FOOD STANDARDS
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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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[13-08]

PROPOSAL P1003
MANDATORY IODINE FORTIFICATION FOR AUSTRALIA
APPROVAL REPORT

Executive Summary

This Approval Report considers mandatory fortification with iodine as a means of addressing the re-emergence of iodine deficiency in Australia. Iodine deficiency, at the level 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.

The specific purpose of this Report 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 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 SD1[1] and SD2[2]). The Australian Health Ministers' Conference subsequently endorsed this advice.

On the basis of the AHMAC advice, FSANZ has prepared Proposal P1003 – Mandatory Iodine Fortification for Australia.

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[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.

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. 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.

Decision

The recommended 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 sodium salt mixtures will be retained at the current range of 25-65 mg per kg, to be consistent with the mandatory requirement.

Reasons for the Decision

- 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 to be the most cost-effective strategy to redress this deficiency.

- Replacement of non-iodised salt with iodised salt in bread will address most of the iodine deficiency in the Australian population, and prevent it from becoming more serious in the future. Currently, 43% of Australians aged two years and over are estimated to have inadequate iodine intakes; following fortification this is estimated to drop below 5%.

- 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, has 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 proposed mandatory iodine fortification 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 SD3[3]). 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 received a total of 25 written submissions on the Assessment Report during the public consultation period from 22 April 2008 to 20 May 2008. Eight responses were from government, five from industry, five from public health professionals and seven from individuals. The key issues raised in submissions are addressed in the relevant sections of this Report.

Government stakeholders, public health professionals and the salt industry indicated support for the Proposal. Most of the other industry submissions were opposed to mandatory fortification, preferring a voluntary approach. Iodine-sensitive individuals noted their concern regarding potential adverse health impacts as a result of increasing the iodine content of the food supply.

While there was general support for the Proposal, many stakeholders acknowledged it did not fully meet the iodine requirements of pregnant and breastfeeding women, and non-bread eaters. Some viewed the current Proposal as an initial step and only part of the solution to address the current iodine deficiency.

A few stakeholders questioned the relevance of the upper level of intake (UL) for young children and believe FSANZ has been overly constrained in its approach. Others noted that mandatory fortification is preferable to voluntary fortification as it provides greater certainty, sustainability, equity, and reach. Most submitters acknowledged the need for effective monitoring systems and a comprehensive education and communication strategy.

As the preferred approach in Proposal P1003 is the same as Proposal P230, FSANZ has also drawn on previous consultations to inform the development of this new Proposal.

[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.)

CONTENTS

SUPPORTING DOCUMENTS

The following materials, which were used in the preparation of this Approval 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 Approval 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, including the Australian Capital Territory. 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*
- *…. 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 Approval 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 consultations 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*[4]. A range of nutrient reference values (NRV) exist for iodine including the estimated average requirement (EAR[5]), the recommended dietary intake (RDI[6]) and the upper level of intake (UL[7]). In the absence of sufficient data to determine an EAR and RDI, an adequate intake (AI[8]) was established for infants aged less than one year instead of an EAR and RDI.

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

[4] This document is available online at http://www.nhmrc.gov.au/publications/synopses/n35syn.htm.
[5] A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.
[6] 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.
[7] 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.
[8] 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.

	Age	AI	EAR	RDI	UL
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 iodine-induced underproduction of thyroid hormone i.e. iodine-induced 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.

The latest guidelines from the ICCIDD state that in populations of children less than two years old and breastfeeding women, a MUIC below 100 μg/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 μg/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).

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

Median urinary iodine concentration (μg/L)	Iodine intake of the population	Iodine status of the population
< 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 μg/L are not recommended because of the risk of iodine-induced hyperthyroidism (see Section 7.2.2.).

Source: ICCIDD *et al*., 2001

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 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 USI[9], 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. 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).

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

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 SD6[10].

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 SD7[11]) 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

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.

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[10] SD6: FSANZ (2007) *International experience with iodine fortification programs.*

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

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*[12] state that essential nutrients may be added to foods for the purposes of restoration, nutritional equivalence of substitute foods, fortification[13], 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 SD8[14]. 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 SD1[15]). 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.

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.

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 ug/L, indicating inadequate iodine nutrition.

Table 3: Australian NINS Median Urinary Iodine Concentration Data

State	Median Urinary Iodine Concentration (µg/L)[16]	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	96		Mild Deficiency

Sources: Li *et al.*, 2006; Li *et al.*, 2008

[12] Codex Alimentarius Commission, 1991.
[13] '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.
[14] SD8: FSANZ (2008) *Nutrition Assessment Report.*
[15] SD1: Australian Population Health Development Principal Committee (APHDPC) (2007) *The Prevalence and Severity of Iodine Deficiency in Australia.* Report commissioned by AHMAC.
[16] According to the WHO and ICCIDD, an MUIC of 50-99 ug/L indicates mild iodine deficiency in a population.

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 *el al*, 2005; Li *et al.*, 2001; Travers *el 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 versus younger adults (Uren *et al*, 2008).

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.

Although two submitters were of the view that iodine deficiency is only regional, recent evidence, as detailed above, shows it is widespread throughout the Australian population, affecting children, adolescents, and adults. The most widely-affected areas are New South Wales, Victoria, and South Australia; Tasmania is also affected, but has taken interim steps to address the problem locally. The survey data indicate that Western Australia and Queensland may be less affected by iodine deficiency in children. However, the APHDPC[15] report noted that pregnant women in these states are still likely to be at risk of iodine deficiency. This is because the iodine status in pregnant women is lower than the iodine status of children in the same region where both have been assessed.

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. A brief summary of the consequences of mild and moderate iodine deficiency follows; a more comprehensive summary can be found in SD8[17].

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.

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

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 SD9[18]).

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).

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 threshold[19] 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 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.

[18] SD9: FSANZ (2007) *Safety Assessment and Risk Characterisation Report.*
[19] The volume below which a given frequency of sound can no longer be heard.

2.4 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.

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 SD2[20]). This report was commissioned by the Commonwealth 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).

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.

[20] 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: SD2[20]

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. This is why they have been 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 50 ug/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.

The Tasmanian Government has subsequently highlighted through its written submission the limitations of the voluntary scheme, notably the failure to provide certainty in relation to the level of iodine in the food supply, the population reach and the long term sustainability of this scheme. In addition, it concluded it is inappropriate to rely on industry goodwill for the protection of public health in this context.

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 SD10[21], 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:

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.

[21] SD10: FSANZ (2008) *Dietary Intake Assessment Report* – Main Report.

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

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 assessed.

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 SD9[22] 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.

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.

[22] SD9: FSANZ (2007) *Safety Assessment and Risk Characterisation Report.*

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 Childrens 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 SD11[23].

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 to:

- be regularly consumed by the population at risk in stable, predictable amounts (upper and lower intake levels known);
- 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 products[24], and cereal-based products and dishes[25].

[23] SD11: FSANZ (2007) *Food Technology Report.*

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

[25] 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.

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 SD10[26]). 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. 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.

One submitter queried FSANZ's estimation that 88% of Australians eat bread daily, citing the 1995 National Nutrition Survey reporting a lower percentage (70.3%), especially among women of child bearing age. However, FSANZ used raw data from the NNS as opposed to the summary data publicly reported, to capture a broader range of bread types that would be included in the mandatory iodine fortification proposal, rather than what was included in the NNS summary report as 'bread'. This raw data includes fancy breads, English-style muffins and mixed dishes containing bread.

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.

[26] SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report.*

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.

Two submitters raised the possibility of iodine being added along with folic acid to flour. However, there is no knowledge or history that this is technically feasibility. Further research would be required to confirm the stability of folic acid and iodine when added together for simultaneous addition.

None of the above means that the concept of iodine addition to bread, independent of salt, may not be suitable in the future, but this would require extensive consultation and resolution of the technical issues prior to proceeding.

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 SD10[27].

Two submitters stated that mandatory fortification should only be instigated as an intervention of last resort. The Ministerial Council's Policy Guideline on fortification does not require all other strategies to be exhausted before considering mandatory fortification. However, the Guideline does specify that mandatory fortification should only be in response to a demonstrated significant population health need and if assessed to be the most effective public health strategy to address the problem.

As outlined in the Introduction, AHMAC advised FSANZ that the re-emergence of iodine deficiency in Australia is significant and acknowledged that mandatory iodine fortification is the most cost-effective strategy to address the deficiency.

8.2.5 Iodine as a processing aid

Two submitters recommended the promotion of iodine as a processing aid to increase the iodine content of the food supply, as part of a strategy for the voluntary fortification of foods with iodine. Standard 1.3.3 - Processing Aids, gazetted in 2005, permits the use of iodine as 'a bleaching agent, washing and peeling agent' on fruits, vegetables and eggs.

In selecting a suitable food vehicle, FSANZ has sought to ensure that it is consumed regularly in stable, predictable amounts. In contrast, the amount of iodine available to the population as a result of this processing aid is highly variable and is dependent on:

- industry uptake;
- the surface area of the product ;
- if a product is consumed peeled or unpeeled; and
- if product is washed prior to consumption.

[27] SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report.*

FSANZ is unaware of any international experience where the use of iodine as a processing aid has successfully addressed iodine deficiency. It is reliant on inadvertent contamination and therefore not recommended as a suitable approach to address the re-emergence of iodine deficiency in the Australian population.

The current uptake of iodine as a processing aid is as yet unknown. Any changes in the iodine contents of foods, for example due to the use of iodine as a processing aid, will be captured in future ongoing monitoring programs.

These submitters also noted that any decision to require mandatory iodine fortification, should not limit the opportunity for innovation and adoption of new technologies for industry to extend the use of iodine as a processing aid to other industries such as poultry processing and dairy industry.

Any application received by FSANZ requesting an extension to permissions for the use of iodine as a processing aid would undergo the usual assessment procedure in accordance with FSANZ's statutory objectives.

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: SD10[28] – 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 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.

[28] 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.

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 SD10[29] 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 SD10[30] 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. 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 in Section 9.4.1) that is iodised based on sales data.

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

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 SD10[31].

9.6.1 Australians Aged Two Years and Over

Currently, 43% of Australians aged two years and over are estimated to have inadequate iodine intakes; following fortification this is estimated to drop below 5%. 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.

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

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.

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

	Proportion of Population with Inadequate Iodine Intakes (%)			
	Market Weighted Model		Consumer Behaviour Model*	
Population Group	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

	Mean Intake of Iodine (μg/day)			
	Market Weighted Model		Consumer Behaviour Model*	
Population Group	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 using data from the 1995 Australian National Nutrition Survey. 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 fully meet their iodine requirements during pregnancy or lactation. 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. After the proposed fortification, this decreases to 13%. For women who use iodised salt, 31% currently have inadequate intakes and this decreases to 6% following the proposed fortification.

Therefore, most women would enter pregnancy after a period of adequate intake, and therefore with iodine stores intact. Notably, the lowest level (5th centile) of intake increases from 53 µg to 93 µg per day after fortification and the highest level (95th centile) from 168 µg to 218 µg. This indicates that fortifying bread improves the intakes of those with very low iodine intakes as well as improving intakes of those with higher intakes at baseline.

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.

In addition, FSANZ has been able to access data from the 2003 follow-up of the Australian Longitudinal Study of Women's Health to assess dietary changes during pregnancy. As part of this study, the Cancer Council of Victoria's food frequency questionnaire was completed by 7324 non-pregnant women and 665 pregnant women. Among non-pregnant women, 17.4% reported consuming less than one slice of bread per day and 19.4% four or more slices per day, compared with 5.3% and 33.2% respectively among pregnant women. It is of interest to note that the bread consumption patterns of non-pregnant women are consistent with the FSANZ estimates reported in Section 8.1.1.

Consequently the increase in iodine intake following mandatory iodine fortification would be expected to be higher in pregnant women than non-pregnant women (Mackerras et al, 2008). FSANZ believes the data derived from the 1995 National Nutrition Survey in Table 9 is likely to under-estimate the impact of mandatory fortification on the intakes of pregnant women.

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 (μg/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 95thcentile Dietary Iodine Intakes of Australian Children Aged 1 Year Based on a Theoretical Diet

Population Group	Mean Intake of Iodine (mg/day)		95th 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.

Considering the data from the NNS and the 2003 follow-up of the Australian Longitudinal Study of Women's Health approximately half of pregnant and breastfeeding women would have inadequate iodine intakes.

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 Group[32] 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 SD8[33] and 9[34].

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). 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.

[32] For a list of members refer to: http://www.foodstandards.gov.au/foodmatters/fortification/iodinescientificadvi3251.cfm
[33] SD8: FSANZ (2008) *Nutrition Assessment Report.*
[34] SD9: FSANZ (2007) *Safety Assessment and Risk Characterisation Report.*

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 (AACE 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.

Exposure to some iodine-containing therapeutic/diagnostic substances and iodine rich foods is known to produce a range of adverse reactions in some individuals.
These individuals will react, sometimes severely, to multiple iodine-containing substances and/or iodine rich foods such as iodinated contrast material, iodine-based antiseptics, and/or seafood. Sometimes such reactions are referred to as 'iodine allergy'. Despite iodine being a common component of these substances and foods, testing has shown that the reactions observed are almost certainly a reaction to the iodine-containing molecule as a whole or some other component of the substance/food, and not to iodine itself (Coakley and Panicek, 1997).

Some individuals are more sensitive to adverse reactions from high iodine intakes, compared to others. This has been referred to as 'iodine sensitivity', and is not a true allergic reaction. These reactions only occur at very high doses that far exceed the amount of iodine that people would receive from the normal diet, even with mandatory fortification. However, very high iodine foods and supplements, such as some seaweed and kelp products may affect sensitive individuals.

The addition of extra iodine to food supply, resulting from mandatory iodine fortification, will not increase the risk of iodine sensitivity reactions occurring, as the amount of additional iodine is consistent with physiological requirements for this nutrient.

Several individual submitters raised concerns about iodine sensitivities. FSANZ sought further advice from the ISAG and an international allergy expert[35]. It was concluded that the risk of adverse effects is minimal. Forms of iodine used in iodised salt, are too small by themselves to cause an allergic reaction.

10.2.5 Iodine and Acne

Very high doses of iodine, doses exceeding normal dietary intake even with fortification, can lead to some forms of inflammatory acne in sensitive individuals. These forms of acne are different from the common comedonal acne. The proposed mandatory fortification will only raise iodine intakes to desirable levels in line with iodine requirements and therefore not cause inflammatory acne.

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 impairments[36]. 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.

[35] Dr Rob Loblay is the Director of the Allergy Unit at the Royal Prince Alfred Hospital and Senior Lecturer in Immunology at the University of Sydney.

[36] 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.

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.

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 in the future. This approach was supported by several submitters.

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 Tasmanian and international research and practice 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.

Several submitters raised the issue 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 represented as 'organic'. Salt used as a topping or in other foods added to bread will not be required to be iodised. Several submitters requested that the legal drafting be amended to ensure the intent of the Standard was clear. In response, FSANZ has revised the drafting at Attachment 1A to include additional subclauses to this effect.

FSANZ will prepare an Industry User Guide to provide further clarification as to the scope of bread included in the fortification scenario. This was supported by several submitters.

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.

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 SD11[37]).

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 7[37]. 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. 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).

[37] SD11: FSANZ (2007) *Food Technology Report.*

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 SD4[38]), 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.

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.

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

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 SD11[39], 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 SD12[40]). 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.

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 ingredients[41] (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. 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.

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

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

[41] 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.

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 deceptive[42]. 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. 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 SD13[43]).

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 SD7[44]. '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.

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[42] *Trade Practices Act 1974,* State and Territory Fair Trading Legislation and *Fair Trading Act 1986.*
[43] SD13: FSANZ (2008) *Communication and Education Strategy.*
[44] SD7: The Australia and New Zealand Food Regulation Ministerial Council Policy Guideline Policy Guideline Fortification of Food with Vitamins and Minerals.

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 the mandatory iodine fortification Standard, 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 was 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.

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. However, some submitters noted that 'organic' bread would incur a premium cost on what is a dietary staple. 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 ingredients[45] 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 SD14[46]).

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.

[45] 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.

[46] 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.

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 SD13[47]) 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.

[47] SD13: FSANZ (2008) *Communication and Education Strategy.*

Several submitters noted strong support for retaining the voluntary permissions to allow for wider use of iodised salt in food manufacturing. In contrast, one submitter recommended 'banning' all iodised table salt believing it 'unethical to promote iodised salt at any age and indefensible in childhood'. Although other submitters have advocated USI as a strategy to address iodine deficiency; in this case, the sale of uniodised salt would not be permitted.

The removal of the voluntary permission would result in all discretionary salt being non-iodised, and prevents manufacturers from being able to add iodised salt to any food product, 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.

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 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 SD13[48]).

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.

[48] SD13: FSANZ (2008) *Communication and Education Strategy.*

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. One industry submitter advised that they manufacture breadcrumbs from returned bread for domestic and overseas markets and if fortified with iodised salt, this may impact on trade.

A survey of the major crumbed fish food manufacturers in Australia established that most crumbed foods are coated with 'purpose-made' crumbs. However, it is not intended that purpose-made breadcrumbs will be required to contain iodised salt as these fall outside the Code's definition of 'bread'. FSANZ understands that few crumbed products made from returned bread are exported to Japan. Therefore, the trade impact of this fortification Proposal is likely to be minimal.

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 (RIS ID: 9576)

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 SD4[49]). 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 SD5[50]). 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.

[49] SD4: Access Economics (2006) *Cost benefit analysis of fortifying the food supply with iodine*. Report commissioned by FSANZ.
[50] SD5: Access Economics (2007) *Costs of fortifying bread and bread products with iodine*. Report commissioned by FSANZ.

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.

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 kilogram. 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.

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 Baseline stakeholder survey	36,000
Update National Food Composition Database Label monitoring survey Label compliance analytical surveys Reporting and tracking system for voluntarily fortified products	63,000
Market basket/store surveys in remote communities Consumer attitude and behaviour research Food frequency surveys (Roy Morgan Research)	118,000
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

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.

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 year[51]. 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 IDDs or their carers and related management costs, improved school attendance and enhanced performance at school.

[51] 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 SD3[52]).

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.

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.

[52] 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 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

A number of submitters noted the importance of educating pregnant and breastfeeding women to take iodine supplements.

Two submitters raised potential equity issues in accessing and relying on supplements to provide sufficient iodine. Advice to take supplements is more likely to be adopted by women on higher incomes and with higher educational levels. The need to target iodine supplements to this sub-group is an integral part of the implementation strategy and is included in the Communication & Education Strategy.

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 the Proposal, 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

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. In addition, FSANZ will develop a fact sheet for the FSANZ website for concerned individuals.

FSANZ's risk assessment, as noted in Section 10.2.4, concluded that mandatory iodine fortification will not increase the risk of iodine sensitivity reactions occurring, as the amount of additional iodine is consistent with physiological requirements for this nutrient. Despite this conclusion, several submitters remained concerned about iodine sensitivities.

In response, FSANZ asked the ISAG and an international allergy expert[53] to review our Risk Assessment of this issue. They reaffirmed FSANZ's conclusion, noting that the risk of adverse effects is minimal. They advised that the chemical forms of iodine used in iodised salt, are too small by themselves to cause an allergic reaction.

Those individuals who are still concerned about mandatory fortification of bread via iodised salt can be tested for reactions specifically to potassium iodate, the form commonly added to iodised salt. General practitioners can provide advice regarding testing and can refer these individuals to specialist allergy clinics.

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 SD13[54]).

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.

[53] Dr Rob Loblay is the Director of the Allergy Unit at the Royal Prince Alfred Hospital and Senior Lecturer in Immunology at the University of Sydney.
[54] SD13: FSANZ (2008) *Communication and Education Strategy.*

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.

Two submitters noted previous FSANZ comments that if manufacturers reduce the salt content of bread, in response to public health calls to lower salt, then mandatory fortification may be less effective. However, the proposed monitoring program, which includes tracking food composition and market changes in the food supply, will determine if future additional strategies are required. For example, FSANZ could expand the number of food vehicles and/or increase the salt iodisation range.

15.2 Labelling and Claims

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);
- 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.

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 breads 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;

- a written declaration of iodised salt as an ingredient without including other ingredients may cause confusion for consumers; and

- the information is generally available to the public upon request.

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 0.75% iodised salt. (This is equivalent to 295 mg Na /100 g derived from iodised salt, assuming 10% loss on baking.)

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.

The proposed new Standard (draft Standard 1.2.7 – Nutrition, Health and Related Claims) will permit a wider range of 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 those which contain enough iodine to qualify to carry nutrition content claims and which foods are eligible for health claims about iodine. In March 2008, the FSANZ Board approved draft Standard 1.2.7 and notified the Ministerial Council of its decision. However, in June 2008, the Ministerial Council requested FSANZ review the draft Standard. Details of the review request are available on the Commonwealth Department of Health and Ageing web site[55].

Three submitters made comments in relation to health claims and iodine fortification. One issue of concern related to the food eligibility criteria for nutrition content claims. It was suggested that the nutrient profiling scoring criteria be applicable for nutrient content claims on foods prepared with iodised salt, using voluntary permissions. This means some foods, such as potato chips, would not be eligible to make iodine content claims. The issue of food eligibility criteria in respect of content claims will be addressed as part of the review of P293.

In contrast, another submitter requested blanket permissions allowing iodine content claims to be made on iodised salt and products containing iodised salt. FSANZ notes that draft Standard 1.2.7 proposes to delete the 'claimable foods' concept, which currently applies to foods making nutrition content claims around vitamins and minerals. This means any food which meets the qualifying criterion[56] for a content claim, could do so; and any food which meets both the qualifying criterion and is eligible under profiling, could make a general level health claim, providing the claim can be substantiated.

[55] http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-request-reviews
[56] For example, a nutrition content claim claim can be made if a serve of the food contains at least 10% of the RDI

The qualifying criterion for a content claim is related to the serving size of the food. The serving size is not set by FSANZ but is at the discretion of manufacturers.

Therefore whether iodised salt, and products containing iodised salt, would be able to make a content claim would be dependent on the serving size specified by the manufacturer and whether the manufacturer wished to make a content claim about the product. Iodised salt would not meet the proposed profiling criteria and so would be ineligible to make a general level health claim.

Some submitters to P1003 requested that pre-approved health claims be available for use by manufacturers of foods containing iodised salt. Bearing in mind that draft Standard 1.2.7 (as presented at the Final Assessment Report) may be subject to change, FSANZ notes the following:

- the draft Standard includes scope for general level health claims around iodine, with Table 2 of Schedule 2 containing two specific nutrient function statements which may form the basis for general level health claims. These statements are:

    - *Iodine is necessary for normal production of thyroid hormones*; and
    - *Iodine is necessary for normal brain development in the unborn child, babies and young children*.

- The list of nutrient function statements included within Table 2 is non-exhaustive and the wording is not prescriptive; the draft Standard 1.2.7 allows that other general level health claims may be made providing substantiation requirements are met.

- No high level health claims around iodine have at this time been pre-approved by FSANZ, however the draft Standard allows for consideration of further high level health claims via the application process.

15.3 Potential for mixed public health messages

During consultations, some submitters were concerned that the use of salt as a carrier for adding iodine to the food supply created conflicting public health messages. Some 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. Alternatively, other submitters 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 the average 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. Alternatively, if considered necessary, the amount of iodine per volume of salt can be increased to accommodate the declining salt levels in bread.

Two submitters supported this view, noting that mandatory fortification enables public health authorities to promote bread as the source of iodine. In contrast, a voluntary system would require educators advising the public to look for 'iodised salt' in the ingredient list, as not all bread would contain iodised salt. FSANZ's key messages, developed as part of the Communication & Education Strategy, see SD13[57], focus on bread as the vehicle, not salt.

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

Another submitter noted that to achieve iodine sufficiency, it would be necessary to consume an undesirably high amount of salt. However, this incorrectly assumed that there is no iodine currently present in the diet. As shown in FSANZ's dietary intake assessment, SD10[58], approximately 75% of current iodine requirements are being supplied from the existing food supply. The additional iodine, delivered from mandatory fortification, builds on this existing baseline.

15.4 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 enforce[59];
- 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.

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 mid-point of 45 mg iodine per kg salt.

15.5 Legal Drafting for Mandatory Iodine Fortification

Submissions were sought on the proposed draft variations to Standards 1.3.2 and 2.1.1 (Attachment 1C).

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[58] SD10: FSANZ (2008) *Dietary Intake Assessment Report – Main Report.*

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

Two submitters noted that the intention of Proposal P1003 was not to require the addition of iodised salt after the bread was baked but during the manufacture of the bread. In addition, one submitter suggested that the drafting be amended to make it clear that iodised salt is not treated as a subset of salt but rather as a distinct product.

Several submitters raised the issue 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.

In light of the above, FSANZ revised the proposed draft variations to Standard 2.1.1 (Attachment 1B) to clarify that iodised salt is to be used during the manufacture of bread where salt would otherwise be used and included additional exemptions for coarse salt and other toppings containing salt which may be added to the surface of the bread, and to other foods containing salt which may be added during the manufacture of bread. The final draft variations to Standard 2.1.1 are at Attachment 1A.

15.6 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.

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 SD13[60]). 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

17.1 Assessment Report for Proposal P1003

In May 2008, FSANZ received **25** submissions on the Assessment Report for Proposal P1003. Eight responses were from government, five from industry, five from public health professionals and seven from individuals. Government stakeholders, public health professionals and the salt industry indicated support for the Proposal. Most of the industry submissions were opposed to mandatory fortification, preferring a voluntary approach. Iodine-sensitive individuals noted their concern regarding potential adverse health impacts as a result of increasing the iodine content of the food supply. A summary of submissions is included at Attachment 2.

While there was general support for the Proposal, many stakeholders acknowledged it did not fully meet the iodine requirements of pregnant and breastfeeding women, and non-bread eaters. Some viewed the current Proposal as an initial step and only part of the solution to address the current iodine deficiency.

[60] SD13: FSANZ (2008) *Communication and Education Strategy.*

A few stakeholders questioned the relevance of the UL for young children and believed FSANZ had been overly constrained in its approach. Others noted that mandatory fortification is preferable to voluntary fortification as it provides greater certainty, sustainability, equity, and reach.

Most submissions highlighted the importance of establishing suitable monitoring systems but noted concern regarding the lack of progress in finalising specific arrangements. Some public health professionals were concerned that the use of salt as a food vehicle resulted in mixed public health messages and suggested alternative iodine delivery methods. The need for a comprehensive education and communication strategy was highlighted by the majority of submitters.

The key issues raised in submissions are addressed in the relevant sections of this Report.

17.2 Previous public consultations on mandatory iodine fortification

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. 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.

17.2.1 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 s*tatus quo,* six did not indicate a preferred option and one submitter stated they were opposed to mandatory fortification.

17.2.2 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 SD15[61].

17.2.3 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. 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.

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

A full summary of the comments received in response to the Issues Paper is provided in SD16[62].

17.2.4 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 SD3[63]).

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).

[62] SD16: FSANZ (2007) Summary of Submitter Comments to Issues Paper for Proposal P230.
[63] 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 determined that notification of P1003 was not required.

CONCLUSION

19. Conclusion and Decision

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.

Decision

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 sodium salt mixtures will be retained at the current range of 25-65 mg per kg, to be consistent with the mandatory requirement.

Reasons for the Decision

- 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 to be the most cost-effective strategy to redress this deficiency.

- Replacement of non-iodised salt with iodised salt in bread will address most of the iodine deficiency in the Australian population, and prevent it from becoming more serious in the future. Currently, 43% of Australians aged two years and over are estimated to have inadequate iodine intakes; following fortification this is estimated to drop below 5%.

- 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, has 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 SD3[64]). 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.

- 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.

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

20. Implementation and Review

20.1 Transitional Period

Upon approval by the FSANZ Board of the draft variations to the Code, as presented in the Approval Report, the Ministerial Council will be notified of the decision. Subject to any request from the Ministerial Council for a review, the draft variations to the Code are expected to come into effect 12 months after gazettal of the Standard. As noted in Section 12.1.8, FSANZ will prepare an Industry User to provide further clarification as to the scope of bread included in the fortification scenario.

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 SD14[65]. This approach was supported by submitters. 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.

The Implementation Sub Committee (ISC) of the Food Regulation Standing Committee (FRSC) has established a working group to develop a National Implementation Strategy for the mandatory fortification standards. FSANZ is assisting the working group to accelerate development of a compliance and enforcement model as part of the National Implementation Strategy. This will assist industry to prepare for mandatory fortification by September 2009.

21. Monitoring

An effective mandatory fortification program will require monitoring; an action that is the responsibility of health and regulatory agencies at the Commonwealth and State/Territory levels in Australia and New Zealand. While the responsibility for establishing and funding a monitoring system extends beyond FSANZ's responsibilities under the FSANZ Act, the Government is committed to fortification monitoring.

[65] 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.

This commitment is demonstrated in the fortification Policy Guideline which states that *any agreement to require fortification also requires that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification*.

In October 2007, AHMAC endorsed the mandatory fortification monitoring frameworks. AHMAC also agreed to fund the AIHW to coordinate monitoring activities for the mandatory fortification standards (folic acid and iodine) in both Australia and New Zealand. The AIHW is an appropriate national organisation to coordinate mandatory fortification monitoring because its core business deals with collecting, analysing and disseminating health related data and information. It works closely with all State/Territory Governments and with the Australian Government, and also has the necessary skills and expertise to oversee such a program.

The AIHW will consult with relevant stakeholders, including jurisdictions, in preparing an initial stocktake report of current and required data to fully inform the fortification monitoring program, the preparation of a baseline quantitative report and reporting on progress. These reports are expected to be finalised before the implementation date for the mandatory fortification standards.

FSANZ will contribute directly to some elements of the monitoring program as part of its ongoing work and may also be involved indirectly in other fortification monitoring program activities. 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 (sodium) and iodine component of its food composition databases with the results of a new 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 4000 foods and supplements.

In Section 13.2.2.5 of this Report, FSANZ has presented and discussed estimates of probable government costs associated with specified activities identified against the proposed monitoring program for mandatory iodine fortification. FSANZ expects that during the AIHW's consultation with relevant stakeholders, there will be discussions regarding jurisdictional and agency responsibilities and the cost implications.

Both the importance of monitoring and the associated costs were highlighted by a number of submitters. Two industry submitters suggested that mandatory fortification should lapse after four years if no monitoring program is instigated. However, FSANZ notes there is a commitment by the Ministerial Council and jurisdictions for ensuring monitoring is commenced in a timely fashion. This commitment is also reflected in the Ministerial Council's decision of May 2007 to support mandatory folic acid fortification on the basis that a comprehensive and independent review would be initiated two years after implementation of the standard. The Policy Guideline also requires that a formal review of mandatory fortification be undertaken to assess its effectiveness and continuing need.

Attachments

1A. Draft variations to the *Australia New Zealand Food Standards Code* (as approved)
1B. Draft variations to the *Australia New Zealand Food Standards Code* as amended (in mark-up) following submissions
1C. Draft variations to the *Australia New Zealand Food Standards Code* proposed at Assessment on which submissions were received
2. Summary of submissions

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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	Moratorium 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
USI	Universal Salt Iodisation
WHO	World Health Organization
WTO	World Trade Organization
µg	micrograms (1000^{th} of a milligram)
mg	milligrams (1000^{th} of a gram)
g	grams

Attachment 1A

Draft variations to the *Australia New Zealand Food Standards Code* (as approved)

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

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) Iodised salt must be used for making bread where salt would otherwise be used.

(3) Subclause (2) does not apply to:

(a) bread which is represented as organic;
(b) the addition of salt (for example rock salt) to the surface of bread; or
(c) the addition of other food containing salt during the making of bread.

The Editorial note below has been provided for completeness only. It has been shaded to highlight that it is not part of the approval of the draft mandatory iodine standard.

Editorial notes are not, by virtue of the definition of 'standard' part of a draft standard and therefore not subject to the standards development process under Part 3 of Food Standards Australia New Zealand Act 1991.

Editorial note:

The intention of clause 5 is to require the replacement of non-iodised with iodised salt where it is used as an ingredient in the manufacture of bread. The New Zealand Standard issued under section 11L of the New Zealand *Food Act* 1981 that adopts clause 5 limits the application of clause 5 to bread produced for the New Zealand domestic market only.

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. The target level of iodine when manufacturing iodised salt for addition to bread ideally would be the mid-point of the iodisation range, ie 45mg of iodine per kilogram of salt.

Attachment 1B

Draft variations to the *Australia New Zealand Food Standards Code* as amended (in mark-up) following submissions

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

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.~~Iodised salt must be used for making bread where salt would otherwise be used.

(3) Subclause (2) does not apply to:

(a) bread which is represented as organic;
(b) the addition of salt (for example rock salt) to the surface of bread; or
(c) the addition of other food containing salt during the making of bread.

The Editorial note below has been provided for completeness only. It has been shaded to highlight that it is not part of the approval of the draft variation to the mandatory iodine standard.

Editorial notes are not, by virtue of the definition of 'standard' part of a draft standard and therefore not subject to the standards development process under Part 3 of Food Standards Australia New Zealand Act 1991.

Editorial note:

The intention of clause 5 is to require the replacement of non-iodised with iodised salt where it is used as an ingredient in the manufacture of bread. The New Zealand Standard issued under section 11L of the New Zealand *Food Act 1981* that adopts clause 5 limits the application of clause 5 to bread produced for the New Zealand domestic market only.

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. The target level of iodine when manufacturing iodised salt for addition to bread ideally would be the mid-point of the iodisation range, ie 45mg of iodine per kilogram of salt.

Attachment 1C

Draft variations to the *Australia New Zealand Food Standards Code* proposed at Assessment on which submissions were received

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

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.

Attachment 2

Summary of Submitter Comments to Proposal P1003 Assessment Report

In May 2008, FSANZ received **25** responses to the Assessment Report for Proposal P1003 –Mandatory Iodine Fortification for Australia. Eight responses were from government, five from both industry and public health professionals, and seven from interested individuals.

Government stakeholders, public health professionals and the salt industry indicated support for the Proposal. Most of the industry submissions were opposed to mandatory fortification, preferring a voluntary approach. Iodine-sensitive individuals noted their concern regarding potential adverse health impacts as a result of increasing the iodine content of the food supply.

Submitters raised the following key issues:

- need for pregnant and breastfeeding women to take iodine supplements;
- relevance of the UL for young children;
- expansion of food vehicles and alternative iodine delivery methods for the future;
- importance of a comprehensive communication and education strategy to support mandatory fortification;
- potential for conflicting public health messages regarding salt;
- need to establish an appropriate monitoring program;
- ability to make health claims;
- recognition of the importance of aligning iodine and folic acid mandatory fortification implementation periods;
- promotion of iodine as a processing aid;
- lack of consumer choice; and
- amendments to the proposed drafting.

The above key issues are addressed in the relevant sections of this Report. A detailed summary of submitter comments is provided in the following table.

SUBMITTER	SUBMITTER COMMENTS
Government	
Department of Agriculture, Fisheries and Forestry Australia Richard Souness	**Supports mandatory fortification with iodine** Supports strategies aimed at addressing iodine deficiency in Australia. • Notes AHMAC advice that iodine deficiency is prevalent and severe enough to warrant intervention in Australia and that mandatory fortification is the most cost-effective strategy to redress this. • Acknowledges FSANZ's proposal to limit iodine fortification to salt used for bread making to minimise trade barriers, as bread is typically made domestically for the local market. • Notes FSANZ has extended the iodisation range to 25-65 mg of iodine, consistent with currently voluntary permissions and the mandatory iodine fortification Standard for New Zealand. *Labelling and claims* • Recommends a pre-approved iodine health claim for bread fortified with iodine be provided under the proposed Standard 1.2.7 – Nutrition, Health and Related Claims. Suggests such a permission will enhance communication and education of the importance of iodine in the diet. *Monitoring and compliance* • Notes iodine status can vary over time due to changes in the food environment, independent of food choice. • Suggests mandatory iodine fortification needs to be accompanied by a robust monitoring framework with a definitive timeframe to review whether mandating iodine fortification in salt used for bread making addresses iodine deficiency. *Implementation* • Considers any transition period needs to align with folic acid and iodine (New Zealand) and should be cognisant of any other impending labelling changes. • Suggests any implementation/user guide developed by FSANZ to assist industry compliance of mandatory iodine and/or folate fortification should be made available at the same time the Standard is gazetted to achieve optimal compliance.
Department of Health and Human Services, Tasmania Judy Seal	**Supports mandatory fortification with iodine** *Consistency with policy principles* • Considers there is no conflict with iodised salt as the food vehicle and the need for Australians to lower their salt intake. • Suggests a mandatory program enables public health authorities to promote bread as a source of iodine rather than advising consumers to choose bread baked with iodised salt. *Safety and efficacy* • Tasmanian experience indicates a small increase in iodine status with iodised salt in bread (Seal et al. MJA 2007; 186:69-71.). • Suggests proposed level of fortification is inadequate to meet the requirements of pregnant and lactating women. (Burgess et al. MJA, 2007; 186:574-576.).

SUBMITTER	SUBMITTER COMMENTS
Department of Health and Human Services, Tasmania Judy Seal (Cont.)	*Safety and efficacy* • Understands a higher level of iodine fortification may increase the proportion of young children exceeding the UL however notes this value was established by extrapolating from adult studies with a wide safety margin. Suggests the NHMRC may have been over cautious in setting the UL for children and believes this will need consideration by the NHMRC in the next reiteration of the Nutrient Reference Values. • Recommends ongoing investigation of alternate sources of increasing iodine in the food supply e.g. fortification of breakfast cereals. • Notes limitations of voluntary fortification i.e. failure to provide certainty and sustainability. *Monitoring and compliance* • Argues appropriate monitoring systems are essential to determine the change to iodine status due to mandatory fortification. • Notes the AIHW to compile a baseline report of iodine status in Australia and recommend strategies for monitoring changes to iodine status. • Requests that this work is undertaken as a matter of priority to determine the effectiveness of the intervention and any adjustments to the level of fortification. *Communication and education* • Notes additional strategies will be required to ensure iodine requirements during pregnancy and lactation are met in an equitable way. • Suggests the potential for mixed public health messages is reduced with mandatory fortification as the focus is bread not salt. *Consumers* • Acknowledges recommendations for pregnant and lactating women to take additional supplemental iodine but notes this is more likely to be taken up by women with higher educational and income levels. *Other comments* • Raises concerns about ongoing delays and believes further delays are unacceptable.
Department of Health, Government of Western Australia Sophe Williamson	**Supports mandatory fortification with iodine** *General* • Supports mandatory fortification in principle and acknowledges there is reasonable evidence of iodine deficiency in the general population and sub population groups of South Eastern Australia. • Notes the iodine intake of the general population in QLD and WA is within an acceptable range. • Acknowledges there is limited current population data on iodine intake via food and water and data on specific urinary iodine status of sub-population groups such as pregnant women and young children in WA. *Safety and efficacy* • Notes the proposed range 25-65 mg of iodised salt per kilogram of salt in bread may not achieve the WHO recommendation for pregnant women and that iodine supplementation may still need to be considered.

SUBMITTER	SUBMITTER COMMENTS
Department of Health, Government of Western Australia Sophe Williamson (Cont.)	*Food vehicle* • Supports bread as the appropriate food vehicle for fortification with non-iodised salt being replaced with iodised salt in the range 25-65 mg of iodine per kilogram of salt. *Costs* • Acknowledges that the cost to the health system of inaction to address iodine deficiency significantly outweighs the cost to industry of implementing mandatory iodine fortification. *Monitoring and compliance* • Considers a comprehensive monitoring and evaluation process is essential to assess the effectiveness and safety of iodine fortification. Furthermore, it is important to monitor both the regions of Australia known to be iodine deficient together with the total iodine intake of the WA and QLD populations, particularly sub-population groups such as young children and pregnant women within these regions as a means to confirm the upper threshold limits for dietary iodine are not being exceeded, particularly in the 2-11 year old age group. • Notes funding arrangements for monitoring iodine status of target and sub-population groups as well as the general population has not been fully addressed. • Acknowledges the AIHW are finalising an initial report on the costs and protocols of monitoring activities. • Considers it appropriate that such arrangements are in place prior to approval of this Proposal by Ministers. • Acknowledges iodine fortification has the potential to increase the incidence of hyperthyroidism and recommends a mechanism to review iodine fortification in the occurrence of adverse health impact on sub-population groups be considered as part of the Standard. *Communication and education* • Recommends comprehensive education programs (strategies) to target pregnant women, mothers of infants, health professionals and the general population are necessary to compliment mandatory iodine fortification. *Implementation* • Supports the alignment of iodine with folic acid fortification on the proviso it does not delay the implementation of mandatory fortification of bread flour with folic acid.
Department of Human Services Victoria Fiona Jones	**Supports mandatory fortification with iodine** *Consistency with policy principles* • Notes both AHMAC and AHMC have indicated their support for this initiative. • Satisfied that iodine deficiency has been demonstrated to be prevalent and severe in Australia at levels that warrant a population wide intervention and that mandatory fortification is the most cost effective strategy to redress this.
Queensland Health Gary Bielby	• **Qualified support for mandatory fortification with iodine** (Advises costings will need to be provided to QLD Health prior to further consideration of this Proposal). Whole of Queensland Government Response.

SUBMITTER	SUBMITTER COMMENTS
Queensland Health Gary Bielby (Cont.)	*Food vehicle* • Supports the proposed salt iodisation range. • Supports voluntary permission to be consistent with mandatory range. *Consumer choice* • Supports exemption for bread represented as 'organic'. *Implementation and transition* • Supports aligning the implementation period for iodine with mandatory folic acid fortification to help reduce the upfront costs of relabeling and label write-offs for industry. *Safety and efficacy* • Acknowledges the proposed approach can be augmented by activities outside FSANZ's remit (education and promotion of iodine supplement use) to target individuals who will not 'get enough iodine' from the replacement of salt with iodised salt in bread. *Costs* • Notes the estimated costs outlined in the DAR will require adjustment following completion of the AIHW *Initial Stocktake Report* and subsequent discussions with DoHA, jurisdictions and other relevant agencies. *Monitoring and compliance* • Acknowledges that 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 sale with iodise salt in products other than bread or exploring the possibility of adding iodine to the food supply other than through iodised salt. • Considers these potential options can only be adequately considered when there is sufficient data on the impact of the proposed mandatory fortification. *Communication and education* • Agree with the Strategy 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.
New South Wales Food Authority/ New South Wales Health Lisa Szabo, Wayne Smith, Bill Porter and Craig Sahlin	**Supports mandatory fortification with iodine** *Safety and efficacy* • Notes the level of fortification will not address the needs of pregnant and breastfeeding women. • Agrees it is inappropriate to manage deficiencies by re-establishing the use of iodophor-containing sanitisers in dairy factories. *Food vehicle* • Concurs with FSANZ's recommendation of salt for bread-making as the sole vehicle for this public health intervention, with a range of 25-65 mg iodine per kg of salt. • Comments that to replace all salt used in processed foods with iodised salt would be unnecessarily problematic for persons with iodine sensitivities.

SUBMITTER	SUBMITTER COMMENTS
New South Wales Food Authority/ New South Wales Health Lisa Szabo, Wayne Smith, Bill Porter and Craig Sahlin (Cont.)	*Costs* • Notes that FSANZ attempted to quantify (in dollars) the cost of the existing iodine deficiency but it was not possible due to the high degree of uncertainty. • Notes the cost-effectiveness of iodine fortification suggest a significant decrease in the proportions of individuals with moderate or mild deficiency. *Labelling/claims* • Agrees that bread manufacturers will be required to list 'iodised salt' in the ingredient list of bread packaging. • Suggests the eligibility criteria applicable to general and high level health claims under Standard 1.2.7 be extended to foods prepared with iodised salt using voluntary permissions. Highlights concerns that retention of voluntary permissions for iodised salt may allow foods, by virtue of their iodised salt content, to make source claims where these claims that are not considered by nutritionists to be healthy (e.g. potato chips). Does not consider this appropriate. *Implementation* • Agrees it is sensible to parallel the implementation of this Proposal with Proposal P295 (folic acid). *Monitoring and compliance* • Concurs with FSANZ that monitoring form part of the overall strategy for iodine fortification. • Notes AHMAC funded the AIHW to coordinate monitoring activities and that this does not include the actual collection and analysis of the data. Further notes a decision on funding these activities awaits the completion of the *Initial Stocktake Report*. • Recommends the prompt finalisation of funding is essential to allow the integration of food fortification proposals in the overall context of health promotion strategies. • Advises that jurisdictions require access to details of the human population monitoring study, particularly its design, before agreeing to commitment of funds. • Suggests FSANZ consult with the respective health portfolios to progress the matter further. • Considers label monitoring and compliance via analytical surveys is appropriate for monitoring however notes these activities do not provide the evidence that the desired health outcome is achieved. Suggests measuring urinary iodine concentration is a more appropriate measure. • Proposes the establishment of an expert steering group to oversee monitoring activities. • Notes the provision of a list of breads encompassed by the Proposal would assist jurisdictions to understand their enforcement obligations • Agrees that the point of compliance will be the salt manufacturer or importer. *Costs* • Notes the cost-effectiveness of iodine fortification, the results of which suggest a significant decrease in the proportion of individuals with moderate or mild iodine deficiency.

SUBMITTER	SUBMITTER COMMENTS
New South Wales Food Authority/ New South Wales Health Lisa Szabo, Wayne Smith, Bill Porter and Craig Sahlin (Cont.)	*Communication and education* • Recommends inclusion of education programs targeting at risk groups in the population, people not receiving their daily iodine requirements from this initiative, and those that do not consume bread. • Notes the promotion of supplements will need to form part of the overall strategy of the Proposal to met the needs of pregnant and breastfeeding women. • Suggests the general public must be appropriately informed on the detail and scope of this public health initiative. • Notes FSANZ is not wholly responsible for education programs and that health portfolios will contribute to delivering messages. • Supports educational material targeted at those sensitive to iodine to enable informed purchase decisions. *Drafting* • Considers the proposed clause 5(2) is contradictory and suggests wording to the effect that iodised salt must be used during the manufacture of bread where salt would otherwise be used.
New Zealand Food Safety Authority, Carole Inkster	**Supports mandatory fortification with iodine** Key comments: • Supports a joint standard for this important public health issue. *Drafting* • Highlights difficulties in relation to the export of bread (in frozen form) from New Zealand to the Japan market which does not permit iodine fortification. - Requests an addition to the first sentence of the Editorial Note to clause 5 to include the following text: *The New Zealand Standard issued under section 11L of the New Zealand Food Act 1981 that adopts clause 5 limits the application of this standard to bread produced for the domestic market only.* - Notes the New Zealand Food Standard 2002, implementing the New Zealand-only iodine standard, already provides an exemption for bread for export. • Salt Iodisation Range - Requests an addition to the third sentence of the Editorial Note to clause 5 to include the following text: *The target level of iodine when manufacturing iodised salt for addition to bread ideally would be at least the mid point of the iodisation range, i.e. at least 45 mg iodine per kg of salt.* - Note the dietary modelling for New Zealanders was based on this level. *Implementation* Advises NZFSA do not wish to see any change to the implementation date for New Zealand (27 September 2009).
South Australian Department of Health Joanne Cammans	**Supports mandatory fortification with iodine** *Drafting* • Recommends amending the editorial note to indicate that iodised salt be used during the manufacture of bread where salt would otherwise be used.

SUBMITTER	SUBMITTER COMMENTS
South Australian Department of Health Joanne Cammans (Cont.)	*Monitoring and compliance* • Suggests finalisation of the AIHW Report and clarification of funding required by jurisdictions prior to implementation. • Seeks clarification in the final Approval Report to alleviate possible confusion over monitoring for compliance (product testing) versus monitoring for outcome (urinary iodine testing).
Industry	
Australian Food and Grocery Council (AFGC) Kim Leighton	**Does not support mandatory fortification with iodine** *Preferred approach* • Recommends a voluntary approach led by industry, together with the AFGC, with a Memorandum of Understanding for the use of iodised salt in bread and other suitable foods and the use of iodine as a processing aid because it: - has evidence of effectiveness in the Australian market; - retains consumer choice; - allows for those with coeliac disease to be reached through use in non-wheat based products; and - it has been shown to be effective internationally. • Recommends FSANZ reconsider the likely uptake of a voluntary scheme based on the Tasmanian situation and the incentive of a general level health claim. *Food vehicle* • Suggests FSANZ's focus on mandatory fortification of a single vehicle is wrong and will not deliver a more effective outcome. • Considers there is potential to improve levels of iodine in the food supply (under a voluntary program) through the broader use of iodine as a processing aid, under Standard 1.3.3, as a sanitising rinse solution for certain fruits and vegetables. - Notes potential to extend this technology to poultry processing and dairy. *Labelling/claims* • Considers it essential that iodised salt and foods fortified with iodised salt be permitted to make an appropriate health claim to inform consumers and improve awareness. • Recommends the following pre-approved general level health claims be permitted: - iodine is necessary for normal/active metabolism; - iodine is necessary for normal/active brain development; and - iodine is necessary for normal/active metabolism, growth and brain development. • Believes health claims should be available for inclusion on products that contribute 10% RDI of iodine per serve. • Notes the current proposed Standard 1.2.7 – Nutrition, Health and Related Claims prevents iodised salt from making an iodine content claim. Also, there are no provisions under Standard 2.10.2 that permit an iodine content claim.

SUBMITTER	SUBMITTER COMMENTS
Australian Food and Grocery Council (AFGC) Kim Leighton (Cont.)	• Considers the current restrictions on content claims provide no incentive for industry to replace salt with iodised salt. *Monitoring and compliance* • If a mandatory approach is adopted, recommends that the Standard should lapse after 4 years if: - no measurement of the health effect has been undertaken; or - if measurement has occurred, such measurement fails to demonstrate a significant improvement in health effect.
Food Technology Association of Australia Tony Zipper	**Supports mandatory fortification with iodine** *Consumer choice* • Highlights a number of considerations in relation to consumer choice: - there is little choice for consumers who object to mandatory fortification yet this is one of FSANZ's functions; - the only choice provided is 'organic' for which there is no standard - individuals with coeliac disease are not accounted for; and - individuals who cannot tolerate excess iodine are only offered 'organic' which is usually at a premium price. *Drafting* • Advises most gluten free or wheat free breads are not yeast leavened and possibly should not be called 'bread'. Furthermore, there is no standard in the Code that compels 'yeast' leavening to use salt of any description.
George Weston Foods Australia and New Zealand Fiona Fleming	**Does not support mandatory fortification with iodine** • Accepts that the use of iodised salt in place of non-iodised salt can be an effective strategy to address iodine deficiency in affected populations. • Does not support the current Proposal as it: - removes consumer choice from those products; - fails to be an effective solution for those with coeliac disease, those who are wheat intolerant or who do not consume wheat based products; - fails to be an effective solution for pregnant and lactating women who will still require a supplement to reach their needs; and - places the burden of responsibility of a public health issue on the food industry. • Notes iodine deficiency appears to be regional rather than nation-wide. *Preferred approach* • Supports the AFGC recommendation of an agreed MoU with industry to voluntarily use iodised salt in food manufacture because it: - has evidence of effectiveness in the Australian market; - retains consumer choice; - allows for those with coeliac disease to be reached through use in non wheat based products; and - it has been shown to be effective internationally.

SUBMITTER	SUBMITTER COMMENTS
George Weston Foods Australia and New Zealand Fiona Fleming (Cont.)	• Also supports the AFGC recommendation to promote iodine as a processing aid (for use for fruits, vegetables and eggs under Standard 1.3.3) as it: - is in line with national nutrition guidelines to increase consumption of fruits and vegetables; and - has the potential to improve the reach of iodine to those who do not consume bread. • Recommends retaining the current permission for iodised salt for discretionary use, and promote substitution of iodised salt for non-iodised salt for such use; *Consistency with policy principles* • Believes the Proposal is not in line with policy principles for mandatory fortification. - Argues iodine deficiency is regional not a demonstrated significant population health problem. - Maintains FSANZ has not adequately assessed other options for increasing iodine intakes; - Suggests voluntarily fortifying a range of products with iodised salt coupled with the promotion of iodine as a processing aid would be consistent with national nutrition policies to promote the consumption of a variety of foods - Cites the policy advice that requires added vitamins and minerals to be present at levels that will not result in detrimental excesses or imbalances across the general population. Notes a small percentage of 2-3 three year olds will exceed the UL. Also comments that ensuring the majority of the population do not exceed the UL limits the effectiveness that mandatory fortification can deliver because of the wide variation in iodine needs across different population groups. - Believes mandatory iodine fortification will not deliver *effective amounts* to meet health objectives. *Safety and efficacy* • Notes a large percentage of pregnant and breastfeeding women will not fully meet their requirements with mandatory fortification and supplementation and other sources of iodine will still be required. *Food vehicle* • Requests that FSANZ investigate the potential for fortification of the water supply as a possible way of alleviating iodine deficiency with the appropriate authorities. • Raises concerns that FSANZ is disregarding iodine addition by other means. • Notes salt content across different bread types will not be uniform as different breads require different amounts of salt from a technical and taste perspective consequently this may result in a wider variation in iodine content. In addition, should manufacturers respond to current public health calls for a reduction in salt in bread; the iodine content will reduce significantly. *Dietary intake assessments* • Questions whether FSANZ's dietary intake assessment has over estimated the average bread consumption (88%) and therefore over estimated the effectiveness of the Proposal.

SUBMITTER	SUBMITTER COMMENTS
George Weston Foods Australia and New Zealand Fiona Fleming (Cont.)	*Costs* • Suggests FSANZ has assumed that industry costs will be passed onto consumers however advises a number of factors effect prices and it may not be possible to pass on any or all of these costs to consumers. • Advises that GWF produce a large number of breadcrumb products for the Australian and overseas market from standard bread products which once fortified may impact on trade as some countries will not accept fortified products and domestic customers may not want iodine in their breadcrumbs. *Implementation* • Recommends outcome-based standards to allow industry flexibility. • Requires the transition period to align with mandatory folic acid fortification. Also notes the Flour Millers Council of Australia has requested an extension to this period. *Monitoring and compliance* • Understands some of the monitoring is outside the scope of FSANZ's responsibility however believes it is imperative that a commitment by all responsible organisations is made prior to implementation. • Raises concerns regarding the history of monitoring within Australia citing lack of monitoring of thiamin fortification. • Recommends developing and maintaining a trans-Tasman monitoring program for urinary iodine status in the target population to estimate prevalence of iodine deficiency disorders (IDD). • Notes that in the editorial note to Standard 1.3.3 of the Code, FSANZ states they will review the extent of the use of iodine as processing aid three years from inclusion in the Standard. States it is imperative that this be reviewed as part of Proposal P1003. • If a mandatory approach is adopted, recommends that the Standard should lapse after 4 years if: - no measurement of the health effect has been undertaken; or - if measurement has occurred, such measurement fails to demonstrate a significant improvement in health effect. • Questions whether FSANZ will monitor the yeast-free bread using iodised salt. *Consumer choice* • Argues mandatory fortification restricts consumer choice. • Notes individuals with pre-existing thyroid conditions will be forced to avoid bread, a staple product. • Believes mandatory fortification removes individual responsibility. • Suggests there are a number of groups that are not effectively targeted by the Proposal including: - those who consume little or no bread because of dietary requirements, choice or cultural preferences; and - those with increased iodine requirements including pregnant and lactating women. • Supports the exemption of 'organic' bread however note this will limit consumer choice as it will attract a premium.

SUBMITTER	SUBMITTER COMMENTS
George Weston Foods Australia and New Zealand Fiona Fleming (Cont.)	• Notes under the Code bread manufacturers will be required to list iodised salt in the ingredient list however there is no requirement to include iodine in the NIP therefore consumers will be unable to determine the amount of iodine in a fortified bread product. *Communication and education* • Supports a campaign which effectively provides consumers with information regarding the need for iodine and sources of iodine in the food supply. • Suggests education campaigns to increase supplement use by pregnant and breastfeeding women. • Recommends that the MoU and promotion of iodine as a processing aid occurs in conjunction with an education campaign that encourages consumers to seek out products naturally high in iodine or fortified with iodine and is specifically targeted to different population groups depending on their needs, including women of child-bearing age and people who don't consume bread. *Communication and education* • Recommends developing and maintaining both an industry awareness campaign of the need to use iodised salt in food manufacture and a consumer education campaign aimed at the target population about the importance of iodine in the diet.
Go Grains Australia Trish Griffiths	**Does not support mandatory fortification with iodine** • Highlights the willingness of industry to extend iodine voluntary fortification noting the current initiative in Tasmania may be repeated in the Northern Territory. *Policy* • Considers the proposed approach is inconsistent with policy guidelines as: - it will not deliver sufficient amount to the target group; and - no monitoring system is in place to monitor and review mandatory fortification. *Food vehicle* • Accepts the use of iodised salt in place of non-iodised salt can be an effective strategy to address iodine deficiency in affected populations • Does not believe the mandatory replacement of non-iodised salt with iodised salt will deliver sufficient iodine to the target group (pregnant and breastfeeding women). • Recommends a consistent approach to food vehicle selection. *Dietary intake assessments* • Recommends modelling for children is based on survey data from the 2007 *Kids Eat Kids Play* national nutrition survey. *Costs* • Highlights increased costs for the bread industry as a result of labelling changes. *Monitoring and compliance* • Emphasises the need for an appropriate monitoring and surveillance program to be developed prior to mandatory fortification.

SUBMITTER	SUBMITTER COMMENTS
Go Grains Australia Trish Griffiths (Cont.)	*Monitoring and compliance* • Seeks commitment from FSANZ and other government agencies if mandatory fortification proceeds to undertake monitoring for urinary iodine status in the target population to estimate prevalence of IDD and undertake analysis to assess the effectiveness of mandatory fortification in comparison to the voluntary fortification alternative. • Suggests monitoring consumption of grain-based foods through public domain data collection such as ABS Apparent Consumption statistics. *Consumer choice* • Believes mandatory fortification compromises consumer choice and 'organic' and 'salt-free' breads are not adequate alternatives. • Notes iodising all or most of the bread in the food supply will result in minimal choice. *Vulnerable groups* • Highlights the proposed strategy will not reach specific population groups e.g. those who follow a gluten free or wheat free diet. *Communication and education* • Supports the development and implementation of an education campaign targeting 'at risk' groups. *Communication and education* • Seeks commitment from FSANZ and other government agencies if mandatory fortification proceeds to actively educate and promote: - the consumption of grain-based foods to the public and particularly young women - the need to use iodised salt in bread manufacture and to label packaged bread to the bread and baking industry. *Implementation* • Emphasises if mandatory iodine fortification goes ahead it must tie in with the implementation of folic acid fortification to minimise the transition burden on industry of packaging changes. • Recommends the transition period be extended to September 2010.
Salt Institute USA Richard Hanneman	**Supports mandatory fortification with iodine** • Believes the proposal would be strengthened by including a strong statement that the Government is committed to protecting and enhancing the mental development of the next generation through the iodisation of salt and that this proposal is the first step to carry that policy into effect. - Notes this will put the public and the food industry on notice that an extension of the use of iodised salt would be in order if the current intervention falls short of its expected achievement of adequate iodine intakes for the population. *Food vehicle* • Notes that because salt is consumed in predictable amounts, which is a major reason why it is the preferred vehicle to deliver iodine supplementation, it is also an important reason to confine iodine fortification to this ingredient alone.

SUBMITTER	SUBMITTER COMMENTS
Salt Institute USA Richard Hanneman (Cont.)	*Food vehicle* • Additional foods may need to be produced using iodised salt in the future. *Safety and efficacy* • Notes the proposed level of fortification is safe and achievable. • Comments the proposed strategy is likely to be highly effective noting women of childbearing age will be better protected. *Monitoring and compliance* • Advises a key component of the strategy must be continuing monitoring
Public Health Professionals	
Australian Division of World Action on Salt and Health (AWASH) Jacqui Webster	**Qualified support for mandatory fortification with iodine** (as an interim measure) *Food vehicle* • Recommends the use of iodised bread initially with a plan to change to a better strategy such as iodised flour in bread. • Believes that there is a public confusion and administrative difficulty with having conjoined food additives with opposite health messages – iodine (you need more because it is good for you) and salt (you need less because it is bad for you). • Cautions that wide variation in the amount of salt in bread will produce different doses of iodine from different bread products. • States BRI has indicated a folate and iodine premix suitable for metered addition to bread flour would be feasible. Suggests alternative methods will not occur without significant financial engagement and investment from industry and/or government. *Food vehicle* • Recommends the government provides financial incentives for industry to develop alternative methods of delivering iodine to the population. *Communication and education* • Notes it is important that any educational campaign to ensure adequate iodine intake does not conflict with health recommendations to reduce blood pressure through reducing dietary salt intake. • Believes a targeted educational campaign on the use of vitamin supplements containing both iodine and folate is fundamental to ensure iodine requirements are met during pregnancy and lactation. • Recommends appropriate education messages are developed for those groups who consume little or no bread. - Caution that it is not acceptable to promote the use of iodised salt in cooking and/or at the table to ensure iodine requirements are met rather the use of supplements and/or the consumption of other foods high in iodine should be recommended. • Recommends the use of iodised bread initially but highlights the importance of reducing salt intake is communicated clearly as a priority.

SUBMITTER	SUBMITTER COMMENTS
Australian Division of World Action on Salt and Health (AWASH) Jacqui Webster (Cont.)	*Monitoring and compliance* • Notes a likely reduction in salt added to manufactured foods over time and suggests only the implementation of a systematic program monitoring iodine status (utilising urine collections) will determine the effectiveness of the strategy. • Suggests any monitoring program must be initiated prior to implementation and must receive support and funding at federal and state levels on an ongoing basis. • Recommends the implementation of a long term monitoring system to assess the impact on iodine status across the population.
Trevor Beard Honorary Research Fellow Menzies Research Institute Australia	**Qualified support for mandatory fortification with iodine** (as a short-term solution) *Food vehicle* • Suggests a pre-mix to fortify bread flour with both iodine and folic acid would have the following advantages: - salt and iodine in bread could be added independently which would allow 'low salt' and 'no added salt' bread to contain as much iodine as other breads; - bread with the Heart Foundation 'Tick' would contain as much iodine as its saltier competitors; - reduced monitoring costs with a few brands of bread flour compared with thousands of brands of bread; and - folate monitoring, which is difficult and expensive, could undertaken using iodine as the marker for folate. • Refers to discussions with the BRI Institute who could provide FSANZ with a feasibility report and associated costs.
Dietitians Association of Australia Annette Byron	**Supports mandatory fortification with iodine** *Food vehicle* • Supports the mandatory replacement of non-iodised salt with iodised salt in bread in the range 25-65 mg iodine per kg of salt. • Supports the retention of the voluntary permission for iodine in iodised salt and reduced salt which is consistent with the mandatory fortification requirement. • Acknowledges the practical reasons for using salt in bread however encourages future research into the direct addition of iodine to foods such as milk. *Consumer choice* • Agrees bread represented as 'organic' will be exempt. *Dietary intake assessments* • Recommends national food composition databases are continually updated to support the evaluation of the implementation. *Implementation* • Strongly supports the application of sufficient resources to implement the Proposal, especially employment of sufficient personnel as was the case in the voluntary fortification of bread with iodine in Tasmania.

SUBMITTER	SUBMITTER COMMENTS
Dietitians Association of Australia Annette Byron (Cont.)	*Monitoring and compliance* • Highlights the importance of monitoring the iodine status of pregnant and lactating women. • Requests monitoring of those at risk of inadequate intake including people from different cultures who irregularly eat bread, those who consume only 'organic' bread and those who restrict bread consumption to reduce their salt intakes. • Acknowledges population nutritional intake surveys are outside the scope of FSANZ however recommends regular intake surveys to ensure data is routinely available on current intakes which reflect the changing food supply and food intake patterns. *Communication and education* • Suggests additional education for specialist medical practitioners to advise patients with existing thyroid conditions; health professionals (gastroenterologists and dietitians) advising clients with coeliac disease; and health professionals advising pregnant and lactating women. • Reiterates concerns that the use of salt as a medium for the delivery of iodine has the potential to confuse public health messages of consuming less salt. Proposes the communication strategy takes this into account. • Suggests the evaluation of the fortification program should provide sufficient information to assess whether manufacturers are reducing the amount of salt added to bread and whether the amount of iodine added to salt needs to be increased.
National Heart Foundation of Australia Anne-Marie Mackintosh	**Qualified support for mandatory fortification with iodine** (some reservations regarding the use of iodised salt in bread alone) *Food vehicle* • Opposes the use of salt as the carrier of iodine and the use of bread alone as the food vehicle. • Recommends that if iodisation of bread is not sufficient to reduce the prevalence of iodine deficiency other core foods should be fortified, e.g. breakfast cereals and dairy products. • Believes that using salt as the food vehicle conflicts with Australian and international public health messages and their 'Tick Program'. • Suggests that using salt as the vehicle sends a conflicting message about salt intake to consumers. • Argues that the Proposal may be a disincentive for the food industry to reduce salt levels noting the food industry need incentives to reduce salt in products. • Seeks clarification regarding the process of increasing the proportion of iodine in salt if manufacturers wish to reduce sodium content of bread. • Believes that lower sodium bread fortified with iodised salt will not be able to meet the conditions to make a 'good source' claim. • Encourages FSANZ to explore alternative approaches to iodine deliver noting iodisation of salt is not the only cost effective method available. • Recommends a consistent approach to food vehicle selection and that the costs resulting from labelling changes, machinery and testing should apply to all processed foods. Further notes it is discriminatory to place the onus on one food type i.e. bread dough.

SUBMITTER	SUBMITTER COMMENTS
National Heart Foundation of Australia Anne-Marie Mackintosh (Cont.)	*Consumers* • Considers the iodisation of bread results in minimal choice for consumers if all bread is fortified. Believes the exemption of 'organic' bread does not legitimately address lack of consumer choice as it is often more expensive and not as widely available. *Monitoring and compliance* • Believes monitoring should encompass dietary sodium and iodine intakes, urine analysis of sodium and iodine and health outcomes such as iodine deficiency levels of at risk sub-groups. • Suggests monitoring should focus on those at most risk of deficiency e.g. pregnant and lactating women or those at risk of exceeding the upper limit e.g. young children. • Supports FSANZ's role in monitoring food composition and market changes in the food supply, predicting nutrient intakes and working with consumers to research attitudes and behaviours towards fortified products. • Recommends national nutrition surveys occur regularly. Notes FSANZ is accessing data from the *Kids Eat Kids Play* survey. *Communication and education* • Believes that an education program on achieving adequate iodine intake and possibility of supplements is FSANZ's responsibility.
Tasmanian Ministerial Thyroid Advisory Council John Burgess	**Supports mandatory fortification with iodine** *Safety and efficacy* • Reiterates concerns that the Tasmanian experience has demonstrated that switching to iodised salt in bread will be insufficient to meet the needs of those with higher iodine requirements, particularly pregnant and lactating women. *Food vehicle* • Recommends ongoing investigation into additional food vehicles post implementation. *Communication and education* • Acknowledges the potential for a mixed public health message with the need to reduce salt intake in the Australian diet. However, notes this is less likely to be a problem with a mandatory approach as the vehicle can be considered to be bread rather than salt. *Monitoring and compliance* • Strongly supports the need for effective monitoring of iodine status in Australia and suggest where possible this should be integrated into a broader health monitoring system to ensure sustainability. *Consumers* • Notes advice to take supplements is likely to be taken up by women on higher incomes and with higher educational levels hence becoming an inequitable strategy.

SUBMITTER	SUBMITTER COMMENTS
Consumers	
Sue Allard Private Australia	**Does not support mandatory fortification with iodine** *Safety and efficacy* • Raises concerns over the adverse health impacts on individuals with Grave's Disease. *Consumer choice* • Advises it is difficult under the current voluntary scheme to find foods not using iodised salt. • Raises concerns that the choice for Iodine-sensitive individuals will be further diminished to either not eat bread or attempt to afford non-iodised alternatives such as 'organic' which will result in increased food costs. *Costs* • Argues Iodine-sensitive individuals will experience increased medical expenses for additional consultations and procedures which in turn will impact on the government through higher costs to the Medicare system.
Rosalind Bellamy Private Australia	**Does not support mandatory fortification with iodine** *Safety and efficacy* • Raises concerns over the adverse health impacts on individuals with Grave's Disease. *Food vehicle* • Suggests the addition of iodine to products which are specifically targeted at vulnerable groups (i.e. cereals or breads for pregnant women). *Consumer choice* • Expresses concerns that Iodine-sensitive individuals may not be aware iodine has been added to bread and many, who should not be adding iodine to their diet, will be forced to unknowingly.
Craig Macbride Private Australia	**Does not support mandatory fortification with iodine** • Highlights adverse reaction between iodine consumption and acne. • Raises concerns that the addition of iodised salt in bread will mean acne sufferers will either no longer able to eat bread or experience worsening acne. They will be forced to take (more) medication which over the long term can damage internal organs. • Suggests the proportion of the population who require more iodine should eat a 'better' diet or take supplements.
Susan McGahan Private Australia	**Does not support mandatory fortification with iodine** *Safety and efficacy* • Refutes FSANZ's conclusion that increased dietary iodine intake is unlikely to increase the risk of iodine sensitivity reactions occurring. • Believes the research referenced in the FSANZ Safety Assessment and Risk Characterisation Report is insufficient and should be re-visited. *Labelling/claims* • Current exemption of labelling on unpackaged foods means Iodine-sensitive individuals will be unable to determine the amount of iodine in these products.

SUBMITTER	SUBMITTER COMMENTS
Susan McGahan Private Australia (Cont.)	*Labelling/claims* • Believes there is an issue in relation to products being incorrectly labelled by manufacturers. Also notes that domestic products are not routinely audited consequently the substitution of ingredients in products may occur without accompanying label changes. *Consumer choice* • Comments that it would be unlikely that manufacturers will purchase two separate types of salt so the use of iodised salt will proliferate to other foods such as cereals, biscuits, cakes etc placing a severe burden on Iodine-sensitive individuals. *Communication and education* • Believes the public consultation on this issue has been insufficient.
McIntosh Family Private Australia	**Does not support mandatory fortification with iodine** *Safety and efficacy* • Raises concerns over the adverse health impacts on individuals with allergies to iodine. • Considers the health risks of excess iodine (including skin and tissue damage) are as great as iodine deficiency. • Reiterates previous attempts to iodise bread products in 1966 proved to be a risk to public health. • Seeks a written guarantee that there will be no excess iodine levels or health problems arising now or in the future should the Proposal go ahead. *Consumer choice* • Argues consumers are not being given a choice. • Believes Iodine-sensitive individuals, will be forced to avoid bread, and as a consequence will miss out on other important vitamins found in bread. • States the added expense of purchasing alternative products (if they exist) will be beyond the family's means. *Communication and education* • Suggests there should be a national education campaign informing the public to visit their doctor to have a 4-5 day urine test.
Gayle Russell Private Australia	**Supports mandatory fortification with iodine** • Strongly supports the Proposal for the mandatory addition of iodine to breads.
Brenda Weeks-Kaye Private Australia	**Does not support mandatory fortification with iodine** *Safety and efficacy* • Raises concern over the adverse health impacts on individuals with thyroid disorders including Grave's Disease. • Suggests that prior to acceptance of a proposal for mandatory iodine fortification, funding is provided for the ABS to establish and collect acceptable and reliable data for policy development.

SUBMITTER	SUBMITTER COMMENTS
Brenda Weeks-Kaye Private Australia (Cont.)	*Safety and efficacy* • Believes the supporting documentation for this Proposal is inadequate for policy development and is lacking adequate statistical data on thyroid disorders within the population as a whole and is biased towards iodine deficiency as defined by the researchers. Furthermore, supporting data for adequate or excessive iodine levels among the Australian population is poorly presented. • Highlights the availability of statistical information regarding the prevalence of thyroid disorders in Australia at: http://www.thyroid.org.au/Information/doodle.html.