption to the population. An assessment of the remaining criteria in selecting a suitable food vehicle is outlined below.

12.2.1 Stability of Iodised Salt

Studies on the stability of iodised salt using potassium iodate, the form used by the Australian salt industry, show that when stored in polyethylene bags for two years there was no significant loss of iodine (see SD11³⁹).

Generally, salt is a very stable carrier for iodine. The permitted forms of iodine, as prescribed in Standard 1.1.1, are potassium iodide or potassium iodate or sodium iodide or sodium iodate.

Limited data exist on the likely iodine losses expected as a result of different food processing situations. It has been estimated that losses in the magnitude of 6-20% can occur during processing of cereal-based foods, see Supporting Document 7³⁹. Data derived from the Tasmanian fortification program showed iodine losses of approximately 10% in baked bread. Minimal loss of iodine has also been reported in iodised salt subjected to heating (Bhatnagar, 1997). On the basis of the information available, FSANZ has estimated that an average loss of 10% should be accommodated in the fortification range to account for any expected losses in processing. This estimated loss was factored into the dietary intake assessment.

12.2.2 Bioavailability of Iodine

The absorption of iodine is considered to be greater than 97% after an ingested dose of soluble iodide salts (Gibson, 2005). As part of the Tasmanian interim fortification intervention, a dietary trial was undertaken to ensure that iodised salt in bread could deliver predicted amounts of additional iodine. The trial, involving 22 participants, concluded that the median 24-hour urinary iodine excretion increased by 14 µg per slice of iodised bread consumed.

³⁹ SD11: FSANZ (2007) *Food Technology Report*.

This was consistent with the amount predicted from the dietary intake assessment and indicates that the consumption of iodised bread resulted in the predicted increase in additional iodine (Seal, 2007).

12.2.3 Economic Feasibility of Iodised Salt

The Australian salt industry indicated that the iodisation of salt would result in only a small price increase. The Cost Benefit Analysis (see SD4⁴⁰), states that production related costs, such as the cost of iodine and the analytical testing would add approximately 10% to the overall cost of salt to the food industry. Salt iodisation is internationally recognised as highly cost effective (WHO FAO, 2006).

12.2.4 Centralised Production Allowing for Quality Control

Cheetham Salt is the major supplier of salt to the bread making industry in Australia. Cheetham Salt's associate companies include Salpak throughout Australia and Western Salt Refinery in Western Australia. Cheetham Salt distributes salt throughout Australia, South East Asia and the Pacific Region. These companies have in place appropriate analytical testing procedures and routinely monitor levels of salt iodisation.

12.2.5 Conclusion

On the basis of the above considerations and those outlined in the risk assessment, it is concluded that the replacement of non-iodised salt with iodised salt in bread is the preferred food vehicle for delivering additional amounts of iodine to the Australian food supply.

12.3 Technical and Industry Considerations

12.3.1 Industry Capacity for Salt Iodisation

In some instances, additional machinery and equipment will be needed to expand outputs. Currently iodised salt is manufactured at a number of sites in Australia: Cheetham Salt operates six refineries and Western Salt Refinery operates one. The increased demand for iodised salt and the associated transport costs may require additional sites to be established. However, salt manufacturers have advised that this could be accommodated within the proposed implementation timeframes.

12.3.2 Appropriate Salt Iodisation Range

Process variations occur during the manufacture of iodised salt. This was acknowledged during development of Proposal P230 when a 'working range' of ± 10 mg of iodine per kg of salt was recommended to compensate for this variation.

⁴⁰ SD4: Access Economics (2006) *Cost benefit analysis of fortifying the food supply with iodine*. Report commissioned by FSANZ.

During consultations, one of the leading salt manufacturers in Australia indicated that a salt iodisation range of 35-55 mg/kg salt is difficult to consistently achieve and requested this range be widened to 25-65 mg/kg salt (the current salt iodisation range). Iodine test samples, provided by the manufacturer, showed a mean close to the mid-point of the current range (45 mg/kg salt), with nearly all samples falling within this wider range (± 20 mg of iodine per kg of salt).

FSANZ has elected to adopt the wider range of 25-65 mg iodine per kg of salt (± 20 mg), as discussed in Section 15.3.2. This range is consistent with the current voluntary permission for salt iodisation as specified in Standard 2.10.2 and the mandatory iodine fortification Standard for New Zealand.

12.3.3 *Technological Feasibility of Adding Iodised to Bread*

Adding iodised salt to bread has shown to be technically feasible in a number of countries, including the Netherlands (Brussaard *et al.*, 1997), Denmark (Rasmussen *et al.*, 1996), and in Tasmania (Seal, 2007). As outlined in SD11⁴¹, iodised salt has been successfully used in a variety of foods, including bread. With few exceptions, the use of iodised salt has not adversely affected the flavour, colour or texture of the product. These exceptions involved highly acidic and pickled foods using very high concentrations of iodine, which are not relevant to the proposed fortification scenario.

During consultations, it was noted that one New Zealand bread company used brine as a method of salt addition. Given the technical difficulty associated with brine use as noted by the breakfast cereal industry (see Section 12.1.2), FSANZ was asked to assess the feasibility and safety of adding iodised salt to bread using a brine solution.

FSANZ engaged an independent consultant, Prof. Ray Winger of Massey University, to assist in the assessment of this issue (see SD12⁴²). The key findings of this investigation are:

- the addition of iodised salt as a dry ingredient directly to the product (dough) has no perceived technological issues;
- the use of brine solutions is used in some manufacturing operations in both Australia and New Zealand;
- provided the iodised salt is completely dissolved, the addition of brine to dough is unproblematic, and iodine addition can be expected to be at least as effective as dry salt addition.

Professor Winger's report notes that there are generally no *technological* issues associated with adding iodised brine solutions to bread. However, the report does highlight the potential difficulty for at least one bakery in adjusting their process line to manufacture both export products without iodine and domestic bread with iodine.

⁴¹ SD11: FSANZ (2007) *Food Technology Report*.

⁴² SD12: Winger, R. J. (2007) *Technological issues with salt brine addition of iodine to foods*. Report commissioned by FSANZ.

12.3.4 Labelling

Under the Code, bread manufacturers will be required to list 'iodised salt' in the ingredient list on the product label. Products exempted from this requirement include unpackaged bread and products with compound ingredients⁴³ (containing iodised salt) that comprise less than 5% of the food, for example bread crumbs used as an ingredient in a food.

If breadcrumbs contain iodised salt and make up greater than 5% of the product then 'iodised salt' must be listed in the ingredient list. However, an accurate quantification of these labelling costs was not possible and so has not been included in the Cost Benefit Analysis. While some crumbs are made from returned bread, it appears that the majority are purpose-made and so don't meet the definition of 'bread'. As such, purpose-made crumbs would not be required to use iodised salt in place of non-iodised salt and so label changes would not be necessary. By virtue of the voluntary permissions, companies could choose to add iodised salt in their purpose-made crumbs if they so wished but would then need to include 'iodised salt' in the ingredient list.

Labelling modifications to include 'iodised salt' in the ingredient list will incur costs for manufacturers. It is acknowledged that parallel introduction of mandatory iodine fortification with folic acid fortification will provide cost savings for industry.

12.3.5 'Organic' Bread

Under the Australian fair trading legislation, food labelling or promotional claims must be factually correct and not misleading or deceptive⁴⁴. It is the opinion of the Australian Competition and Consumer Commission (ACCC) that the use of the term 'organic' in relation to fortified foods could mislead consumers into believing that products had been produced naturally and this would risk breaching the Australian fair trading legislation.

Consistent with the New Zealand Only Mandatory Iodine Fortification Standard, FSANZ proposes an exemption for bread that is represented as 'organic'. This approach does not require definition of 'organic' under the Code and is consistent with the exemption from mandatory folic acid fortification for bread-making flour represented as 'organic' under Standard 2.1.1 – Cereals and Cereal Products. During consultations, there was general support for exempting bread represented as 'organic'. This will allow manufacturers of organic bread to follow existing organic practices and standards in Australia. In addition, the exemption provides an additional element of choice for consumers wishing to avoid fortified bread.

Although a number of submitters to Proposal P230 supported an exemption for organic bread, some public health and government submitters were concerned that consumers of only organic bread will not receive the benefits from mandatory iodine fortification.

⁴³ A compound ingredient means an ingredient of a food which is itself made from two or more ingredients. Standard 1.2.4 of the Code requires the components of a compound ingredient to be labeled where the amount of compound ingredient in the food is 5% or more.

⁴⁴ *Trade Practices Act 1974*, State and Territory Fair Trading Legislation and *Fair Trading Act 1986*.

FSANZ recognises that consumers of organic bread will require specific targeted messages on alternative sources of iodine. This group has been identified in the Communication and Education Strategy (see SD13⁴⁵).

12.4 Consistency with Ministerial Policy Guidance

As noted in Section 1.8, in considering mandatory fortification as a possible regulatory measure, FSANZ must have regard to the Ministerial Council's Policy Guideline on fortification (see SD7⁴⁶). 'Specific Order' Policy Principles 1 and 2 have been considered by AHMAC and advice provided to FSANZ. Consideration of the other 'Specific Order' Policy Principles 3, 4 and 5 are discussed below.

12.4.1 Consistency with Australian National Nutrition Guidelines

The Dietary Guidelines for Australians (NHMRC 2003a, 2003b) promote eating plenty of cereals including bread with particular emphasis on wholegrain varieties. Therefore, the selection of a broad range of breads as the preferred food vehicle is consistent with, and supports, the current nutrition guidelines and healthy eating messages.

The Dietary Guidelines for Australian adults (NHMRC, 2003a) and children and adolescents (NHMRC, 2003b) also recommend choosing foods low in salt. The quantity of salt is not being mandated but simply that any salt added to bread dough must be iodised. This option is not intended to promote increased salt intake as iodised salt will replace non-iodised salt currently used in the manufacture of bread. Although salt is the primary carrier for adding iodine to bread, education messages will emphasise bread as a source of iodine, rather than salt.

12.4.2 Safety and Effectiveness

FSANZ has identified the food vehicle and fortification level to deliver effective amounts of iodine to the target population. This amount has been constrained by the desire to ensure significant proportions of the population, especially children, do not exceed the UL.

When developing Proposal P230, some submitters questioned the relevance of the UL for young children and urged FSANZ to ask the National Health and Medical Research Council (NHMRC) to reconsider the level. FSANZ wrote to the NHMRC regarding this issue and were advised that it is NHMRC policy to review publications every five years or earlier, if the evidence supports this. The UL for iodine deficiency for children aged 2-3 years will be considered when the *Nutrient Reference Values for Australia and New Zealand (NRVs)* (2006) is next reviewed. Until the UL is reviewed, FSANZ will continue to use this reference health standard as a guide to establish the amounts of additional iodine that can be safely added to the food supply.

⁴⁵ SD13: FSANZ (2008) *Communication and Education Strategy*.

⁴⁶ SD7: The Australia and New Zealand Food Regulation Ministerial Council Policy Guideline Policy Guideline Fortification of Food with Vitamins and Minerals.

12.4.3 Additional Policy Guidance

The Policy Guideline also provides additional policy guidance in relation to labelling and monitoring. Consideration of these policy matters are discussed elsewhere in Section 15.2 – Labelling and Information Requirements and Section 21 – Monitoring.

12.5 Consumer Issues

The mandatory requirement to replace non-iodised salt with iodised salt in bread raises a number of important concerns from the perspective of consumers. These include:

- choice and availability of non-iodised bread;
- awareness and understanding of fortification with iodine;
- impacts of mandatory fortification on consumption patterns; and
- labelling and product information as a basis for informed choice.

In understanding the impacts on, and responses of, consumers FSANZ has drawn upon relevant consumer studies and literature regarding mandatory fortification, as well as the more general literature regarding the factors that influence health-related attitudes and behaviours to food.

A range of psycho-social and demographic variables influence health-related attitudes to food, for example age (Kearney and Gibney *et al.*, 1997; Childs and Poryzees, 1988; Worsley and Skrzypiec, 1998), gender (Worsley and Scott, 2000), income (Childs and Poryzees, 1988), values (Ikeda, 2004) and personality (Cox and Anderson, 2004). Accordingly, the response to the requirement to replace non-iodised salt with iodised salt in bread is unlikely to be uniform, but rather will be mediated by the particular circumstances of individuals and the communities within which they live. Attitudes and responses to mandatory fortification are also likely to vary within groups and over time.

The difficulty of assessing the likely responses of consumers to mandatory fortification is further exacerbated by a lack of specific studies exploring likely consumers' responses. Some evidence may be drawn from experiences in other fortification scenarios such as fortification of bread-making flour with folic acid (FSANZ 2006). The Tasmanian (interim) Iodine Supplementation Program also provides some evidence of consumer response to the widespread fortification of bread with iodised salt (Seal, 2007).

A recent representative survey of Australia and New Zealand adults suggests that the use of iodised salt in foods is not a concern for the majority of adults. Only 9% of Australians nominated the use of iodised salt in foods as a concern from a prompted list (TNS, 2007).

12.5.1 Choice and Availability of Non-Iodised Products

The mandatory requirement to replace non-iodised salt with iodised salt in bread is expected to reach a large proportion of the Australian population. Some individuals may choose to avoid iodised products.

The availability of some salt-free bread options or organic bread may provide non-fortified options for those who choose them. Additionally, ingredient labelling on packaged foods will provide information for consumers.

The Tasmanian (interim) Iodine Supplementation Program was well received by the community (Seal, 2007). The communication strategy presupposed community concern and the public launch and media associated with the program were used to disseminate information about iodine and the impact of the use of iodised salt in bread. Following the launch of the program, only a handful of public inquiries were received and these individuals were readily reassured (Seal, 2007).

In other fortification scenarios, consumer research has found varying levels of support. In New Zealand studies on the fortification of bread making flour with folic acid, the majority of participants were opposed (Brown, 2004; Hawthorne, 2005). This opposition was primarily based on strong support for individual rights rather than any specific concerns regarding folic acid fortification. The level of stated opposition for mandatory requirements to replace non-iodised salt with iodised salt in bread is likely to be similar to that found for mandatory folic acid. However, the experience in the Tasmanian (interim) Iodine Supplementation Program suggests that in practice consumers may show little opposition.

As part of its deliberations over folic acid fortification, the United Kingdom Food Standards Agency (UKFSA) commissioned two pieces of research to explore consumer responses to various options (Forum Qualitative, 2007; Define Research & Insight, 2007). Four options were explored, including:

1. continue with current Government advice;
2. run a public education campaign to encourage women to take folic acid supplements;
3. encourage food companies to fortify more foods with folic acid on a voluntary basis; and
4. introduce a legal requirement for flour to be fortified with folic acid.

The first piece of research used a two-stage deliberative approach with workshops representative of the general public. The deliberative approach provides opportunities for participants to be given information about the risks and benefits of each option, and provides opportunities for participants to reflect and query the information in forming their views. The second piece of research focused on low-income women living in deprived communities to understand this group's views on lifestyle changes during pregnancy (e.g. stopping smoking and drinking alcohol, taking supplements, healthy eating). The research sought their responses to four options using in-depth interviews and focus groups to better understand the likely efficacy of alternatives to fortification that required behaviour change.

Both pieces of research found support for the mandatory fortification option. Among the general population sample nearly half the participants supported the mandatory option, as did the majority of women of lower socio-economic communities.

Initially among the general population sample, there were low levels of support for mandatory options; however, as the deliberative process continued and participants were provided with evidence and information there was a change from supporting a public education campaign to the mandatory fortification option. Among women of lower socio-economic communities options requiring behaviour change, such as healthier diets, were not viewed as being efficient. Behaviour change was viewed as difficult to encourage and not likely to take place and thus mandatory fortification was preferred. Were mandatory fortification to be introduced the majority of participants would be accepting and would not change their consumption behaviour. A minority of participants suggested they would seek non-fortified alternatives.

Exposure to mandatory fortification is also likely to impact on the level of support for such measures. In Canada, there was significant change between the public response to thiamin fortification in 1930s and 1940s and the response to folic acid fortification in the 1990s. The shift in response has been linked to a growing acceptance of fortification and of technological solutions (Nathoo *et al.*, 2005).

12.5.2 Awareness and Understanding of Fortification with Iodine

Given the lack of data about the response of consumers to iodine fortification, FSANZ has assumed that levels of awareness and knowledge would be no greater than those exhibited for folic acid fortification. Accordingly there are likely to be low levels of awareness of the need and purpose of iodine fortification among the general population (see Hawthorne, 2005). As with folic acid fortification, women are likely to have higher levels of awareness and understanding than men. Parents and guardians are a major determinant in the food choices of children and ensuring their awareness and understanding of the importance of adequate dietary iodine to the cognitive development of young children is important.

While there is likely to be a link between awareness and understanding and the level of support for mandatory fortification, the link may not be simple nor in expected directions (Wilson *et al.*, 2004).

As part of the monitoring program for mandatory iodine fortification, it is proposed that the level of consumer awareness and understanding of the mandatory requirement to replace non-iodised salt with iodised salt in bread will be monitored.

12.5.3 Impacts of Mandatory Fortification on Consumption Patterns

The potential for opposition to mandatory fortification raises a concern that consumers may change their consumption patterns to avoid fortified products. The limited evidence available suggests that this is unlikely.

For example the recent consumer research by the UKFSA suggests that majority of consumers would be accepting of fortified product and would not change their consumption behaviour, though a minority may seek non-fortified alternatives (Forum Qualitative, 2007). Additionally some individuals may consume less of the fortified food categories. A key element here is the extent to which any opposition is based on a notion of individual choice rather than other concerns such as health and safety.

As parents and guardians are a key determinant of the food choices in children their understanding of iodine fortification may impact on fortified products reaching this segment of the target audience. Parents may be particularly cautious about the foods they provide young children, and food choices that limit salt intake or limit 'additives' in general may limit the effectiveness of mandatory fortification. The provision of information and advice about the role of iodine in the development of young children through appropriate networks will be important.

There is also a potential that some pregnant or breastfeeding women may feel that they will receive enough iodine through fortification and not seek further supplementation. Public health campaigns and advice from medical practitioners will continue to be important mechanisms to ensure these women receive enough dietary iodine.

There may be some groups of women and children who will not receive the health benefit of mandatory fortification as a consequence of other socio-demographic factors. However there is no evidence that can be drawn upon to characterise these groups and the dietary intake data indicates that bread is widely and regularly consumed.

12.5.4 Labelling and Informed Choice

Consumers will be informed about the addition of iodised salt to bread through general labelling provisions requiring the ingredients of a product to be identified in the ingredient list. In some situations however, products are exempt from the requirement to label with an ingredient list. These exemptions are listed in subclause 2(1) of Standard 1.2.1 and include:

- unpackaged foods;
- food made and packaged on the premises from which it is sold; and
- food packaged in the presence of the purchaser.

In addition, the ingredients of compound ingredients⁴⁷ are not required to be declared in the list of ingredients (except for additives that perform a technological function in the final food).

Currently unpackaged retail bread and bread products are estimated to be approximately 30% of Australian total bread sales (see SD14⁴⁸).

⁴⁷ A compound ingredient means an ingredient of a food which is itself made from two or more ingredients. Standard 1.2.4 of the Code requires the components of a compound ingredient to be labelled where the amount of compound ingredient in the food is 5% or more.

⁴⁸ SD14: Brooke-Taylor & Co Pty Ltd. (2006) Report on the logistics and labelling changes related to the introduction of mandatory fortification of bread and breakfast cereals with iodised salt (and the impact of a preceding requirement for mandatory fortification of bread with folic acid). Report prepared for FSANZ P295 Final Assessment Report, Appendix 1.

While the majority of bread will be required to have iodised salt included in the ingredient list, the exemptions outlined above mean that consumers may not always be informed about the presence of iodised salt at point of sale.

The importance of labelling as a means of informing consumers about the presence or absence of iodised salt was noted by submitters during the development of Proposal P230. There was concern that consumers who need to avoid iodine on medical grounds should be clearly informed as to which food products contained iodised salt. Safety considerations with respect to consumers with iodine sensitive medical conditions are discussed under Section 15.1.2.

12.6 Factors Affecting Safe and Optimal Intakes

12.6.1 Factors Influencing the Mandatory Addition of Iodine to the Food Supply

The amount of additional iodine that can be delivered to the target population from mandatory fortification is influenced by:

- the consumption of bread;
- the salt levels in bread; and
- the use of iodised salt in other commercial foods.

If the future consumption of bread differs significantly from the amounts in FSANZ's dietary intake assessment, then the predicted increases in dietary iodine are unlikely to be achieved. However the consumption of dietary staples remains fairly constant over time (Cook *et al.*, 2001a; Cook *et al.*, 2001b).

The predicted increase in dietary iodine from this mandatory fortification scenario is based on the current salt levels in bread. If future salt levels decrease, for example they are lowered in response to public health campaigns; this will reduce the effectiveness of the mandatory fortification scenario. While it may be possible to further reduce added salt levels, there is a critical point in most foods where it is difficult to lower the salt content further without compromising consumer acceptance and undermining the technological function of the added salt.

Some manufacturers have indicated that if they are required to use iodised salt in bread production, they may use iodised salt in their other products. If this occurs, a broader range of products such as pancakes, crumpets and other hot plate items may also contain iodised salt. As a consequence, more food products than those required under this mandatory fortification scenario may contain iodised salt.

FSANZ proposes to monitor these potential sources of iodine variability in the food supply and will change the level of iodisation if necessary to ensure the ongoing safety and effectiveness of mandatory fortification.

12.6.2 Influences of Voluntary Iodine Fortification Permissions on Iodine Levels in the Food Supply

FSANZ's dietary intake assessments are based on the current consumption of discretionary iodised salt. If future consumption of discretionary iodised salt varies significantly, this could impact on the mandatory fortification scenario. For example, education campaigns highlighting the re-emergence of mild iodine deficiency in the population could potentially increase discretionary iodised salt intakes. However, it is not the intention of the proposed fortification to promote increases in salt intake, including iodised salt intakes. The Communication and Education Strategy (see SD13⁴⁹) reiterates support for the Nutrition Guidelines, which focus on reducing salt intakes.

FSANZ examined the possibility of removing the voluntary permissions for iodised salt following introduction of the proposed mandatory fortification. This would have resulted in all discretionary salt being non-iodised, and removed the option for manufacturers choosing to add iodised salt to any food products, except bread. Maintaining the current voluntary permission for use of iodised salt may help to enhance the effectiveness of the proposed mandatory fortification. It would also provide alternative iodine sources for people who do not consume bread. A variety of submitters to Proposal P230 noted strong support for retaining the voluntary permissions for use of iodised salt in food manufacturing.

12.6.3 Increased Iodine Requirements of Pregnant and Breastfeeding Women

Although the proposed mandatory fortification can deliver sufficient amounts of iodine to the general population, for a large percentage of pregnant and breastfeeding women it will not fully meet their increased requirements. Thus supplementation or other sources of iodine will still be required by many pregnant and breastfeeding women. Many submitters to Proposal P230 expressed concern over this, noting that the unborn child is vulnerable to the most serious consequences of iodine deficiency.

The amount of additional iodine that can be delivered to pregnant and breastfeeding women via mandatory fortification is constrained by the desire to minimise exceedance of the UL for iodine in young children. The UL for children is approximately one fifth of the adult UL.

If a woman is iodine replete before pregnancy, her iodine stores may be adequate to provide sufficient iodine for her child. If a mother is deficient before pregnancy, there is a greater risk the child will be iodine deficient. Until the population is iodine replete, supplementation for pregnant and breastfeeding women is recommended.

The need for targeted education to raise awareness of pre-pregnancy counselling to improve iodine supplementation was raised and the limitations of similar pre-pregnancy counselling programs noted. These issues have been incorporated into the Communication and Education Strategy (see SD13⁵⁰).

⁴⁹ SD13: FSANZ (2008) *Communication and Education Strategy*.

⁵⁰ SD13: FSANZ (2008) *Communication and Education Strategy*.

12.7 Impact on Trade

The removal of breakfast cereals and biscuits as food vehicles considerably reduced the trade impacts of the initial mandatory fortification Proposal. The overall impact on trade from the use of iodised salt in bread is anticipated to be minimal as bread is generally manufactured locally for Australian domestic markets. Very little bread is imported or exported into Australia. The impact of mandatory fortification on the manufacturers of bread products for export and on the importation of salt and bread products are considered below.

12.7.1 Exports

The perishable nature of the product and difficulties with logistics are the main obstacles for exporting 'fresh bread' and as a consequence very little is exported from Australia. In contrast, frozen dough, par-baked products and breadcrumbs can be exported. However, it has been difficult to accurately quantify this specific export market category, both in terms of volume and monetary value.

12.7.1.1 Breadcrumbs

The export of foods which contain breadcrumbs made from returned bread may also be affected by the mandatory use of iodised salt in bread. It would not be possible to export these foods to Japan.

However, bread product baked specifically for the manufacture of breadcrumbs will not be required to contain iodised salt as these do not meet the Code's definition of bread. A survey of the major crumbed fish food manufacturers in Australia established that most crumbed foods are coated with 'purpose made' crumbs. Very few crumbed products made from returned bread are exported to Japan. Therefore, the trade impact of this fortification Proposal is likely to be immaterial.

12.7.2 Imports

It is unlikely that the proposed fortification would have a significant impact on imports. Very little bread is imported into Australia. Imported crumbed products would also not be affected by this mandatory fortification requirement. FSANZ is unaware of the importation of any iodised salt products but if there were, these products would need to comply with the current iodisation range of 25-65 mg per kg.

12.8 Summary

A number of risks and issues arising from this mandatory iodine fortification Proposal have been identified. Strategies for the management of these risks are addressed in Section 15 of this Report.

13. Impact Analysis

13.1 Affected Parties

- Industry: Salt manufacturers and manufacturers of bread and bread products.

- Government: Australian state and territory government enforcement agencies.
- Consumers generally, and particularly the following sub-groups: Infants during foetal development and up to 3 years of age, and pregnant and breastfeeding women.

13.2 Cost Benefit Analysis

During development of Proposal P230, FSANZ commissioned Access Economics to investigate the costs and benefits of replacing non-iodised salt with iodised salt in bread and other cereal-based products (see SD4⁵¹). In line with the decision to remove biscuits and breakfast cereals as food vehicles for iodine fortification, Access Economics provided an additional report outlining the costs of fortifying bread as the sole food vehicle (see SD5⁵²). These two reports are applicable to Proposal P1003 as the cost benefit analysis was undertaken for both Australia and New Zealand and the food vehicle is the same.

13.2.1 Methodology

The usual approach to cost benefit analysis is to identify and quantify the costs and benefits of the Proposal, then compare the magnitudes of the costs and benefits to determine whether the Proposal can deliver a net-benefit to the community. In this case, the costs were identified and measured by Access Economics from information provided by industry and government. Access Economics also identified benefits from a review of relevant literature and an attempt was made to quantify them.

Although the nature of the benefits could be established, the magnitude of the effect in dollar terms was subject to very large uncertainty. For example, at mild levels of iodine deficiency, while some effects on young children may be irreversible and may include small decreases in IQ, subtle fine motor control deficits; and small hearing impairments, it is difficult to attach a dollar value to these clearly undesirable consequences of iodine deficiency. FSANZ considered the quantitative estimates of benefits were not sufficiently reliable to use in the analysis. FSANZ consulted various experts on this matter and they affirmed the difficulties of attempting to quantify the benefits in dollar terms.

Instead, the analysis in this section presents the costs of introducing the Proposal, describes the nature of the benefits and then comes to a conclusion as to whether the likely benefits would be worthwhile in relation to the expected costs. This approach was supported by the peer reviewer of the overall cost benefit analysis.

13.2.2 The Costs

The costs of mandatory fortification quantified here include the costs to industry and costs incurred by government in administering, enforcing and monitoring mandatory fortification.

⁵¹ SD4: Access Economics (2006) *Cost benefit analysis of fortifying the food supply with iodine*. Report commissioned by FSANZ.

⁵² SD5: Access Economics (2007) *Costs of fortifying bread and bread products with iodine*. Report commissioned by FSANZ.

In general, across-the-board increases in the cost structure of an industry tend to be rapidly passed onto consumers in the form of higher prices for products. It is expected that the costs incurred by industry in complying with this fortification Proposal would be fully passed onto consumers.

13.2.2.1 Industry

Two specific industry sectors will be affected by this Proposal, namely salt suppliers and manufacturers of bread and bread products.

13.2.2.2 Salt Manufacturers

Some salt processing firms would require plant upgrades to install a dry mixing system to enable increased production of iodised salt. In addition, where salt products are certified as an organic allowed input, firms need to ensure that there is no cross contamination, so a separate processing area would be required. In Australia, around \$AUD143,000 worth of additional machinery and equipment would be required (including installation costs).

Salt manufacturers would also be required to make some changes to their labelling to ensure that iodised and non-iodised salt are not confused. Upfront labelling costs would be around \$AUD18,000. Therefore total upfront costs for the salt industry are estimated to be approximately \$AUD161,000.

Salt manufacturers would also incur a range of ongoing costs. Extra iodine, in the form of potassium iodate, would need to be purchased and added to a pre-mix of fine salt, at a cost of \$AUD30 to \$AUD40 per kg. Additional analytical testing would be required to ensure that the concentration of iodine in salt products was within the prescribed range. The industry would incur costs of warehousing iodised salt separately from the non-iodised salt. A salt manufacturer also indicated that one of its plants is not structured to manufacture iodised salt. It would therefore incur substantial inter-state transport costs (as an alternative to building a new plant). Overall the ongoing costs to Australian salt manufacturers would be \$AUD314,000 each year.

13.2.2.3 Manufacturers of Bread and Bread Products

It is estimated that iodised salt would cost bread manufacturers around 10% more than non-iodised salt. The additional cost of iodised salt to cereal processing firms was taken into account when analysing the costs of fortification to salt manufacturers.

The major costs for bread manufacturers when implementing the mandatory requirement to replace non-iodised salt with iodised salt will be the upfront costs of relabelling and writing off existing stocks of old labels.

Bakers producing pre-packaged bread would incur costs of re-designing labels, estimated within the range of \$AUD550 to \$AUD2000 per stock keeping unit (SKU) and amounting to approximately \$AUD1.31 million for the large plant bakers.

Other bread manufacturers including supermarkets, franchise bakeries and individual bakers would incur some labelling costs, but to a lesser extent than the manufacturers of pre-packaged products. Incorporating total costs provided by industry it is estimated that the total upfront costs of revising labelling for this segment of the baking industry would be \$AUD484,000. Label changes would also be required by the manufacturers of bread ingredients, pre-mixes and improvers. Their upfront costs are estimated to be \$AUD242,000.

A further and substantial cost is that of writing off old stocks of packaging and labelling. A transition time would be necessary for the introduction of the proposed standard, so firms could pre-order new labels, allow them to be printed and delivered, rearrange label storage and then change over labels. A transition period may also moderate the problem of disposing of unused pre-printed labels, allowing old stock to be reduced. However even allowing for a transition period, write-off cost would still be incurred. Incorporating total costs provided by industry, FSANZ estimated that the labelling and packaging write-off costs would be around \$AUD5 million.

Therefore total upfront costs to the baking industry including supermarkets, franchise bakeries and ingredient suppliers for label re-design and write-off amounts to approximately \$AUD7.1 million.

Access Economics investigated the impact on the bread making industry if the current Proposal to fortify bread with iodine was implemented at the same time as the Proposal to fortify bread with folic acid. They found that the upfront costs of re-labelling and label write-offs would be reduced by between \$AUD4.5 million and \$AUD6.5 million, if the changes were introduced simultaneously.

Bread manufacturers would in general rely on the salt suppliers' guarantee that the iodine concentration complied with the proposed standard. Only one ongoing cost was identified, where the plant bakers would undertake some spot checks annually, at a cost of around \$AUD30,000.

13.2.2.4 Government – Administration and Enforcement of Regulation

The costs of Government enforcement of the proposed standard are estimated to be \$AUD31,000 upfront and \$AUD137,000 ongoing each year. The upfront costs cover initial set up and training and awareness raising with industry, while the ongoing annual costs cover auditing, responding to complaints, administration and some continuing training.

13.2.2.5 Government – Monitoring

For the purposes of this report an attempt has been made to estimate some of the costs likely to be associated with monitoring iodine fortification in Australia. The costs quoted in this section of the report are therefore approximate values only and will require adjustment once the Australian Institute of Health and Welfare (AIHW) have completed their initial report on the proposed monitoring program and data sets required, and discussions with DoHA, the jurisdictions and other relevant agencies.

Decisions on funding specific monitoring activities will not be finalised until the AIHW Initial Stocktake Report is completed. The proposed monitoring program for mandatory iodine fortification in Australia is discussed in Section 21 of this Report.

The predicted costs for ensuring manufacturers, retailers and importers nationally, are aware of the new fortification requirement were a survey to be undertaken are approximately \$AUD36,000 per year. The costs of updating the National Food Composition Database, maintaining a reporting and tracking system for voluntarily fortified products, monitoring labels and undertaking label compliance analytical surveys are estimated to be about \$AUD63,000 per year.

The costs of consumer attitude and behaviour research in relation to use of fortified foods and market basket/store surveys were such surveys undertaken are estimated to be about \$AUD118,000 per year for Australia. Assuming data from the 2007 Kids Eat Kids Play Survey and the proposed 2008/09 adults NNS can be used, rather than commissioning a specific survey, it is expected to cost another \$AUD20,000 per year to assess iodine intakes for different population groups.

In addition, the costs of checking iodine levels in target groups of the Australian population through urine testing, are estimated to be \$AUD168,000 per year. Finally, the cost of an officer to provide overall fortification monitoring system support through the AIHW is approximately \$AUD100,000 per year. The required monitoring activities and estimated costs are provided in the Table 11.

Table 11: Indicative Costs of potential Monitoring Activities

Monitoring activity in Australia	Estimated Cost Per Year *
	\$AUD
Promote awareness of the new iodine fortification requirement within food industry	36,000
Baseline stakeholder survey	
Update National Food Composition Database	63,000
Label monitoring survey	
Label compliance analytical surveys	
Reporting and tracking system for voluntarily fortified products	
Market basket/store surveys in remote communities	118,000
Consumer attitude and behaviour research	
Food frequency surveys (Roy Morgan Research)	
Identify changes in iodine levels within the population via National Nutrition Survey data	20,000
Urine testing for iodine for target groups	168 000
Australian Institute of Health and Welfare Fortification Monitoring - Project Support officer	100,000
Total Monitoring Costs per Year	Approx. 505,000

* One off costs averaged over the 5 year period

13.2.2.6 Summary of Total Costs

Overall, the total upfront cost from this Proposal is \$AUD7,278,000. The total ongoing cost for industry and government, excluding monitoring, is \$AUD481,000 each year. These ongoing costs equate to two cents per person per year⁵³.

Table 12 summarises all the costs to industry and government from this iodine fortification Proposal.

Table 12: Summary of Total Cost of Iodine Fortification to Industry and Government

Summary of total costs	(\$AUD)
Upfront costs	
Salt industry (machines and labelling)	161,000
Bakers (label re-design and write-offs)	7,086,000
Government – administration and enforcement of regulation	31,000
Total upfront	7,278,000
Ongoing costs (per year)	
Salt industry (maintenance, iodine, analytical testing, transport and storage)	314,000
Bakers (some annual analytical testing)	30,000
Government – administration and enforcement of regulation	137,000
Total ongoing (per year)	481,000
Monitoring costs (per year)*	505,000
Costs of iodine fortification per head	
Population	20,111,297
Upfront cost per head	0.36
Ongoing cost per head (per year)	0.02
Monitoring cost per head (per year)*	0.03

* Note: monitoring costs are very approximate as FSANZ does not have responsibility for this aspect of the fortification program.

13.2.3 The Benefits

Addressing the mild-to-moderate iodine deficiency in Australia will deliver two principal benefits. First, it will prevent the possible escalation of iodine deficiency. Second, there is a growing evidence base showing that addressing mild-to-moderate iodine deficiency will improve cognitive and psychomotor function, including a small rise in IQ; that in turn may affect real behaviour including improved productivity.

The introduction of mandatory iodine fortification would also be expected to deliver other benefits including reduced morbidity from reduction in iodine deficiency disorders (IDDs), fewer years of life lost due to premature death, reduction of absenteeism from work by sufferers of IDD or their carers and related management costs, improved school attendance and enhanced performance at school.

⁵³ These costs do not include the monitoring costs as currently the monitoring costs are only estimates and are less likely to be directly passed onto the consumer.

As noted in Section 11, the proposed mandatory iodine fortification will contribute considerably to alleviating the consequences of existing iodine deficiency, and prevent it from becoming even more widespread and serious in the future.

13.2.3.1 Benefit of Avoiding the Possible Escalation of Iodine Deficiency

Pregnancy and lactation increase the iodine requirement of women and can accentuate their deficiency. Increasing the iodine intake of women of child bearing age will prevent them from becoming progressively more iodine deficient through successive pregnancies, further increasing the risk of their children being born with iodine deficiency. Addressing iodine deficiency will reduce the risk of iodine-induced hyperthyroidism and could lead to an improvement in the prognosis of thyroid cancer.

13.2.3.2 Benefit of Avoiding Harm of Cognitive Impairment

As outlined in the Risk Assessment, addressing a mild-to-moderate iodine deficiency may improve cognitive function. Studies of the health impacts of iodine deficiency suggest benefits from fortification across a range of human capabilities, for example cognitive function, hearing, concentration, reproduction, fertility and infant survival.

Access Economics estimated the lost earnings and production due to mild-to-moderate iodine deficiency using a 'human capital' approach. By preventing cognitive impairment through mandatory fortification, those otherwise affected would participate in the labour force and obtain employment at the same rate as other Australians, and earn the same average weekly earnings. Access Economics noted that an empirical relationship between iodine status and improvements in productivity and health has not been quantitatively established in the literature. It is therefore extremely difficult to quantify the benefits except within a large range to account for the high degree of uncertainty. FSANZ recognised the high degree of uncertainty in the quantitative estimates of benefits and considered they were not sufficiently reliable to use in the analysis.

13.3 Cost-Effectiveness Analysis

Due to the difficulties in quantifying the benefits of this Proposal in financial terms, FSANZ commissioned the CHERE to examine the cost-effectiveness of iodine fortification of bread in Australia and New Zealand (see SD3⁵⁴).

Using Tasmanian data on voluntary fortification, CHERE estimated the effect of the proposed fortification on the iodine status of the Australian population. The results suggest a significant decrease in the proportions of individuals with moderate or mild iodine deficiency.

⁵⁴ SD3: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of iodine fortification in Australia and New Zealand*. Report commissioned by FSANZ.

CHERE concluded that in terms of cost-effectiveness ratios, the cost of reducing the risk of iodine deficiency disorders appears small compared with the potential benefits associated with improved health, reduced health care costs and/or gains in productivity and Gross Domestic Product (GDP).

14. Comparison of Options

Introducing mandatory fortification as proposed in this report, is expected to result in ongoing costs (excluding monitoring) of \$AUD481,000 each year. This equates to two cents per person per year.

The important benefits of mandatory iodine fortification relate to addressing iodine deficiency and its associated risks, including cognitive and psychomotor impairment, as well as goitre and related thyroid dysfunction. An additional important benefit is the prevention of a further decline in population iodine status, which left unaddressed, would increase the risk of serious iodine deficiency disorders.

Although quantifying the dollar values of the recognised benefits proved extremely difficult, nonetheless these benefits would be worthwhile, especially in relation to the small cost to the community that would be incurred. FSANZ considers that the recommended mandatory fortification would deliver net-benefits to Australia.

Therefore, FSANZ considers Option 2, to require the mandatory replacement of salt with iodised salt in bread, provides net benefits superior for the population of Australia in comparison to the current arrangements (Option 1 – *status quo*).

14.1 Conclusion

As requested by the Ministerial Council, FSANZ has considered the feasibility of mandatory fortification of the food supply with iodised salt as a means of increasing iodine levels in the general population of Australia.

On the basis of the available evidence FSANZ concludes that the mandatory replacement of non-iodised salt with iodised salt in bread would deliver substantial benefits to Australia. The important benefits of mandatory fortification with iodine relate to addressing iodine deficiency and its associated risks including cognitive and psychomotor impairment, as well as goitre and related thyroid dysfunction. An additional important benefit of addressing iodine deficiency now is the prevention of a further decline in population iodine status, which left unaddressed, would increase the risk of serious iodine deficiency disorders. At a cost of two cents per person per year in Australia, the cost of this Proposal is considered to be small.

15. Strategies to Manage Risks Associated with Mandatory Fortification

Risks associated with the mandatory requirement to replace non-iodised salt with iodised salt in bread have been identified as part of this Proposal. Approaches to minimising these risks are outlined below.

15.1 Managing Safety and Effectiveness

The proposed mandatory fortification scenario will deliver a substantial improvement in iodine intakes across the population, alleviating the current deficiency and preventing future deficiencies, especially among children.

The amount of additional iodine in the food supply will not, however, be sufficient for the majority of women during pregnancy and lactation. Thus, other risk management strategies for this group will be needed. The potential for adverse effects, resulting from additional iodine in the food supply, in some individuals were also noted.

15.1.1 Optimising Effectiveness of the Mandatory Fortification Proposal

15.1.1.1 Iodine Supplement Use

There is currently no formal policy for iodine supplementation in pregnant and breastfeeding women. In the literature, it is recommended that pregnant and breastfeeding women take iodine supplements supplying an additional 100-200 µg per day (Eastman, 2005). The only exceptions to this recommendation are women with pre-existing thyroid disease or high iodine intakes from other sources. FSANZ supports the recommendation that pregnant and breastfeeding women receive iodine supplements. FSANZ has referred this issue to the relevant health authorities.

15.1.1.2 Non-reach Groups

Although the majority of the population eat bread (88% aged two years and above), FSANZ recognises some people do not or may consume different forms of bread e.g. gluten or salt free; therefore may receive limited benefit from the proposed mandatory fortification. This may include individuals with coeliac disease; people from different cultures who irregularly eat bread, those who consume only organic bread; and members of the population who restrict their bread consumption to reduce their salt intakes.

During development of Proposal P230, some submitters expressed concern that people who avoid bread will not be covered by the proposed mandatory fortification. These consumers have been identified as a primary target audience in the Communication and Education Strategy (see Section 16). The Strategy highlights potential alternative sources of iodine for these individuals.

For people with coeliac disease, some commercially produced gluten-free and wheat free breads are 'yeast leavened' and therefore will be required to contain iodised salt. Other gluten-free and wheat free breads may contain iodised salt by virtue of the voluntary permissions for the use of iodised salt.

15.1.2 Safety Considerations of the Mandatory Fortification Proposal

15.1.2.1 Iodine-Induced Hyperthyroidism

A potential health risk from increased intake of iodine is iodine-induced hyperthyroidism, particularly for those individuals who have had prolonged iodine deficiency, see Section 7.2. However, the risk of iodine-induced hyperthyroidism is considered to be low, and is unlikely to occur as a result of this mandatory fortification. FSANZ has adopted a conservative approach to mandatory fortification, which incorporates a prescribed level of fortification and recommends a comprehensive monitoring system.

15.1.2.2 Pre-Existing Thyroid Disease

Individuals with pre-existing thyroid disease, for example Graves' Disease, are more sensitive to increases in iodine intake. It is anticipated the proposed level of fortification would not aggravate existing thyroid disease in most cases, although it is acknowledged that it may in some. The majority of individuals with pre-existing thyroid disease will likely be under the care of a physician, and therefore changes in their condition can be monitored and treated.

The Communication and Education Strategy has identified consumers with thyroid disorders as a primary target audience (see Section 16). The Strategy highlights that general labelling laws will require iodine to be included in the ingredient list which will allow consumers either to select foods fortified with iodine or avoid them. Health professionals play an important role in informing consumers of the proposed mandatory fortification.

15.1.2.3 Iodine Sensitivity Reactions

Adverse reactions have been observed in certain individuals following exposure to particular iodine-containing substances, such as iodinated contrast media and iodine-based antiseptics. Where the same individuals have also reacted adversely to high iodine containing foods such as seafood, they have sometimes been led to believe they have an allergy to iodine. Testing has shown that the reactions observed are almost certainly a response to other parts of the iodine-containing compound and not to the iodine itself (Coakley and Panicek, 1997).

The Communication and Education Strategy has identified consumers with possible iodine sensitivities as a primary target audience (see Section 16). The Strategy highlights that fortification is set at a conservative level, making it unlikely to cause any adverse reactions. General labelling laws will require iodine to be included in the ingredient list allowing consumers to either select foods fortified with iodine or avoid them.

15.1.2.4 Children above the Upper Level of Intake

A small proportion of young children might exceed the UL for iodine following the proposed fortification. Although it is generally not desirable to exceed the UL, it is expected that these intakes would not represent a health and safety risk to these children. Consistent with the Dietary Guidelines, information advising carers of young children to avoid adding salt to food will be disseminated as part of the Communication and Education Strategy (see SD13⁵⁵).

15.1.3 Limitations of the Mandatory Fortification Proposal

FSANZ acknowledges that not all Australians will get enough iodine from the replacement of salt with iodised salt in bread. The approach put forward in this Report can be augmented by activities outside the scope of FSANZ's remit such as education and promotion of iodine supplement use. Further, FSANZ is aware of the need to consider the outcomes of population wide monitoring of iodine status, which may warrant measures such as increasing the concentration of iodine in iodised salt, replacing salt with iodised salt in products other than bread, or exploring the possibility of adding iodine to the food supply other than through iodised salt. These potential options can only be adequately considered when there is sufficient data on the impact of the mandatory fortification as it is currently proposed.

Several submitters to Proposal P230 raised concern that infant formula products may contain insufficient amounts of iodine. FSANZ will consider these issues as a part of a future review of Standard 2.9.1 – Infant Formula Products.

15.1.4 Impact on Future Iodine Levels in the Food Supply

The causes of the re-emergence of iodine deficiency are not fully understood. As mentioned in Section 12.6.1, there are a number of variables that may influence future levels of iodine in the food supply, namely the consumption of, and salt levels in, bread, use of iodised salt in other commercial foods and the use of discretionary iodised salt.

Given the range of uncertainties influencing future trends, FSANZ proposes monitoring changes in the key sources of dietary iodine.

15.2 Labelling and Information Requirements

Labelling provides an important source of information for consumers and enables consumers to make informed decisions regarding their consumption of fortified foods.

The generic labelling requirements of the Code applicable to foods which contain iodised salt include:

- listing of ingredients (Standard 1.2.4);

⁵⁵ SD13: FSANZ (2008) *Communication and Education Strategy*.

- nutrition information requirements for foods carrying nutrition claims (Standard 1.2.8); and
- the conditions applying to nutrition claims about vitamins and minerals (Standard 1.3.2).

The Ministerial Policy Guideline for mandatory fortification states that consideration should be given, on a case-by-case basis, to a requirement to include information in the nutrition information panel of mandatorily fortified food.

Similar to the New Zealand situation, FSANZ considers the generic requirements of the Code to be appropriate for providing consumers with information and therefore does not believe mandating the declaration of iodine content in the nutrition information panel is warranted.

The declaration of iodised salt in the ingredient list will alert consumers to the presence of iodine in bread and may be used by consumers to assist in the selection of fortified foods for improving iodine status, or conversely, to avoid foods containing iodised salt if they so wish.

While the presence of iodised salt will be indicated in the ingredient list on bread and bread products, in some situations (see Section 12.5.4) these products are exempt from the requirement to label with an ingredient list. In these cases consumers will not necessarily be informed about the presence of iodised salt. FSANZ considers that the current exemptions from the labelling provisions that apply to bread should remain in place and that declaration of iodised salt as an ingredient in these unlabelled bread is not required, for the following reasons:

- the approach is consistent with the approach for mandatory fortification with thiamin and folic acid;
- the approach is consistent with the approach in the Code for labelling of other ingredients where declaration is not required for health and safety reasons; and
- a written declaration of iodised salt as an ingredient without including other ingredients may cause confusion for consumers.

15.2.1 Use of Nutrition and Health Claims

Mandatory fortification presents an opportunity for food manufacturers to make nutrition claims, as currently permitted under the Code, related to the iodine content of bread. The level of iodised salt in bread will determine whether bread reaches sufficient levels of iodine to permit nutrition claims about the presence of iodine. For example, a 'source' claim can currently be made on bread if the iodine content is greater than 15 µg per 50 g reference quantity (approximately two slices of bread), which is likely to occur if bread contains at least 1% iodised salt.

Although nutrition and health claims can be a useful source of information for consumers, it is noted that food manufacturers may choose not to use these claims to promote the iodine content of their foods if no marketing advantage is perceived.

During the development of Proposal P230, some public health submitters were concerned that the use of salt as a food vehicle had the potential to create conflicting health messages and therefore opposed the use of an iodine claim on products. Some consumer and public health submitters believed that the ability to make an iodine claim was a disincentive for manufacturers to lower the level of salt in their bread products. Industry submitters, on the other hand, supported an improved ability to make iodine content claims and health claims about the positive benefits of iodine.

FSANZ does not believe that the mandatory use of iodised salt in bread is inconsistent with proposed salt reduction programs. Generally, even with a 30% reduction in salt content, the majority of bread can still make a nutrition claim about iodine. The use of iodised salt in bread should not therefore impede public health initiatives to lower the salt content of bread in the future.

The proposed new Standard (draft Standard 1.2.7 – Nutrition, Health and Related Claims) will permit a wider range of health claims in the future. This Standard is being considered under Proposal P293 – Nutrition, Health & Related Claims and will provide a framework for the assessment of fortified foods to determine which are permitted to carry nutrition content claims or health claims about iodine. In March 2008, the FSANZ Board approved the draft Standard and notified the Ministerial Council of its decision.

15.3 Level of Iodine Fortification in Iodised Salt

In determining the appropriate level of iodisation in salt to address the re-emergence of mild-to-moderate iodine deficiency, the Risk Assessment recommends a level of 45 mg iodine per kg of salt for use in bread.

One level of salt iodisation for use in bread and in table salt is considered most practical by salt manufacturers and FSANZ. The advantages of having one level of salt iodisation include:

- consistency with the recommended level set by WHO and ICCIDD;
- less impost for salt manufacturers;
- easier to enforce⁵⁶;
- less confusion for food manufacturers purchasing small quantities of iodised salt more suited to the retail packaging sizes;
- less likely to be trade restrictive as it conforms to international guidelines; and
- overcomes the difficulty of defining salt for retail use versus salt for manufacturing.

Submitters to Proposal P230 supported a single level of iodisation in both bread and discretionary salt for the same reasons listed above.

⁵⁶ The proposal for two iodisation levels would create a situation where the potential overlap creates difficulties with ensuring regulatory compliance.

Originally, a 'working range' of ± 10 mg was proposed. However, information recently provided by one of the leading salt manufacturers in Australia showed that this range could not always be achieved. Consequently, salt manufacturers have suggested a 'working range' of ± 20 mg per kg in the iodisation level to ensure effective regulatory compliance. Potassium iodate is added as a finely crushed powder and the final concentration is dependent on the accurate dispersal throughout the product. While the amount of variation around the midpoint is typically small, the ± 20 mg per kg accommodates the normal distribution range.

Therefore, FSANZ recommends a salt iodisation range of 25-65 mg iodine per kg of salt. This range provides a ± 20 mg 'working range' around the recommended midpoint of 45 mg iodine per kg salt.

15.4 Risk Management Conclusion

A number of potential risks and issues arising from this mandatory iodine fortification Proposal have been identified. These include public health and safety risks as well as social, technical and economic issues. FSANZ has considered the totality of these issues and has devised the following strategies to help mitigate any potential risks:

- the adoption of a conservative mandatory fortification approach so as to maximise iodine intakes in target groups, while minimising exceedance of UL in the population;
- the identification of the need for an iodine supplement program for pregnant breastfeeding women, as an adjunct to mandatory fortification, to meet their increased iodine requirements. This issue has been referred to the relevant authorities;
- the selection of a food vehicle that it consumed widely and consistently, results in minimal trade impacts, and has been shown to be technologically feasible;
- the adoption of the generic labelling requirements of the Code to inform consumers as to the presence of iodised salt in fortified food;
- an exemption for bread represented as organic to allow manufacturers of organic bread to follow existing organic practices;
- the selection of a food vehicle that is consistent with nutrition policies and guidelines. Education messages emphasise bread as a source of additional iodine, rather than salt. The substitution of non-iodised salt with iodised salt in bread is likely to have minimal impact on salt intakes and will not impede public health campaigns aimed at reducing salt intakes;
- the provision of a salt iodisation range of 25-65 mg to ensure effective regulatory compliance for the salt industry;
- the development of an Industry User Guide to assist industry interpret and apply the compliance requirements for this mandatory fortification Standard;

- aligning the implementation period for the mandatory iodine fortification with the mandatory folic acid fortification to help reduce the upfront costs of relabelling and label write-offs for industry;
- the development of a Communication and Education Strategy (see Section 16.1) to increase awareness of the mandatory iodine fortification standard, including specific messages for:
 - pregnant and breastfeeding women;
 - parents/carers of young children;
 - people with thyroid conditions and iodine sensitivities;
 - non-bread eaters; and
 - individuals who choose not to consume iodine fortified foods.

The Communication and Education Strategy includes the recognition and contribution of a monitoring program to ensure the ongoing effectiveness and safety of this Proposal.

COMMUNICATION AND CONSULTATION

16. Communication and Education

It is generally acknowledged that the proposed mandatory iodine fortification is an effective means of improving iodine intakes across the population. It will help alleviate the current deficiency and prevent future deficiency, especially among children. The need for an effective and comprehensive communication and education strategy was raised by many key stakeholder groups during FSANZ's consultations on Proposal P230.

16.1 Communication and Education Strategy

FSANZ has prepared a Communication and Education Strategy to raise awareness and understanding of the proposed standard and its implementation for Australia (see SD13⁵⁷). This Strategy has been developed to facilitate communication between consumers, food industry groups, media, and government departments on the mandatory iodine fortification standard. Key messages have been developed for each of the target audiences and the suitable channels identified for communication. The New Zealand Food Safety Authority (NZFSA) and the New Zealand Ministry of Health have prepared a similar communication strategy for New Zealand.

17. Consultation

FSANZ will undertake one round of public consultation on this new Proposal. As the preferred approach is the same as Proposal P230, FSANZ has drawn heavily on previous consultations to inform the development of this new Proposal. During the development of Proposal P230, FSANZ undertook extensive consultation.

⁵⁷ SD13: FSANZ (2008) *Communication and Education Strategy*.

FSANZ released an Initial Assessment in 2005, a Draft Assessment in 2006 and an Issues Paper in May 2007 for public consultation. The key issues raised during these consultations are discussed below.

17.1 Initial Assessment for Proposal P230

FSANZ received a total of 38 written submissions in response to the Initial Assessment Report for Proposal P230. This report was released for public consultation from 15 December 2004 to 23 February 2005.

All health professional submissions and the majority of government submissions supported mandatory iodine fortification. With the exception of the two salt manufacturers, the majority of industry submitters supported voluntary fortification as a means to increase population iodine intakes.

While no submitters supported maintaining the *status quo*, six did not indicate a preferred option and one submitter stated they were opposed to mandatory fortification.

17.2 Draft Assessment for Proposal P230

FSANZ received a total of 68 written submissions in response to the Draft Assessment Report for Proposal P230 during the public consultation period from 18 August 2006 to 18 September 2006. At Draft Assessment, FSANZ's preferred option was the mandatory replacement of non-iodised salt with iodised salt in bread, breakfast cereals and biscuits for both Australia and New Zealand.

The majority of submissions from government, health professionals, and consumer organisations supported the preferred option of mandatory fortification, noting the importance of establishing a monitoring program prior to implementation and the need to conduct a national nutrition survey in the next 12 months to establish baseline data.

Some public health professionals were concerned that the preferred option did 'not go far enough' for increasing iodine intakes and believed that FSANZ has been overly constrained by not wishing to exceed the UL for iodine in young children. Many thought USI would be more effective. A number of individual submitters, who had a history of thyroid conditions, supported the *status quo* as they were concerned with adverse effects resulting from increased amounts of iodine in the food supply. The issue of consumer choice was also raised. Many submitters considered that the small manageable risks associated with mandatory fortification were outweighed by the public good.

The majority of industry submitters opposed mandatory fortification, preferring a voluntary approach. The key issues raised were that mandatory fortification restricts consumer choice and had considerable trade impacts, especially for biscuits. Submitters questioned the suitability of biscuits as a food vehicle due to their reach and contribution to overall salt intake. Industry primarily supported an extension of the voluntary fortification permissions in conjunction with targeted education and promotion strategies to increase iodine intakes in the population.

A full summary of the issues raised in submissions is provided in SD15⁵⁸.

17.3 Issues Paper for Proposal P230

In May 2007 FSANZ released an Issues Paper outlining the proposed changes under consideration for the Final Assessment of Proposal P230. The paper addressed the major themes that arose from submissions to the Draft Assessment and outlined additional work undertaken. FSANZ received 48 comments in response to the Issues Paper during the consultation period from 9 May 2007 to 6 June 2007.

The majority of government stakeholders, public health professionals and consumer groups indicated qualified support for the Proposal. There was general acknowledgement among stakeholders of the inability of the Proposal to fully meet the substantially increased iodine requirements of pregnant and breastfeeding women, and breastfed infants. The need to address deficiency in non-bread eaters was also raised.

Some public health stakeholders viewed the current Proposal as an initial step and only part of the solution to the current iodine deficiency, and noted mandatory fortification is preferable to voluntary fortification as it provides greater certainty, sustainability, equity, and reach. However, a number of public health stakeholders believed that USI would provide higher iodine intakes for pregnant and breastfeeding women. Consumer organisations were generally supportive of the mandatory fortification option but noted the need for effective monitoring and education/health promotion strategies.

Most industry stakeholders continued to oppose mandatory fortification citing the increased regulatory burden, removal of consumer choice, and trade impacts as reasons for their opposition. They did not consider mandatory fortification to be the most effective public health strategy. They stated a strong preference for voluntary fortification and the promotion of iodine as a processing aid. A Memorandum of Understanding (MoU) and an education campaign were presented as an integral part of a voluntary approach. Industry considered that international studies and the Tasmanian results demonstrate the success of voluntary fortification in decreasing iodine deficiency.

Industry and some government stakeholders also argued that Proposal P230 was inconsistent with the Australian Government's Best Practice Regulation Requirements and that to meet these requirements, all strategies for addressing iodine deficiency would need to be evaluated.

A full summary of the comments received in response to the Issues Paper is provided in SD16⁵⁹.

⁵⁸ SD15: FSANZ (2007) Summary of Submitter Comments to Draft Assessment Report for Proposal P230.

⁵⁹ SD16: FSANZ (2007) Summary of Submitter Comments to Issues Paper for Proposal P230.

17.4 Targeted Consultation for Proposal P230

Issues identified from public submissions and stakeholder consultations for Proposal P230 formed the basis of further targeted consultation with key groups, including salt, bread, breakfast cereal and biscuit manufacturers. FSANZ also commissioned independent consultants, Brooke-Taylor & Co Pty Ltd and Professor Ray Winger from Massey University, to consult with industry regarding technical issues raised during consultations. Other key stakeholder groups consulted were the Australian State and Territory, and New Zealand, jurisdictions, and consumer and public health organisations. Consultations involved face-to-face meetings, teleconferences, information updates and e-mail correspondence.

As part of the targeted consultation process, FSANZ involved the Fortification Standards Development Advisory Committee (SDAC) to help identify views and issues associated with mandatory iodine fortification. The Fortification SDAC is comprised of members with a broad interest in, and knowledge of, fortification-related issues and represents groups from public health nutrition, food manufacturing, enforcement, food policy, health promotion and consumer education.

Information received informed FSANZ's review of the appropriateness of the food vehicles, identification and investigation of risk management issues, further cost-benefit analysis, recommendations for the implementation phase, and the monitoring requirements for mandatory fortification.

An Iodine Scientific Advisory Group (ISAG) was also established by FSANZ to advise on scientific and medical matters relating to mandatory iodine fortification. ISAG members have considerable expertise in iodine and health-related matters, endocrinology, public health, epidemiology and/or nutrition. Members represent various tertiary institutions, hospitals, international councils and government organisations in Australia and New Zealand.

FSANZ commissioned an independent economic consultancy organisation, Access Economics, to undertake further analysis to investigate the impact on the cost benefit analysis of removing biscuits and breakfast cereals from the mandatory fortification standard in Australia and New Zealand. Access Economics held further consultations with key stakeholders, particularly industry groups and jurisdictions, in regard to the financial and health implications of mandatory fortification. FSANZ also commissioned CHERE, to undertake further work on the costs and benefits of the Proposal (see SD3⁶⁰).

To ensure a consumer perspective on the proposed standard, FSANZ undertook consultation with the FSANZ Consumer Liaison Committee, a group formed to provide a consumers' perspective with members drawn from both Australia and New Zealand and the Maori Reference Group (Kahui Kounga Kai).

⁶⁰ SD3: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of iodine fortification in Australia and New Zealand*. Report commissioned by FSANZ.

18. World Trade Organization

As a member of the WTO, Australia is obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards for the mandatory fortification of salt with iodine used in the manufacture of bread. A number of countries have legislation allowing, and in some cases mandating, the iodisation of salt and/or use of iodised salt in food products, these include the United States, Canada, Switzerland, Belgium, the Netherlands, Denmark and Germany. FSANZ recognises that imports of foods fortified with iodine are proscribed in some countries, for example in Japan.

WTO member nations were notified of the proposed mandatory iodine fortification regulations during the development of Proposal P230, in accordance with the WTO Technical Barriers to Trade Agreement. No responses to the notifications were received by FSANZ; therefore FSANZ has determined that notification of P1003 is not required.

CONCLUSION

19. Conclusion and Preferred Approach

As requested by the Ministerial Council, FSANZ has considered the feasibility of mandatory fortification of the food supply with iodine as a means of reducing the prevalence of iodine deficiency, especially in children.

On the basis of the available evidence, FSANZ concludes that the mandatory replacement of salt with iodised salt in bread at 25-65 mg of iodine per kg of salt would deliver net-benefits to Australia. This approach maintains the current voluntary permission for iodised salt.

The level of iodisation in salt has been selected to maximise iodine intakes in the target group, while preventing significant proportions of young children exceeding the upper safe levels of intake. While mandatory fortification can deliver sufficient amounts of iodine to the general population, for a large percentage of pregnant and breastfeeding women it will not meet their increased requirements. Therefore supplementation for pregnant and breastfeeding women may be necessary.

Preferred Approach

The preferred approach is to amend the New Zealand only mandatory iodine fortification Standard so it becomes a joint Standard for both Australia and New Zealand.

The joint Standard would require the mandatory replacement of non-iodised salt with iodised salt in bread. The salt iodisation level is to be in the range of 25-65 mg of iodine per kg of salt. Bread represented as organic will be exempt from this requirement.

The voluntary permission for iodine in iodised salt and reduced salt will be retained at the current range of 25-65 mg per kg, to be consistent with the mandatory requirement.

Reasons for the Preferred Approach

- FSANZ received advice from AHMAC, endorsed by Health Ministers, confirming that iodine deficiency is prevalent and severe enough to warrant intervention in Australia and that mandatory fortification is considered the most cost-effective strategy to redress this.
- Replacement of non-iodised salt with iodised salt in bread will address iodine deficiency across much of the Australian population, and prevent it from becoming more serious in the future.
- Replacement of non-iodised salt with iodised salt in bread is technologically feasible and well tested internationally.
- Use of iodised salt to reduce the prevalence of iodine deficiency is consistent with international guidance and experience.
- The Tasmanian voluntary program using iodised salt in bread, at an average of 45 mg iodine per kg salt, led to an improvement in the iodine status of a mildly deficient population.
- Based on the available evidence, including overseas experience with mandatory fortification, the proposed level of fortification does not pose a risk to general public health and safety. The level has been set to minimise any potential health risks. In groups that are generally more sensitive to increases in iodine intake, e.g. individuals with existing thyroid conditions, the risk of a negative impact on health is still considered to be very low.
- The Proposal delivers net-benefits to Australia. These benefits compare well with a small ongoing cost of fortification of around two cents per person each year.
- FSANZ commissioned CHERE to assess the cost-effectiveness of mandatory fortification with iodine (see SD3⁶¹). CHERE concluded that in terms of cost-effectiveness ratios, the cost of reducing the risk of iodine deficiency disorders appears small compared with the potential benefits associated with improved health, reduced health care costs and/or gains in productivity and GDP.

⁶¹ SD3: Centre for Health Economics Research Evaluation (CHERE) (2007) *Cost effectiveness analysis of iodine fortification in Australia and New Zealand*. Report commissioned by FSANZ.

- The Proposal is consistent with Ministerial policy guidance on mandatory fortification.

Monitoring is considered an essential component of implementing this Proposal consistent with Ministerial policy guidance. It will provide a means of ensuring the ongoing effectiveness and safety of this strategy to reduce the prevalence of iodine deficiency in Australia.

20. Implementation and Review

20.1 Transitional Period

Upon approval by the FSANZ Board of the proposed draft variations to the Code, the Ministerial Council will be notified of that decision. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code are expected to come into effect 12 months after gazettal of the Standard. This date has been selected to generally align with the current mandatory fortification transition periods for folic acid and iodine (New Zealand only), thereby reducing the costs to industry for labelling changes, as noted in SD14⁶². The transition period provides sufficient time for the salt industry to increase their production of iodised salt and for bread manufacturers to make the required changes to manufacturing and labelling.

It should be noted that the success of this important public health strategy extends beyond implementing mandatory fortification as the sole strategy, and incorporates the key components of education, potential iodine supplementation policy and monitoring.

20.2 Regulatory Compliance Issues

The point of compliance for the amount of iodine in salt will be the responsibility of the salt manufacturer. Currently salt manufacturers are required to stay within the existing fortification range and will need to continue to do so under mandatory fortification.

For the bread industry, the main impacts will be replacing ordinary salt with iodised salt as an ingredient and labelling changes. It is technologically feasible to add iodised salt to bread at the concentration being considered. The ingredients' list on food labels will need to be altered to reflect this change. The point of compliance for the baker will be the requirement to replace salt with iodised salt, not the amount of iodine in the final product.

⁶² SD14: Brooke-Taylor & Co Pty Ltd. (2006) Report on the logistics and labelling changes related to the introduction of mandatory fortification of bread and breakfast cereals with iodised salt (and the impact of a preceding requirement for mandatory fortification of bread with folic acid). Report prepared for FSANZ P295 Final Assessment Report, Appendix 1.

21. Monitoring

An effective fortification program will require monitoring. The responsibility for establishing and funding a monitoring system to assess the impact of mandatory fortification on the population extends beyond FSANZ's responsibilities under the FSANZ Act. In October 2007, AHMAC agreed to fund the AIHW to coordinate monitoring activities for mandatory fortification standards in both Australia and New Zealand (folic acid and iodine). However, the funds allocated to the AIHW were for the coordination and reporting of relevant data, not the actual collection and analysis of the data. The monitoring frameworks for Australia and New Zealand for the mandatory fortification of folic acid and iodine developed by the Food Regulation Standing Committee (FRSC) and agreed by the APHDPC in August 2007 were accepted by AHMAC at its subsequent meeting in October 2007. As highlighted in Section 13.2.2.5, decisions on funding specific monitoring activities will not be finalised until the AIHW Initial Stocktake Report is completed.

FSANZ will be responsible for monitoring food composition, market changes in the food supply, predicting nutrient intakes and working with consumers to research their attitudes and behaviour towards fortified products. FSANZ has recently updated the salt and iodine component of its food composition databases with the results of a new Key Foods Analytical program that it commissioned. It has also developed a database for the new Kids Eat Kids Play national nutrition survey with more comprehensive data that includes iodine for over 6000 foods and food supplements.

The costs for the proposed monitoring program for mandatory iodine fortification are discussed in Section 13.2.2.5 of this Report.

Attachments

1. Draft variations to the *Australia New Zealand Food Standards Code*

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ABBREVIATIONS AND ACRONYMS

ABS	Australian Bureau of Statistics
ADHD	Attention-deficit and hyperactivity disorder
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
AIHW	Australian Institute of Health and Welfare
APHDPC	Australian Population Health Development Principal Committee
CNS	New Zealand Children's Nutrition Survey
COAG	Council of Australian Governments
EAR	Estimated average requirement
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia New Zealand
FSFYC	Formulated supplementary foods for your children
GDP	Gross domestic product
ICCIDD	International Council for the Control of Iodine Deficiency Disorders
IDD	Iodine deficiency disorder
IQ	intelligence quotient
ISAG	Iodine Scientific Advisory Group
MoU	Memorandum of Understanding
Ministerial Council	Australia and New Zealand Food Regulation Ministerial Council
MUIC	Median urinary iodine concentration
NHMRC	National Health and Medical Research Council
NINS	Australian National Iodine Nutrition Study
NNS	National Nutrition Survey
NRV	Nutrient reference value
NZFSA	New Zealand Food Safety Authority
RDI	Recommended Dietary Intake
SDAC	Standards Development Advisory Committee
SKU	Stock keeping unit
UL	Upper Level of Intake
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WTO	World Trade Organization
µg	micrograms (1000 th of a milligram)
mg	milligrams (1000 th of a gram)
g	grams

Draft variations to the *Australia New Zealand Food Standards Code*

Subsection 87(8) of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting.

To commence: 12 months from gazettal

[1] *Standard 1.3.2 of the Australia New Zealand Food Standards Code is varied by –*

[1.1] omitting the Purpose, substituting –

This Standard regulates the addition of vitamins and minerals to foods, and the claims which can be made about the vitamin and mineral content of foods. Standards contained elsewhere in this Code also regulate claims and the addition of vitamins and minerals to specific foods, such as, the mandatory addition of thiamin and folic acid to wheat flour for making bread (Australia only) and the mandatory replacement of non-iodised salt with iodised salt in bread in Standard 2.1.1, the addition of vitamin D to table edible oil spreads and margarine in Standard 2.4.2, formulated caffeinated beverages in Standard 2.6.4, special purpose foods standardised in Part 2.9 and the addition of iodine to certain salt products in Standard 2.10.2.

[2] *Standard 2.1.1 of the Australia New Zealand Food Standards Code is varied by –*

[2.1] omitting the Purpose, substituting –

This Standard defines a number of products composed of cereals and qualifies the use of the term 'bread'. It also requires the mandatory fortification of wheat flour for making bread with thiamin and folic acid (Australia only) and the mandatory replacement of non-iodised salt with iodised salt in bread in Australia and New Zealand.

[2.2] omitting clause 5, substituting –

5 Mandatory addition of iodised salt to bread

- (1) Subclause 1(2) of Standard 1.1.1 does not apply to this clause.
- (2) Where salt is added to bread it must be iodised salt.
- (3) Subclause (2) does not apply to bread which is represented as organic.

Editorial note:

The intention of clause 5 is to require the replacement of non-iodised salt with iodised salt where it is used as an ingredient in bread.

Clause 5 will be reviewed when sufficient monitoring data are available to assess the impact of this mandatory requirement.

Standard 2.10.2 sets out the compositional requirements for iodised salt.