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FINAL ASSESSMENT REPORT

PROPOSAL P230

CONSIDERATION OF MANDATORY FORTIFICATION WITH IODINE FOR NEW ZEALAND

For Information on matters relating to this Report or the assessment process generally, please refer to <http://www.foodstandards.gov.au/standardsdevelopment/>

Executive Summary

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

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

In October 2005, the Ministerial Council noted the advice of the Australian Health Ministers' Advisory Council and Australian Health Ministers' Conference that mandatory fortification with iodine is an effective public health strategy subject to clinical safety and cost-effectiveness. FSANZ was asked to progress consideration of mandatory fortification with iodine as a matter of priority and on this basis has expedited this process.

In September 2007, FSANZ was advised that Australian Health Ministers were re-evaluating the evidence on the prevalence and severity of iodine deficiency in Australia, and that FSANZ should defer its consideration of mandatory iodine fortification for Australia until further advice is received. In addition Health Ministers noted that the situation in New Zealand presents a significant health problem, and that mandatory fortification with iodine is considered the most effective strategy to address it.

While the severity and prevalence in Australia is being further considered, a separate standard for New Zealand was suggested, using the provisions in the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards system* (the Treaty) Annex D(I) which state:

(1) Where the analysis or consultation undertaken by the Authority in the preparation of a food standard indicates that for exceptional health and safety or environmental reasons separate food standards will be required for New Zealand and Australia, the Authority shall approve food standards that relate to each Member State and notify those standards to the Council.

The New Zealand Government subsequently asked FSANZ to develop a separate Standard for New Zealand. The Government also notes that there is clear evidence of population-wide iodine deficiency in New Zealand and that the seriousness of the iodine deficiency in New Zealand satisfies the criteria for exceptional health and safety reasons allowing the development of a New Zealand only standard in accordance with Annex D(1) of the Treaty. In light of this advice FSANZ was satisfied that exceptional health and safety reasons exist that require the development of a separate standard for New Zealand, while the Australian situation is being further investigated.

FSANZ has therefore prepared this Final Assessment Report approving a Standard for mandatory fortification with iodine for New Zealand only under Annex D(1) of the Treaty.

The Decision

The mandatory replacement of non-iodised salt with iodised salt in breads is the preferred option to address the re-emergence of iodine deficiency in New Zealand. The salt iodisation level is to be in the range of 25-65 mg of iodine per kg of salt. Bread represented as organic are to be exempt from this requirement.

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

Reasons for the Decision

Amendments to the *Australia New Zealand Food Standards Code* (the Code), outlined in Attachment 1, are approved for the following reasons:

- Replacement of non-iodised salt with iodised salt in bread would address iodine deficiency across much of the New Zealand population, and prevent it from getting even more serious in the future.
- Replacement of non-iodised salt with iodised salt in bread is technologically feasible and well tested internationally.
- Use of iodised salt to reduce the prevalence of iodine deficiency is consistent with international guidance and experience.
- The Tasmanian voluntary program using iodised salt in bread, at an average of 45 mg iodine per kg salt, led to an improvement in the iodine status of a mildly deficient population.
- Based on the available evidence, including overseas experience with mandatory fortification, the proposed level of fortification does not pose a risk to general public health and safety. The level has been set to minimise any potential health risks. In groups that are generally more sensitive to increases in iodine intake, e.g. individuals with existing thyroid conditions, the risk of a negative impact on health is still considered to be very low.
- FSANZ considers that this Proposal would deliver net-benefits to New Zealand. Mandatory fortification with iodine will provide important benefits to the New Zealand population. This benefit compares well with a small ongoing cost of fortification of around three cents per person each year.
- The Centre for Health Economics Research and Evaluation (CHERE) assessed this Proposal in terms of cost-effectiveness ratios. 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.
- It 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 sustain reductions in the prevalence of iodine deficiency in New Zealand.

Consultation

FSANZ received a total of 68 written submissions in response to the Draft Assessment Report for this Proposal during the public consultation period from 18 August 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. Many public health professionals were concerned that the preferred option does 'not go far enough' in increasing iodine intakes. They believe FSANZ has been overly constrained by not wishing to exceed the Upper Level of Intake (UL) for young children. Overall, 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.

Due to the unavoidable delay in finalising this Proposal, FSANZ released an Issues Paper in May 2007 for a four-week consultation period. The paper addressed the major issues that arose from submissions to the Draft Assessment and outlined the proposed changes under consideration for the Final Assessment, especially the removal of breakfast cereals and biscuits as food vehicles. FSANZ received 48 comments in response to the Issues Paper.

At that time, the majority of government stakeholders, public health professionals and consumer groups indicated support for the mandatory fortification Proposal. There was general acknowledgement of the inability of this Proposal to fully meet the substantially increased iodine requirements of pregnant and lactating women given the desire not to bring about exceedance of the UL for iodine in young children.

Some stakeholders still viewed this mandatory fortification Proposal as an initial step and only 'part of the solution', but noted that mandatory fortification is preferable to voluntary fortification as it provides greater certainty, sustainability, equity, and reach. A few public health professionals believed that Universal Salt Iodisation (USI) would provide higher iodine intakes for pregnant and lactating women. Consumer organisations were generally supportive of the Proposal 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, costs to industry, removal of consumer choice, and trade impacts as reasons for their opposition. They considered mandatory fortification was not the most effective public health strategy and stated a strong preference for voluntary fortification. Industry considered that international studies and the Tasmanian results demonstrate the success of voluntary fortification in decreasing iodine deficiency.

Issues identified from public submissions and consultations formed the basis of further targeted consultation with key stakeholder groups. FSANZ commissioned a number of consultants and experts to consult with industry regarding issues raised during consultations. FSANZ also involved the Fortification Standards Development Advisory Committee (SDAC) to help identify key views and issues. An Iodine Scientific Advisory Group (ISAG) was also established, prior to Draft Assessment, to advise on scientific and medical matters.

FSANZ commissioned an independent economic consultancy organisation, Access Economics, to undertake a cost benefit analysis of the Proposal and also commissioned the CHERE, to undertake further work on the cost effectiveness of this Proposal.

Implementation

The Ministerial Council will be notified of the decision. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code are expected to come into effect on 27 September 2009. This will coincide with the mandatory folic acid fortification implementation period and will help reduce upfront costs of relabelling and label write-offs for industry.

This transitional period will allow time for the salt industry to increase the production of iodised salt and for manufacturers of the bread to make the required changes to manufacturing and labelling. Additionally, a transitional period will allow for consumers to be informed about the changes.

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INTRODUCTION

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

New Zealand has a history of iodine deficiency. This is due to very low concentrations of iodine in the soil leading to low iodine concentrations in much of the food supply grown in these soils. 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-to-moderate 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. New Zealand 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*. At that time, 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 this Proposal (Proposal P230) and released an Initial Assessment for public consultation in December 2004.

In December 2004, FSANZ sought clarification from the Food Regulation Standing Committee (FRSC) on two policy issues that it had referred to FSANZ as they were outside FSANZ's capacity to appropriately assess and/or implement:

- whether mandatory fortification with iodine is the most effective public health strategy; and
- a process to establish a health monitoring and review system in support of mandatory fortification.

FRSC sought advice from the Australian Health Ministers' Advisory Council (AHMAC) and the Australian Health Ministers' Conference (AHMC). An Expert Panel¹ convened by AHMAC concluded that mandatory fortification fulfilled their criteria² of effectiveness, equity, efficiency, certainty, feasibility and sustainability, and was the most effective strategy for redressing iodine deficiency.

In October 2005, the Ministerial Council noted the advice of AHMAC and AHMC that mandatory fortification with iodine is an effective public health strategy subject to clinical safety and cost-effectiveness. FSANZ was asked to progress consideration of mandatory fortification with iodine as a matter of priority and on this basis has expedited this process.

¹ *The effectiveness of mandatory fortification as a public health strategy to increase nutrient intakes, with reference to iodine and folate*. Expert public health advice prepared for AHMAC, June 2005.

² Case studies of public health interventions to increase nutrient intakes were used to generate effectiveness criteria.

In 2006, Ministers agreed to amend their Policy Guideline to indicate that the responsibility for determining the prevalence and severity of the health problem, and that mandatory fortification is the most effective public health strategy to address the health problem. AHMAC, or with respect to a specific New Zealand health issue, an appropriate alternative body will provide advice to the Ministerial Council, prior to FSANZ preparing a proposal to consider mandatory fortification. The amended policy can be found at Attachment 2.

In September 2007, FSANZ was advised that AHMC had asked the Australian Population Health Development Principal Committee to provide formal advice to the AHMAC and the AHMC on the prevalence and severity of iodine deficiency and the effect on health outcomes in Australia. At the same time FSANZ was also advised that Health Ministers noted that the prevalence and severity of iodine deficiency in New Zealand is significant and that mandatory fortification with iodine is considered the most effective strategy to address it.

While the severity and prevalence in Australia is being further considered, a separate standard for New Zealand was suggested, using the provisions in the *Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards system* (the Treaty) Annex D(I) which state:

(1) Where the analysis or consultation undertaken by the Authority in the preparation of a food standard indicates that for exceptional health and safety or environmental reasons separate food standards will be required for New Zealand and Australia, the Authority shall approve food standards that relate to each Member State and notify those standards to the Council.

The New Zealand Government subsequently asked FSANZ to develop a separate Standard for New Zealand. The Government also noted clear evidence of population-wide iodine deficiency in New Zealand and that the seriousness of the iodine deficiency in New Zealand satisfied the criteria for exceptional health and safety reasons allowing the development of a New Zealand only standard in accordance with Annex D(1) of the Treaty. In light of this advice, FSANZ was satisfied that exceptional health and safety reasons existed that required the development of a separate Standard for New Zealand, while the Australian situation was further investigated.

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

Scope of this Proposal

The Initial Assessment Report presented four options, namely: maintenance of the *status quo*; extension of permissions for voluntary iodine fortification; promotion of voluntary options to increase industry use of iodised salt; and mandatory fortification with iodine.

Following referral back to FRSC, seeking advice on determining the most effective strategy for addressing iodine deficiency, and on the basis of Ministerial advice that mandatory fortification with iodine is an effective strategy, FSANZ reduced the number of options considered at Draft Assessment to consideration of maintenance of *status quo*, including the existing permission to voluntarily use iodised salt in food, and mandatory fortification.

On the basis of further advice, as outlined above, FSANZ has reduced the scope of this Final Assessment Report to the consideration of mandatory fortification with iodine in New Zealand only.

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). In New Zealand soil iodine levels are generally low (Smith *et al.* 1999). 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 because of small amounts of iodine contamination from iodine-based drenches, teat sprays and sanitisers.

Iodised salt, dairy products, seafood, fruits, vegetables, eggs, meat and cereals can all contribute to the dietary iodine intake. Of these, certain seafood and kelp can contain very high levels of iodine. Iodine containing supplements and medicines can also be major contributors of 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 lactating 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 values for adequate iodine intakes are set out in the *Nutrient Reference Values for Australia and New Zealand*³. A range of nutrient reference values (NRVs) exist for iodine including the estimated average requirement (EAR⁴), the recommended dietary intake (RDI⁵) and the upper level of intake (UL⁶). In the absence of sufficient data to determine an EAR and RDI, an adequate intake (AI⁷) was established instead. The most recent NRVs, released in May 2006, are higher than previous recommendations, especially during pregnancy and lactation, and ULs have been established for the first time. The NRVs for iodine are given in Table 1 arranged by age, gender and physiological state.

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

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

1.2.1.1 Basis for the Upper Level of Intake for Iodine

The UL is based on the underproduction of thyroid hormone i.e. hypothyroidism, observed in supplementation studies in adults given 1700-1800 µg of iodine per day. An uncertainty factor of 1.5 has been applied to give a margin of safety to yield an adult UL of 1100 µg of iodine per day. ULs for children and adolescents were extrapolated from the adult recommendation on a metabolic body weight basis. The adult UL was also used for pregnancy and lactation, as there was no evidence of increased sensitivity associated with those physiological states. Individuals with thyroid disorders or a long history of iodine deficiency may respond adversely at levels of intake below the UL. Further explanation of iodine-induced hypothyroidism is provided in Section 6.2.1.

³ This document is available online at <http://www.nhmrc.gov.au/publications/synopses/n35syn.htm>.

⁴ A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group.

⁵ 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.

⁶ 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.

⁷ 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.

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).

It is worth noting that goitrogens have been reported only as a problem when intakes are unusually high, e.g. where the diet is very high in cassava 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 8 respectively indicate that goitrogens are not major contributors to iodine deficiency in New Zealand.

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 (Gibson, 2005). Because individuals' iodine intake and therefore excretion can be highly variable from day-to-day, a survey based on single urine samples from each participant is best suited to describe population status rather than assessment of individual iodine status (Gibson, 2005, ICCIDD *et al.*, 2001).

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

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

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

[†]In populations characterised by longstanding iodine deficiency and rapid increment in iodine intake, median value(s) for urinary iodine above 200 µg/L are not recommended because of the risk of iodine-induced hyperthyroidism.

The latest guidelines from the ICCIDD state that in children less than two years old and lactating 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 MUIC below 150 µg/L indicates an *insufficient* iodine intake. Evidence from New Zealand, Australia, and elsewhere suggests that women of childbearing age have poorer iodine status than school children (Burgess *et al.*, 2007, Chan *et al.*, 2003; Gunton *et al.*, 1999; Hamrosi *et al.*, 2003; Hamrosi *et al.*, 2005; McElduff *et al.*, 2002; Travers *et al.*, 2006).

1.4 Iodine Deficiency Disorders

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

1.5 History of Iodine Deficiency in New Zealand

New Zealand has low levels of iodine in the soil leading to very low iodine concentrations in plant foods (Thomson, 2004). The locally produced food supply is predominantly low in iodine. In the early parts of last century, iodine deficiency was common as indicated by widespread goitre. Iodisation of table and cooking salt was introduced in 1924 to address this deficiency and the salt iodine concentration was increased in 1938 to improve the health benefits (Mann and Aitken, 2003). Following salt iodisation, the proportion of children with enlarged thyroids fell from 61% in 1920 to 1.1 % in 1953 (Thomson, 2004). Studies of iodine status from the mid 1960s to the mid 1980s indicated that iodine intake throughout this period was adequate or more than adequate (North and Fraser, 1965; Simpson *et al.*, 1984; Cooper *et al.*, 1984).

1.6 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 USI⁸, 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 and Ralph, 1987; Mattes and Donnelly, 1991).

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

As not all of these countries have introduced regular monitoring, the *relative* impact of these initiatives is unclear although there has been a documented overall improvement in iodine status following the implementation of the various approaches to iodine fortification. Further details of iodine fortification programs in selected countries are provided at Attachment 3.

1.6.1 Tasmania

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.

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 showed 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).

⁸ Universal Salt Iodisation (USI) – the iodisation of all salt used for human and animal consumption.

However, the results for the pregnant women were based on convenience samples and may not be representative of the change in iodine status across pregnant women or the broader population.

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 lactating 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 Ministerial Council's Policy Guideline on the *Fortification of Food with Vitamins and Minerals*

The Ministerial Council's Policy Guideline on *Fortification of Food with Vitamins and Minerals* (the Policy Guideline, see Attachment 2) 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.

Advice on whether Specific Order' Policy Principles 1 and 2 are met will be sought from the Australian Health Ministers' Advisory Council, or an appropriate alternative body for a specific New Zealand health issue⁹.

1.8 Codex Alimentarius

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

For generally consumed foods, the *General Principles for the Addition of Essential Nutrients to Foods*¹⁰ state that essential nutrients may be added to foods for the purposes of restoration, nutritional equivalence of substitute foods, fortification¹¹, or ensuring the appropriate nutrient composition of a special purpose food.

2. Description of Current Situation

The following sections outline the current mild-to-moderate iodine deficiency in New Zealand and the negative implication for population health and performance. A more detailed description of the iodine status of New Zealanders and the potential consequences is at Attachment 5.

2.1 Iodine Status of the New Zealand Population

The surveys and studies described in this section assessed iodine status by comparing median urinary iodine excretion with the WHO guidelines described in Section 1.3.1

The 2002 New Zealand Children's Nutrition Survey (CNS) involving a geographically and demographically representative sample of 1793 children aged 5-14 years indicated children in all age categories had MUICs indicative of mild iodine deficiency overall, but with 25% of males and 31% of females at <50 µg/L (Ministry of Health, 2003). This indicates that the population as a whole is approaching moderate iodine deficiency.

⁹ *The Australian Health Ministers Advisory Council, or with respect to a specific New Zealand health issue, an appropriate alternative body, be asked to provide advice to the Australia and New Zealand Food Regulation Ministerial Council with respect to Specific Order Policy Principles 1 and 2, prior to requesting that Food Standards Australia and New Zealand raise a Proposal to consider mandatory fortification.*

¹⁰ Codex Alimentarius Commission, 1991.

¹¹ '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.

A separate survey in Dunedin and Wellington children aged 8-10 years detected enlarged thyroids in approximately 30% of the sample when revised international guidelines for assessing thyroid size were applied (Skeaff *et al.*, 2002; Zimmerman *et al.*, 2004). This indicates prolonged iodine deficiency in this group.

Mild and moderate iodine deficiency, as indicated by a MUIC 99 µg/L and 44 µg/L respectively, have been identified in New Zealand formula-fed and breastfed infants respectively; toddlers were also found to be iodine deficient (Skeaff *et al.*, 2005). A study in the late 1990s of 35 pregnant and 17 non-pregnant women showed both groups were iodine deficient with a MUIC of 33-52 µg/L and 49-60 µg/L respectively, varying throughout gestation (Thomson *et al.*, 2001). A subsequent study of 170 pregnant women conducted in 2005-6 found a MUIC of 38 µg/L, suggesting ongoing and potentially worsening iodine deficiency in this part of the population (Pettigrew Porter *et al.*, 2006). Adult males have also been shown to have mild-to-moderate iodine deficiency (Thomson *et al.*, 1997).

This evidence suggests that iodine deficiency is a problem for women even before they become pregnant. Therefore, it is likely that many women's iodine stores are low prior to pregnancy and further depleted during pregnancy potentially with little or no repletion of these stores in between successive pregnancies.

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. In the case of iodine deficiency 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 at Attachment 4.

2.2.1 Mild and Moderate Iodine Deficiency and Thyroid Health

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; Lauberg *et al.*, 2000; Pedersen *et al.*, 2002). 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).

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. The impact of mild-to-moderate iodine deficiency is covered in more detail at Attachment 4 but a summary is provided below.

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 subsequently 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, what if any, impairments can be alleviated into later adolescence and adulthood. Thus iodine deficiency is of greatest concern in the foetus, infant and young child to 3 years of age, and therefore also in pregnant and breastfeeding women.

2.2.1 *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 New Zealand 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 (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) (Vermiglio *et al.*, 2004).

Moderately 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 (Delange, 2001).

Iodine deficiency may also result in impaired hearing at both high and normal speech frequencies. Elevation of the auditory threshold¹² 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; Soriquer *et al.*, 2000; van den Briel *et al.*, 2001). A small body of research also suggests an increased risk of ADHD in children exposed to iodine deficiency (Alvarez-Pedrerol *et al.* 2007; Hauser *et al.*, 1993; Vermiglio *et al.*, 2004).

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.

2.2.2 *Non-Cognitive Consequences of Mild-to-Moderate Iodine Deficiency*

Iodine deficiency over a prolonged period of time can lead to adverse changes in the thyroid, including various forms of goitre. These changes can predispose affected individuals to thyroid disease later in life (Delange and Hetzel, 2005). Many years of deficiency can increase the thyroid's susceptibility to iodine-induced hyperthyroidism following increases in iodine intake as described in Section 6.2.2.

¹² The volume below which a given frequency of sound can no longer be heard.

Iodine deficiency may also lead to a poorer prognosis for thyroid cancer (Delange and Hetzel, 2005). The longer a state of deficiency exists, the greater the potential for these problems to manifest.

2.3 Relevant Standards in the Code

Current provisions in Standard 2.10.2 – Salt and Salt Products permit the 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.

2.4 Current Availability and Use of Iodised Salt

Information from industry indicates that approximately 50-60% of salt sold as table and cooking salt is iodised in New Zealand.

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-to-moderate iodine deficiency in New Zealand. 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 periods. 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 New Zealand 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 New Zealand food supply is important to reduce the prevalence of iodine deficiency and the resulting adverse effects on population health.

4. Objectives

The specific objective of the regulatory measures outlined in this Proposal is to reduce the prevalence of iodine deficiency in New Zealand, especially in children, to the maximum extent possible so as to reduce the risk of related 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 through mandatory fortification without jeopardising the safety of the food supply.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 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.

In developing and varying standards, FSANZ must also have regard to:

- 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.

RISK/BENEFIT ASSESSMENT OF MANDATORY FORTIFICATION

5. 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?

6. 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 New Zealand see Section 9.

6.1 Potential Health Benefits

6.1.1 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).

Children from severely iodine deficient areas whose mothers were given adequate iodine supplementation during pregnancy, or those who lived in an area supplied by iodine fortified food had intelligence quotients (IQ) only marginally lower than those living in iodine sufficient areas (Qian *et al.*, 2005). 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.

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

6.1.2 *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).

6.2 **Potential Health Risks**

A number of potential health risks have been associated with increased iodine intakes (FAO and WHO, 1989; Delange and Hetzel, 2005). The most relevant of these in the context of the expected increase in iodine intake is the potential for disturbance of normal thyroid activity. The effect produced, i.e. iodine-induced hypothyroidism or iodine-induced hyperthyroidism, depends on the current and previous iodine status of the individual and any current or previous thyroid dysfunction. See Attachment 5 for a review of the potential consequences of excess iodine and tolerable levels of iodine in both healthy and sensitised populations.

6.2.1 *Iodine-Induced Hypothyroidism*

Iodine-induced hypothyroidism, the endpoint on which the UL for iodine is based, is an underproduction of thyroid hormones in response to recently substantially increased or chronically very high iodine intakes (FAO and WHO, 1989; ATSDR, 2004; Delange and Hetzel 2005). The condition, which may or may not be accompanied by goitre, has generally been observed only in populations with either long-term very high iodine intakes or a recent increase in iodine intake from deficient to above adequate or excessive (Delange and Hetzel 2005, Teng *et al.*, 2006).

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).

6.2.2 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 9.2.1.

7. Food Vehicle Selection

FSANZ has drawn on international experience in identifying appropriate food vehicles for considering mandatory iodine fortification. The WHO, ICCIDD, and 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, 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, 2005). Further details on the food technology aspects of iodine fortification are provided at Attachment 6.

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

- be regularly consumed by the population at risk in stable, predictable amounts (upper and lower intake levels known);
- 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 that 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 the food vehicles and will be addressed in the sections below.

7.1 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).

At Draft Assessment, dietary intake estimates showed that approximately 50% of salt in processed foods came from cereals, cereal products¹³, and cereal-based products and dishes¹⁴. 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 at Draft Assessment was the mandatory replacement of salt with iodised salt in bread, breakfast cereals and biscuits.

Trade and technical issues have 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 11.1.

7.1.1 Selection of Bread

FSANZ's dietary intake estimates indicate that 87% of New Zealanders aged 15 years and over consume bread. Seventy one per cent of children aged 5-14 years reported having bread at least once per day, the other 29% reported less frequent consumption. 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.

By increasing the iodine concentration in salt, a similar outcome can be achieved by mandating the use of iodised salt in bread only, as 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.

7.2 Alternative Food vehicles

7.2.1 Universal Salt Iodisation

As noted in Section 1.6, USI is the WHO's preferred option to address iodine deficiency internationally. In submissions, several public health stakeholders stated a preference for USI, believing it would deliver higher iodine intakes for pregnant and lactating women.

At Draft Assessment¹⁵, the impact of replacing salt with iodised salt in *all processed foods*, assuming all discretionary salt was also iodised, was explored.

¹³ Includes grains, cereal flours and starch powders, breads and rolls, breakfast cereals, English-style muffins, crumpets, tortillas, pastas, noodles and rice.

¹⁴ 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.

¹⁵

<http://www.foodstandards.gov.au/srcfiles/P230%20Iodine%20Fortification%20DAR%20+%20Attachs%201-10,12.doc>

This 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 lactating 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.

7.2.2 Direct Addition

There is a paucity of evidence as to the impact of the addition of iodine to food other than via salt (Winger, 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.

7.2.3 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.

It has been suggested by some submitters 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.

7.2.4 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.

It is for the Ministerial Council to determine whether mandatory or voluntary fortification is the preferred option. However, FSANZ notes that voluntary fortification is not as sustainable, and does not provide as stable and certain an iodine supply as mandatory fortification. Further, addition of iodised salt to processed foods is currently permitted in the Code, and has been for many years, but with minimal uptake by industry.

In response to the Draft Assessment, the food industry proposed a voluntary iodine fortification scheme. Certain food manufacturers proposed signing a 'Memorandum of Understanding (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 at Draft Assessment. 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 Attachment 7.

8. 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. Based on the current iodine status of the New Zealand 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 impact of fortifying bread with iodine, the Final Decision, was compared with the Preferred Option at Draft Assessment and estimated baseline values i.e. the current situation.

It should be noted that the dietary intake assessment also considers the impact of mandatory iodine fortification if it were implemented in Australia as well as New Zealand. This section of the Report, however, focuses on New Zealand, consistent with the development of a Standard for New Zealand only at this point in time.

A detailed description of the dietary intake assessment methodology and results can be found in: Attachment 7 – Dietary Intake Assessment Report – Main; Attachment 7a – Dietary Intake Assessment Methodology; Attachment 7b – Summary of Fortification Scenarios Considered Attachment 7c – Breads and Breakfast Cereals; Attachment 7d - Universal Salt Iodisation; Attachment 7e – Alternative Approaches.

8.1 Sources of Food Consumption Data

Several sources of data were used to estimate the impact of mandatory iodine fortification with iodine in different sections of the New Zealand population. The food consumption data sources used in the dietary intake assessment are summarised in Table 3. As food consumption survey data for children aged 1-4 years is not available for New Zealand two approaches were used to predict iodine intake in this group: 1) development of a theoretical diet, and 2) dietary intake assessment results for Australia. 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. This age group is therefore the most likely to have excessively high intakes in any fortification scenario.

Table 3: Key Sources of Food Consumption Data Used to Conduct the Dietary Intake Assessment

Data Source	Data Type	Data Details
2002 New Zealand Children’s Nutrition Survey*	Food consumption data from children aged 5-14 years	Single-day data [†] , unadjusted
1997 New Zealand National Nutrition Survey	Food consumption data for the general population aged 15 years and over, including pregnant and lactating women	Second-day adjusted [†]
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 1-3 years	Used in the absence of survey data. Does not provide a distribution of dietary intake

* Dietary intake assessments based on CNS data were performed by the University of Otago and provided by the New Zealand Food Safety Authority.

[†]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 lactating women are an important target group for iodine fortification. There were not enough pregnant and lactating women surveyed in the 1996-7 New Zealand 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, as a proxy for women of child-bearing age, in the NNS with the reference standards for pregnant and for lactating women. This does not allow for the higher energy, and hence food, intakes 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 the real change in baseline or post-fortification iodine intakes for these specific population groups.

8.2 Updated Food Composition Data

Although food consumption data were sourced from the 1996-7 New Zealand and 1995 Australian NNSs, the salt and iodine content of food have been updated using the following four major sources:

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

These data, which were obtained with the help of the New Zealand Food Safety Authority (NZFSA), contain 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.

8.3 Assessment of Dietary Inadequacy

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). Using this approach involves: (1) *determining the probability of inadequacy for each intake level in the group; and (2) calculating the average of those individual probabilities. To use the probability method, the requirement distribution must be known (so the probability of inadequacy associated with each intake level can be determined), and nutrient requirements and intakes must be independent* (Health Canada, 2004)¹⁶. 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 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, for the following reasons (Health Canada, 2004):

1. *Although the probability of inadequacy exceeds 50% when usual intakes are below the EAR, not everyone with an intake below the EAR fails to meet their own requirement. Some individuals with lower-than-average requirements will have adequate intakes (their usual intake, although below the EAR, exceeds their own requirement).*

¹⁶ A more detailed description of the Probability Approach for calculating nutrient inadequacy can be found here: http://www.hc-sc.gc.ca/fn-an/surveill/nutrition/commun/cchs_guide_esc_a3_e.html

2. *Similarly, although the probability of inadequacy is less than 50% when usual intakes are above the EAR, not everyone with intakes above the EAR meets their own requirement. Some individuals with higher-than-average requirements will have inadequate intakes (their usual intake, although above the EAR, is below their own requirement).*
3. *When the requirement distribution is symmetrical, when intakes are more variable than requirements, and when intakes and requirements are independent, the proportion of the group described in (1) above cancels out the proportion described in (2) above. The prevalence of inadequacy in the group can thus be approximated by the proportion with usual intakes below the EAR.*

The EAR Cut-Point Method has been used to estimate the prevalence of inadequate intakes in the current document. The New Zealand Ministry of Health has also endorsed this type of approach and has noted that, when assessing population intakes, 'do not use the RDI' (NHMRC *et al.*, 2006).

8.4 Key Uncertainties in the Dietary Intake Assessment

A full list of the assumptions and limitations inherent in dietary intake assessment can be found at Attachment 7a. This section addresses the uncertainties that are specific to this Proposal.

8.4.1 Uncertainties in Relation to Discretionary Salt

There was insufficient quantitative data on the use of discretionary salt in NNSs and CNS 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 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 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 (Food Safety Authority of Ireland, 2005). Therefore 76-82% of salt (sodium chloride) was derived from processed foods and 18-24% from discretionary uses.

Therefore, at Final Assessment, FSANZ has re-estimated salt intake, 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 both countries, with some variation around this value for different age/gender groups.

Neither the New Zealand nor the Australian surveys ascertained whether respondents used iodised or non-iodised discretionary salt.

Therefore an iodine concentration value, weighted by the relative sales of iodised and non-iodised salt was assigned to the quantity of discretionary salt calculated as described above for the primary analysis (the 'market-weighted' analysis).

In addition, sensitivity analyses were done to determine the range of possible iodine intakes, assuming that respondents always or never chose iodised salt ('consumer behaviour' models).

8.5 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.

8.5.1 Market Weighted Model

This approach factors in the proportion of discretionary salt that is iodised based on sales data. In New Zealand ~60% of table salt sales are for iodised salt, and this was used to derive a weighted average concentration of iodine in discretionary salt i.e. table and cooking salt. 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. For example, for New Zealand teenagers aged 15-18 years at *Baseline*, the estimated market-weighted mean intake of iodine is 106 µg/day compared 69 µg/day and 131 µg/day for those who never and always choose iodised discretionary salt respectively.

8.5.2 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:

- (a) where it was assumed that individuals always select non-iodised salt; and
- (b) where it was assumed that individuals always select iodised salt.

In the dietary intake assessments, 100% of New Zealanders aged 15 years and above were assumed to be consumers of discretionary salt (whether iodised or non-iodised).

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 option (a) and the upper number in the range represents option (b).

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.

8.6 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.

Given the variety of sources of data and methods of analysis that have been used to conduct the assessment, the results are presented for the general population first because these are the most robust data. Results for other population groups are then presented.

8.6.1 New Zealanders Aged 15 Years and Over

Currently, over half of New Zealanders aged 15 years and over are estimated to have inadequate iodine intakes; following fortification this is estimated to drop below 10%. No one aged 15 and over is expected to exceed the UL currently or following fortification.

Table 4 and Table 5 present the proportion of New Zealanders aged 15 years and over with inadequate iodine intakes and mean intakes at baseline respectively.

Table 4: Estimated Proportion of New Zealanders Aged 15 Years and Over with Inadequate Dietary Iodine Intakes at Baseline and Following the Proposed Fortification

Population Group	Percentage of Population with Inadequate Iodine Intakes (%)			
	Market Weighted Model		Consumer Behaviour Model*	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread
15-18 years	27	0	91 - 0	6 - 0
19-29 years	49	0	91 - <1	10 - 0
30-49 years	46	0	90 - <1	8 - 0
50-69 years	54	0	92 - 8	7 - 0
70 years & above	72	0	96 - 22	6 - 0

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

Table 5: Estimated Mean Iodine Intakes at Baseline and Following the Proposed Fortification in New Zealanders Aged 15 Years and Over

Population Group	Mean Intake of Iodine ($\mu\text{g/day}$)			
	Market Weighted Model		Consumer Behaviour Model*	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread
15-18 years	106	193	69 – 131	157 – 218
19-29 years	106	190	72 – 129	155 – 213
30-49 years	109	195	75 – 131	162 – 218
50-69 years	103	185	72 – 123	154 – 206
70 years & above	95	173	67 – 114	145 – 192

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

8.6.2 Women of Childbearing 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 6. No women of childbearing age are predicted to exceed the relevant UL for iodine either at baseline or when bread are fortified with iodised salt.

As explained in Section 8.1.1, it was not feasible to do a dietary intake assessment based on food consumption survey data from pregnant and lactating women.

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

At present, 95% of non-pregnant non-lactating 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.

Table 6: Estimate of Inadequate and Mean Dietary Iodine Intakes in New Zealand Women of Childbearing Age at Baseline and Following Fortification

Population Group	Percentage 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	68	0	95 - 1	14 - 0
Compared to EAR for Pregnant Women	97	45	99 - 95	80 - 17
Compared to EAR for Lactating Women	99	77	99 - 98	91 - 55
	Mean Intake of Iodine (µg/day)			
Women Aged 16-44 years	99	172	66-122	138-194

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

8.6.3 New Zealand Children and Adolescents Aged 5-14 Years

The dietary intake assessment for New Zealand children aged 5-14 years from the 2002 CNS was provided by the University of Otago and the New Zealand Food Safety Authority. Results are shown in Table 7. The survey data have not been second-day adjusted, so the spread of intakes reported is wider than if the correction had been done. Only a consumer behaviour approach was used.

One-to-three per cent of children aged 5-8 years are estimated to exceed the UL for iodine following fortification, whereas less than 1% are currently estimated to be exceeding the UL. Less than 1% of 9-14 year-olds are estimated to exceed the UL, currently or following the proposed fortification. These are likely to be overestimates owing to the use of single day adjusted data.

Table 7: Estimate of Inadequate and Mean Dietary Iodine Intakes in New Zealanders Aged 15 Years and Over at Baseline and Following Fortification

Population Group	Percentage of Population with Inadequate Iodine Intakes (%)		Mean Intake of Iodine (µg/day)	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread
5-8 years old	79 - 13	26 - 2	50 - 95	106 - 151
9-13 years old	81 - 28	28 - 6	54 - 99	119 - 164
14 years old	85 - 54	33 - 11	64 - 109	137 - 182

Note: the left-hand number in the range is the parameter for consumers who never choose iodised discretionary salt and the right-hand number in the range represents the parameter for consumers who always choose iodised discretionary salt, i.e. salt with a mean iodine concentration of 45 mg iodine/kg salt.

8.6.4 Children Aged 1-3 Years

The available dietary surveys from New Zealand do not include children aged less than 5 years. Therefore, two alternative estimates were derived for children aged 1-3 years: 1) theoretical diets, and 2) the 2-3 year age group from the 1995 Australian NNS was analysed.

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 these are theoretical diets based on a single consumption value for each food, there is no distribution; the 95th centile was estimated, by using a simple equation and the mean intake, as an indication of how high iodine intakes might be in some children. The results from the theoretical diets shown in Table 8 suggest that iodine intakes in a high proportion of children are inadequate. There is a substantial improvement in mean intake with fortification, although the impact on 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 8: Estimated Mean and 95th centile Dietary Iodine Intakes of New Zealand Children Aged 1-3 Years Based on Model Diets

Population Group	Mean Intake of Iodine (mg/day)		95 th Percentile of Iodine Intake	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread*
Without FSFYC	48	77	119	193
With FSFYC	72	102	180	254

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

Estimates based on Australian survey data from 2-3 year-olds are shown in Table 9. Currently less than 1% of this group are estimated to exceed the UL; post fortification 6% are estimated to exceed the UL. How closely these estimates reflect the intake of New Zealand children of the same age is unclear. The concentration of iodine in Australian milk is higher than in New Zealand, which results in a higher mean iodine intake for Australian adults compared to New Zealand adults, so it could be assumed that this would also be the pattern between Australian and New Zealand children.

Table 9: Estimate of Inadequate and Mean Dietary Iodine Intakes in Australian Children Aged 2-3 Years and Over at Baseline and Following Fortification

Model Type	Percentage of Population with Inadequate Iodine Intakes (%)		Mean Intake of Iodine (mg/day)	
	At Baseline	After Fortification of Bread	At Baseline	After Fortification of Bread
Market Weighted [†]	16	1	95	133
Consumer Behaviour [*]	18 - 12	2 - <1	93 – 105	130 – 143

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

[†] 36% of children this age consumed discretionary salt which was assigned an iodine value based on the relative sales of iodised and non-iodised salt

8.7 Dietary Intake Assessment Conclusions

In the general population aged 15 years and older, the proposed fortification is predicted to reduce the prevalence of inadequate intakes from 51% to less than 1% overall. In children aged 5-14 years, a large improvement in status would also be achieved. In all age groups, it is evident that those who do not use iodised discretionary salt are more likely to have inadequate intakes than those who do use iodised salt.

As discussed in Section 2.1, mild-to-moderate iodine deficiency has been identified in New Zealand infants and toddlers. The absence of New Zealand dietary survey data for young children makes estimating current and post fortification intakes difficult. However, it is apparent that the proposed fortification would increase the iodine intake in this group; potentially to the point where a small proportion of children exceed the UL for iodine.

Although the proposed mandatory fortification will increase the iodine intakes of pregnant and lactating 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 intakes exceeding 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.

9. Assessment of the Health Outcomes from Mandatory Iodine Fortification

This section outlines the anticipated improvement in health and performance of the New Zealand populations following 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.

9.1 Expected Reductions in Iodine Deficiency and Impact on Health

9.1.1 New Zealand Children and Adolescents

Difficulties in estimating current and post-fortification iodine intakes in young children aside, it is reasonable to expect that following the proposed fortification children and adolescents would be at reduced risk of 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. 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, as those incurred earlier are irreversible.

9.1.2 New Zealand Women of Childbearing 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 substantial reduction in the risk of iodine deficiency-related goitre and future thyroid problems.

During pregnancy the majority of women would still not achieve iodine intakes consistent with the elevated requirements. However, the anticipated increase in iodine intakes raises the likelihood of iodine stores being replete before pregnancy, allowing a portion of the added iodine requirement during pregnancy to be met by iodine stores. Though the situation would still not be ideal, a decreased risk of impaired information processing, attention, word articulation, and overall IQ would be expected in children born after introduction of mandatory fortification.

9.1.3 New Zealand General 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. Further, 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.

9.2 Potential Adverse Effects of Raising Population Iodine Intake

Following Draft Assessment FSANZ reconvened the Iodine Scientific Advisory Group¹⁷ to address 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 have also conducted extensive reviews of available scientific and medical literature and guidelines to assess the safety of increasing the iodine content of the food supply. The outcomes of our investigation are provided below. More detail is provided at Attachment 4 and Attachment 5.

¹⁷ For a list of members please refer to:
<http://www.foodstandards.gov.au/foodmatters/fortification/iodinescientificadvi3251.cfm>

9.2.1 International Experience

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 to 1.228 cases per 1000 people per 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, levels had declined but were 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.

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 moderate deficiency;
- 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.

9.2.2 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 described in Section 1.2.1.1. 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 also 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.

9.2.3 *Impact of Iodine Fortification on those with Existing Thyroid Conditions*

9.2.3.1 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 iodine fortified products for the period of restriction, typically 2-3 weeks prior to being given radioiodine.

9.2.3.2 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 in 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 and as iodine deficiency has only recently re-emerged long-term deficiency is likely to be rare. Further, the proposed increase to iodine intake is modest and therefore unlikely to cause harm even in the majority of sensitive individuals.

9.2.2.3 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. While 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 New Zealand population is considered unlikely.

10. Risk Assessment Summary

There is strong evidence, from studies and surveys measuring urinary iodine excretion, showing widespread re-emergence of mild-to-moderate iodine deficiency throughout the New Zealand population.

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 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. 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 would exceed the UL. Although it is generally not desirable to exceed the UL, in this case the estimated worst-case iodine intakes for young children are calculated to be below a level at which adverse effects may be observed. This, and the reversible nature of the endpoint on which the UL is based, means such intakes are unlikely to represent a health and safety risk to young children, though a reduced margin of safety exists.

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

RISK MANAGEMENT

11. 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 New Zealand. 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.

11.1 Food Vehicle Selection

At Draft Assessment, FSANZ proposed the mandatory replacement of non-iodised salt with iodised salt in bread, biscuits and breakfast cereals. In response to technical and trade issues raised, FSANZ has removed biscuits and breakfast cereals as food vehicles for iodine fortification.

At Final Assessment, FSANZ is proposing the *mandatory* replacement of salt with iodised salt in bread; with a salt iodisation range from 25-65 mg of iodine per kg of salt. The *voluntary* permission for iodine in iodised salt and reduced sodium salt in Standard 2.10.2 will be retained and the iodisation range will be consistent with the mandatory requirement.

11.1.1 Removal of Biscuits as a Food Vehicle for Iodine Fortification

At Draft Assessment, bread, biscuits and breakfast cereals were selected as food vehicles because approximately 95 % of salt in 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.

Under the preferred option at Draft Assessment, all imported biscuits would have needed to use iodised salt, requiring overseas manufacturers to set up separate production lines. New Zealand biscuit manufacturers who export to Japan would also need separate production lines, as Japan does not allow the importation of iodised foods. Setting up additional production lines imposes considerable costs for these manufacturers for comparatively small overall gains in population iodine intakes.

The removal of biscuits as a food vehicle from this Proposal eliminates nearly all the trade related costs, and therefore results in considerable cost savings. It also significantly reduces 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 this 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'.

11.1.2 Removal of Breakfast Cereals as a Food Vehicle for Iodine Fortification

After the release of the Draft Assessment Report, FSANZ was alerted to a potential technical difficulty for one of the leading breakfast cereal manufacturers in New Zealand and Australia. 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 at this stage. If monitoring reveals insufficient iodine in the food supply following mandatory fortification of bread, FSANZ will reconsider breakfast cereals as an additional food vehicle.

As part of any future consideration, FSANZ could explore the possibility of directly adding iodine to breakfast cereals, 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. The removal of biscuits and breakfast cereals reduces the reach to the population of the proposed fortification from 94% to 87% for New Zealanders aged 15 years and above. Furthermore, it also significantly reduces the reach to 'non-bread eaters'.

To compensate for having removed biscuits and breakfast cereals from the Proposal, the level of iodine required in salt has been increased from that proposed at Draft Assessment; giving comparable dietary intake estimates.

11.1.3 Selection of Bread as a Food Vehicle for Iodine Fortification

FSANZ's dietary intake estimates indicate that 87 % of New Zealanders aged 15 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 as outlined in Attachment 6. Both national and international research shows iodised salt can successfully be added to bread. In practice, the salt content, and hence the iodine content, does not vary significantly over a range of bread. In contrast, the salt content of different biscuits and breakfast cereal categories varies considerably.

11.1.4 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 bread products such as bread crumbs and stuffing where these are yeast leavened.

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

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

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

11.1.4.1 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 sold in a frozen state for subsequent proofing and baking by the purchaser. Frozen dough is produced in New Zealand 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 New Zealand market will be required to use iodised salt as it will be sold and consumed as bread.

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

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

As outlined in Section 7.1, 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, as outlined in Section 7, is outlined below.

11.2.1 Stability of Iodised Salt

Studies on the stability of iodised salt using potassium iodate, the form used by the New Zealand salt industry, show that when stored in polyethylene bags for two years there was no significant loss of iodine, see Attachment 6.

Generally, salt is a very stable carrier for iodine. The permitted forms, 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 Attachment 6. 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.

11.2.2 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 urinary iodine 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).

11.2.3 Economic Feasibility of Iodised Salt

The New Zealand salt industry indicated that the iodisation of salt would result in only a small price increase. The Cost Benefit Analysis, at Attachment 8, 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, 2006).

11.2.4 Centralised Production Allowing for Quality Control

The New Zealand salt company, Dominion Salt Ltd, is the major supplier of salt to the bread making industry in New Zealand. This company has in place appropriate analytical testing procedures and routinely monitors levels of salt iodisation to ensure they are within specifications.

11.2.5 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 food supply.

11.3 Technical and Industry Considerations

11.3.1 Industry Capacity for Salt Iodisation

Dominion Salt Ltd indicated that additional machinery and equipment may be needed to expand outputs. Currently iodised salt is manufactured at only one of their two refineries in New Zealand. However, they have advised that increased production of iodised salt for the bread industry could be accommodated within the proposed implementation timeframe.

11.3.2 *Appropriate Salt Iodisation Range*

Process variations occur during the manufacture of iodised salt. This was acknowledged at Draft Assessment when a ‘working range’ of ± 10 mg of iodine per kg of salt was recommended to compensate for this variation.

Following Draft Assessment, 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).

At Final Assessment, 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.

11.3.3 *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 Attachment 6, 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 with New Zealand Industry, it was noted that one 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 11.1.2), 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 Attachment 9). 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. This trade-related issue is further discussed in Section 11.7 and at Attachment 8.

11.3.4 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 are unpackaged bread and bread forming part of a compound ingredient¹⁸ that is less than 5% of the food, for example in bread crumbs.

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

Labelling modifications to include 'iodised salt' in the ingredient list will incur costs for manufacturers. During consultations on the Proposal, industry representatives raised the cost of labelling as an issue. To minimise costs, FSANZ was asked, where possible, to align the introduction of this Proposal with other major Proposals with labelling implications, namely Proposal P293 - Health Nutrition and Related Claims and Proposal P295 – Mandatory Fortification with Folic Acid.

11.3.5 'Organic' Bread

Under the New Zealand fair trading legislation, food labelling or promotional claims must be factually correct and not misleading or deceptive¹⁹. It is the opinion of the New Zealand Commerce Commission (NZCC) that the use of the term 'organic' in relation to fortified foods could mislead consumers into believing that the product had been produced naturally and thus would risk breaching New Zealand fair trading legislation.

If an organic certification system permitted fortification, then the product could be labelled 'certified organic' (logo or mark) providing the product complied with the rules. New Zealand has a number of national organic certification bodies²⁰, none of which have identical standards. However, organic standards do not allow synthetically produced substances into organic production systems, and the addition of vitamins and minerals are generally not permitted.

The regulation of 'organic' foods is not covered by the Code. Any reference to 'certified organic' in the Code would require a new standard which defined 'certified organic'. This standard would require detailed specifications of methods of production, permitted chemicals and testing procedures, all of which fall outside FSANZ's remit. However, an exemption from mandatory fortification for bread represented as 'organic' would not require a definition of 'organic' under the Code.

¹⁸ 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.

¹⁹ *Trade Practices Act 1974*, State and Territory Fair Trading Legislation and *Fair Trading Act 1986*.

²⁰ http://www.organicnewzealand.org.nz/organic_certification.htm

An exemption for organic bread was supported by a number of submitters. Two jurisdictions recommended that the term 'organic' be defined by FSANZ to assist with compliance and enforcement. One jurisdiction felt that the exemption for 'organic' bread should cover only bread certified by an organic certification agency.

11.3.6 'Natural' Bread

Mandatory iodine fortification may be an issue for food manufacturers producing products using only 'natural ingredients'. Iodised salt may not be considered a 'natural ingredient' and therefore may impact on manufacturers producing 'all natural' bread products fitting the Code's definition of bread.

The NZCC consider that 'natural' claims imply that the product is made up of natural ingredients, i.e. ingredients nature has produced, not man made or interfered with by man. Iodised salt is manufactured, and therefore an 'all natural' claim for foods containing iodised salt could potentially be considered misleading.

Manufacturers may however label foods using 'natural ingredients', and add additional qualifications in order to produce a label which is unlikely to mislead the consumer.

11.4 Consistency with Ministerial Policy Guidance

As noted in Section 1.7, in considering mandatory fortification as a possible regulatory measure, FSANZ must have regard to the Ministerial Council's Policy Guideline on fortification (Attachment 2). The 'High Order' Policy Principles in the Guideline reflect FSANZ's statutory objectives (see Section 4) and are therefore integral to developing a mandatory standard. FSANZ must also have regard to the five 'Specific Order' Policy Principles for mandatory fortification.

The Policy Guideline states that 'Specific Order' Policy Principles 1 and 2 are to be determined by AHMAC, or an appropriate alternative body for a specific New Zealand health issue.

The then Chair of the Ministerial Council requested FSANZ defer finalising Proposal P230 as it related to Australia. Due to a degree of geographic variation in iodine status across Australia, Australian Health Ministers are re-evaluating the evidence on the prevalence and severity of iodine deficiency in Australia.

In the interim, Health Ministers acknowledged that the magnitude and severity of iodine deficiency in New Zealand warrants intervention with mandatory fortification. While the severity and prevalence in Australia is being further considered, a separate standard for New Zealand was suggested. On the basis of this advice, FSANZ has proceeded with a New Zealand only Standard for mandatory iodine fortification. FSANZ will consider a standard for Australia after receiving further advice from the Ministerial Council on the severity and prevalence of iodine deficiency in Australia.

FSANZ's consideration of the other 'Specific Order' Policy Principles 3, 4 and 5 are discussed below.

11.4.1 Consistency with New Zealand National Nutrition Guidelines

The New Zealand Nutrition Guidelines²¹ recommend choosing foods low in salt, particularly pre-prepared foods, drinks and snacks. The proposed mandatory fortification option is to add iodised salt, in place of non-iodised salt, to bread. 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 mechanism for adding iodine to bread, education messages will emphasise bread as a source of additional iodine, rather than salt. The New Zealand Nutrition Guidelines for all age groups 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 removal of biscuits as a food vehicle provides further consistency with national nutrition guidelines, which encourage limiting intake of fat, salt and sugar.

The New Zealand nutrition guidelines also state that if using salt, choose iodised salt. This guideline is in response to the low iodine intakes of New Zealanders. Both the *status quo* and the proposed mandatory fortification option allow for the continued iodisation of retail salt for discretionary use.

11.4.2 Safety and Effectiveness

As outlined in Section 9, 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.

Some submitters questioned the relevance of the UL for young children 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 the NHMRC advised it was their policy to review publications every five years or earlier, if the evidence supports this. They stated that 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.

11.4.3 Additional Policy Guidance

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

²¹ Ministry of Health. Food and Nutrition Guidelines for Healthy Adults: A background paper. Wellington. Ministry of Health, 2003.

11.5 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). Most of the empirical research on knowledge, attitudes and behaviour regarding various iodine fortification scenarios comes from the Indian sub-continent (Mohapatra *et al.*, 2001; Sarker *et al.*, 2002; Khoja *et al.*, 2000) and South Africa (Jooste *et al.*, 2005).

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 8% of New Zealanders nominated the use of iodised salt in foods as a concern from a prompted list. Of those who nominated it as a concern, the mean level concern was a rating of 5.3 on a scale from 1 for 'not concerned at all' to 7 for 'extremely concerned' (TNS, 2007²²).

11.5.1 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 population (see Attachment 7). Some individuals may choose to avoid iodised products. The availability of some salt-free bread options or organic bread, may provide non-fortified options for those who choose them. Additionally, ingredient labelling on packaged foods will provide information for consumers.

²² This report is expected to be released in early 2008.

The Tasmanian (interim) Iodine Supplementation Program was well received by the community (Seal, 2007). The communication strategy presupposed community concern and 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 *per se*. 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 Food Standards Agency of the United Kingdom 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. to continue with current Government advice;
2. to run a public education campaign to encourage women to take folic acid supplements;
3. to encourage food companies to fortify more foods with folic acid on a voluntary basis; and
4. to introduce a legal requirement for flour to be fortified with folic acid.

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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).

11.5.2 Awareness and Understanding of Fortification with Iodine

Given the lack of data about the response of consumers to iodine fortification we have assumed that their 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).

It is proposed to monitor the level of consumer awareness and understanding of the mandatory requirement to replace non-iodised salt with iodised salt in bread as part of the monitoring program for mandatory iodine fortification.

11.5.3 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 United Kingdom Food Safety Agency 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 indicate that bread is widely and regularly consumed (Attachment 9).

11.5.4 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 ingredients²³ 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 15% of New Zealand total bread sales²⁴.

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 to the Draft Assessment Report and the Issues Paper. There was concern that consumers who needed 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.

11.6 Factors Affecting Safe and Optimal Intakes

11.6.1 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.

²³ 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.

²⁴ Brooke-Taylor & Co Pty Ltd, Report prepared for FSANZ P295 Final Assessment Report, Attachment 10, Appendix 1.

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, it is thought that the consumption of these dietary staples remains fairly constant over time (Cook *et al.*, 2001).

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 the 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 on-going safety and effectiveness of mandatory fortification.

11.6.2 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 reiterates support for the Nutrition Guidelines, which focus on reducing salt intakes.

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

11.6.3 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 lactating women it will not fully meet their increased requirements.

Thus supplementation or other sources of iodine would still be required by many pregnant and lactating 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 lactating women, using iodised salt in the food supply 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 and yet salt intakes for children are over half that of adult women.

Several submitters suggested that iodine requirements of pregnant and lactating women would be more adequately met by Universal Salt Iodisation (USI). At Draft Assessment, FSANZ explored USI as outlined in Section 7.2.1 above. However, this option would still be constrained by the desire to minimise exceedance of the UL for iodine in young children. This option would therefore be little better for pregnant and lactating women than the proposed mandatory fortification.

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 Strategy at Attachment 10.

11.7 Impact on Trade

The removal of breakfast cereals and biscuits as food vehicles considerably reduced the trade impacts of the propose fortification. 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 New Zealand domestic markets. Very little bread is imported or exported into New Zealand. 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.

11.7.1 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 New Zealand. 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. While it is anticipated that the export market impact of this fortification is small, at least one manufacturer has been identified as potentially being disproportionately affected, as discussed in the section below.

11.7.1.1 Frozen Dough

Frozen dough and par-baked products are emerging as export opportunities for New Zealand, particularly to Asian markets.

The value of sales to meet Japanese Subway frozen dough exports has been estimated at \$NZ12 million per annum²⁵. However, Japan currently proscribes the importation of food fortified with iodine. Trade related costs will be incurred if a company must separately produce unfortified products for export and fortified products for domestic production. As noted in the cost benefit analysis at Attachment 8; trade related costs include:

- the upfront costs of isolating products for export and associated revised labelling costs; and
- ongoing costs of additional transport and warehousing for separately produced products for export and labour costs associated with switching between fortified and unfortified product.

At least one New Zealand bakery has a considerable export market of frozen dough to Japan. Their operating system is a highly mechanised, computer-controlled closed system. All bakery products are manufactured using this one system and there is no straightforward process for allowing the addition of iodised salt to domestic bread, but excluding it from products destined for export. Further details can be found at Attachment 9.

11.7.1.1 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 import these foods into Japan.

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

11.7.2 Imports

In New Zealand, it is unlikely that the proposed fortification would have a significant impact on imports. Very little bread is imported into the country. 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.

11.8 Summary

A number of risks and issues arising from this mandatory iodine fortification Proposal have been identified. Strategies for the management of these risks as they relate to the Decision is addressed later in this Report (see Section 15).

²⁵ Brooke-Taylor & Co Pty Ltd, Report prepared for FSANZ, Attachment

12. Regulatory Options

FSANZ selected iodised salt as an ingredient in bread to be the fortification vehicle, on the basis of its ability to effectively deliver and sustain an increase in the iodine intake of the population.

Prior to selecting bread as the preferred food vehicle, FSANZ considered adding iodised salt to breakfast cereals and biscuits and also to all manufactured processed food. Bread was selected as the preferred food vehicle because it is the most cost-effective, taking into account technical feasibility and trade related costs. It could also deliver a similar outcome on population iodine status compared with the other potential food vehicles.

Consequently at Final Assessment, two options have been identified, as detailed below.

12.1 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.

12.2 Option 2 – The mandatory replacement salt with iodised salt in bread

This option proposes 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-to-moderate iodine deficiency in New Zealand. The current level of salt iodisation (from 25-65 mg/kg) will be retained, as will the current voluntary permission.

Under a mandatory fortification option, monitoring is necessary and would be included in the implementation of the proposed draft Standard. Monitoring is discussed in more detail in Section 21.

13. Impact Analysis

13.1 Affected Parties

- Industry: Salt manufacturers and manufacturers of bread and bread products
- Government: New Zealand Food Safety Authority and Ministry of Health
- Consumers generally, and particularly the following sub-groups: Infants during foetal development and up to 3 years of age, and pregnant and lactating women

13.2 Cost Benefit Analysis

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, and subsequently to refine their assessment of the costs of fortifying bread. The analyses prepared by Access Economics are provided at Attachment 8.

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 on to 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 New Zealand two plants would be affected and around \$NZ300,000 worth of machinery would be required.

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 \$NZ3000.

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 \$NZ55 to \$NZ65 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. Overall the ongoing costs to the New Zealand salt manufacturers would be \$NZ20,000 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 redesigning labels, estimated at \$NZ500 per stock keeping unit (SKU) and to total \$NZ392,000 for the 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. It is estimated that the total upfront costs of revising labelling for this segment of the baking industry would be \$NZ255,000. Label changes would also be required by the manufacturers of bread ingredients, premixes and improvers. Their upfront costs are estimated to be \$NZ128,000.

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 changeover 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. The labelling and packaging write-off costs for New Zealand industry are estimated to be \$NZ720,000.

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 relabelling and label write-offs would be reduced by almost \$NZ1 million.

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 \$NZ30,000.

FSANZ is aware of one manufacturer of bread products that introduces salt into the production process through a brine solution. The process of preparing the brine, of adding salt to a vessel to which water is then pumped through, may be unsuitable for iodised salt if a high proportion of the iodine was leached out early in the process. Some adjustment to the brining process would be necessary to ensure even dissolution of iodised salt and an even dispersal of dissolved iodine. This would require some additional equipment to be acquired at a once-off cost to the company. The additional equipment could be installed within an 18 month transition period.

13.2.2.4 Impact on Exports

Exporters would consult their export markets to determine whether iodine fortified bread products would be acceptable. For some markets, such as Australia, iodine fortification will not be an issue. In other markets iodine fortification may not be acceptable, such as Japan which is replete in iodine and prohibits the addition of iodine to food. In these cases unfortified bread products could be prepared manually to avoid contamination with mainstream production, at an ongoing higher cost because the efficiencies of automated systems would be foregone in manual production. The overall cost to New Zealand manufacturers would depend on the scale of exports to such countries, which FSANZ understands is quite small currently.

13.2.2.5 Government – Administration and Enforcement of Regulation

The costs of Government enforcement of the proposed standard are estimated to be \$NZ8000 upfront and \$NZ89,000 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.

13.2.2.6 Government – Monitoring

An effective fortification program will require monitoring. Although monitoring is not part of FSANZ's responsibilities under the FSANZ Act, for the purposes of this report an attempt has been made to estimate some of these costs. The costs quoted for monitoring in this section of the report are therefore approximate. The costs of monitoring are discussed in Section 21.

The monitoring activities and costs that would be expected are:

- \$NZ150,000 pa for key monitoring activities. This includes liaison with relevant agencies and stakeholders; collation and analysis of data; convening expert technical groups to assist with interpretation; preparation of reports (stocktake, baseline, and 2-year follow-up); advice re new or enhanced data collection activities.
- \$NZ40,000 pa for food composition work.
- \$NZ400,000 over five years for new data collections in target populations not included in existing surveys (e.g. children <5 years and pregnant women).
- \$NZ100,000 for industry compliance work over the first two years, reduced to \$20,000 pa after 3 years.
- \$NZ80,000 over five years for consumer research.

13.2.2.7 Summary of Total Costs

Overall, the total upfront cost from this Proposal is \$NZ1,806,000. The total ongoing cost for industry and government, excluding monitoring, is \$NZ139,000 each year. These ongoing costs equate to three cents per person per year²⁶.

²⁶ 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.

The following table summarises all the costs to industry and government from this iodine fortification Proposal.

Summary of total costs		(\$NZ)
Upfront costs		
Salt industry (machines and labelling)		303,000
Bakers (labelling)		1,495,000
Government – administration and enforcement of regulation		8,000
Total upfront		1,806,000
Ongoing costs (per year)		
Salt industry (maintenance, iodine, analytical testing, transport and storage)		20,000
Bakers (some annual analytical testing)		30,000
Government – administration and enforcement of regulation		89,000
Total ongoing (per year)		139,000
Monitoring costs (per year)*		320,000
Costs of iodine fortification per head		
	Population	4,186,900
	Upfront cost per head	0.43
	Ongoing cost per head (per year)	0.03
	Monitoring cost per head (per year)*	0.08

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

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

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. As noted in Section 9.1.3, 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, research shows that addressing a mild-to-moderate iodine deficiency may improve cognitive function. Studies of the health impacts of iodine deficiency suggested 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 New Zealanders, 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 Centre for Health Economics Research and Evaluation (CHERE), University of Technology, Sydney, to examine the cost-effectiveness of iodine fortification of bread in Australia and New Zealand.

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

CHERE estimated the cost per unit reduction in at-risk populations over a ten year period. Their estimates suggest that there would be 181,709 and 1,901,722 fewer people with moderate and mild iodine deficiency respectively in New Zealand. The cost-effectiveness ratios, which estimate the costs of preventing one person from being moderately or mildly deficient are \$NZ15.30 and \$NZ1.46 respectively.

It should be noted that the cost effectiveness ratios are quite different to the per capita costs in the summary of costs table, above. While both approaches start with the same costs of intervention, the per capita costs simply express the ongoing yearly cost in terms of the impact over the entire New Zealand population. The cost effectiveness ratios measure the cost of intervention for particular sub-groups of New Zealand's population that are iodine deficient, calculated over a ten year period.

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 full report is provided at Attachment 11.

14. Comparison of Options

Introducing mandatory fortification as proposed in this report, is expected to result in ongoing costs (excluding monitoring) of \$NZ139,000 each year. This equates to three cents per person per year.

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.

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 New Zealand.

Hence FSANZ considers that Option 2, to require the mandatory replacement of salt with iodised salt in bread, provides net benefits superior for the population of New Zealand 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 New Zealand.

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 New Zealand. 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 three cents per person per year in New Zealand, 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 Risk Assessment Summary, see Section 10, concluded that the proposed mandatory fortification scenario will deliver a substantial improvement in iodine intakes across the population, alleviating the current deficiency and preventing future deficiencies, especially among children.

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

15.1.1 Optimising Effectiveness of the Mandatory Fortification Proposal

15.1.1.1 Iodine Supplement Use

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

The lack of a suitable iodine supplement, with appropriate dosage and Good Manufacturing Practice (GMP), for pregnant and breastfeeding women in New Zealand was noted by the New Zealand Government in its submissions to the Proposal. Currently in New Zealand only registered medicines are required to meet GMP requirements. The Ministry of Health has engaged in recent discussions with a potential industry provider of a suitable iodine supplement for the future²⁷, but it is the provider who makes the decision to proceed with an application for a product to become a registered medicine.

15.1.1.2 Groups Who Would Not Receive Additional Iodine from the Recommended Mandatory Fortification

Although the majority of the population eat bread (87 % aged 15 years and above), FSANZ recognises some people do not or may consume different forms of bread e.g. gluten or salt free. These might 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 intake in order to reduce salt intake for medical reasons.

In submissions to the Draft Assessment Report and Issues Paper, some submitters expressed concern that people who avoid bread will not be covered by this mandatory fortification scenario. These consumers have been identified as a primary audience in the Communication Strategy developed by the NZFSA and (MoH) (see Section 16). The Strategy highlights potential alternative sources of iodine. These consumers will be targeted through mediums such as media releases, fact sheets and news articles.

For people with coeliac disease, some commercially produced gluten-free and wheat free breads are 'yeast risen' 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.

²⁷ Personal communication, Ministry of Health July 2007.

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 6. 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 will be monitored and treated.

The NZFSA Communication Strategy has identified consumers with thyroid disorders as a primary audience. 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. These consumers will be reached through mediums such as fact sheets and articles in newspapers and magazines. Health professionals play an important role in informing consumers and they will be reached through articles in medical and public health publications and via presentations at conferences and workshops.

15.1.2.3 Iodine Sensitivity Reactions

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

The NZFSA Communication Strategy has identified consumers with possible iodine sensitivities as a primary audience. The Strategy highlights that the form of iodine used in iodised salt has not been linked to any types of adverse reactions or allergies. It also outlines 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. Consumers will be reached through methods such as fact sheets and articles in newspapers and magazines. Health professionals will also play an important role in informing consumers.

15.1.2.4 Children above the Upper Level of Intake

As discussed in the Risk Assessment, 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 not expected that these intakes would represent a health and safety risk to these children. The Communication Strategy outlines that kelp supplements are not recommended for children.

Given this situation, information advising young children not to consume table salt or to use salt in cooking will be disseminated to parents as part of the Communication Strategy.

15.1.3 Limitations of the Mandatory Fortification Proposal

FSANZ acknowledges that not all New Zealanders will get enough iodine from the replacement of salt with iodised salt in bread. The approach put forward in this Report can be augmented by activities outside the scope of FSANZ's remit such as education and promotion of iodine supplement use. Further, FSANZ is aware of the need to consider the outcomes of population wide monitoring of iodine status, which may warrant measures such as increasing the concentration of iodine in iodised salt, replacing salt with iodised salt in products other than bread, or exploring the possibility of adding iodine to the food supply other than through iodised salt. These potential options can only be adequately considered when there is sufficient data on the impact of the mandatory fortification as it is currently proposed. Several submitters 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 11.6, there are a number of other variables that may influence future levels of iodine in the food supply, namely the consumption and salt levels of 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. The monitoring program is outlined in Section 21.

15.2 Labelling and Information Requirements

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

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

- listing of ingredients (Standard 1.2.4);
- 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 *there is no mandatory requirement to label a food product as fortified, however consideration should be given, on a case-by-case basis, to a requirement to include information in Nutrition Information Panel.*

FSANZ considers the generic requirements of the Code to be appropriate for providing consumers with information and therefore does not believe mandating inclusion 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 11.5.4) these products are exempt from the requirement to label with an ingredient list. In these cases consumers will not necessarily be informed about the presence of iodised salt.

FSANZ considers that the current exemptions from the labelling provisions that apply to bread should remain in place and that declaration of iodised salt as an ingredient in these unlabelled bread is not required, for the following reasons:

- mandatory provision of ingredient information on unlabelled foods was recently considered under Proposal P272 - Labelling Requirements for Foods for Catering Purposes and Retail Sale, and rejected;
- this is consistent with the approach for mandatory fortification with thiamine and folic acid;
- this is consistent with the approach in the Code for labelling of other ingredients where declaration is not required for health and safety reasons; and
- a written declaration of iodised salt as an ingredient and not accompanied by other ingredients, for example, 'Contains iodised salt'; may cause confusion for consumers.

15.2.1 Use of Nutrition and Health Claims

Mandatory fortification presents the 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 the breads reach 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 resultant iodine content is greater than 15 µg per 50 g reference quantity (approximately two slices of bread), which is likely to occur if bread contains at least 1% salt.

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

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

FSANZ does not believe that the mandatory use of iodised salt in bread is inconsistent with proposed salt reduction programs. Generally, even with a 30% reduction in salt content, the majority of bread can still make an iodine content claim and a general level health 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.

A new Standard (draft Standard 1.2.7 – Representations about Food) is currently under development and will permit a wider range of health claims in the future. This Standard is being considered under Proposal P293 – Nutrition, Health & Related Claims and will provide a framework for the assessment of fortified foods to determine which are permitted to carry nutrition content claims or health claims about iodine.

15.2.2 'Organic' Bread

As noted in Section 11.3.5, the use of the term 'organic' in relation to a fortified food could breach New Zealand fair trading legislation by misleading consumers into believing the product had been produced naturally.

As a result, FSANZ proposes an exemption from mandatory iodine fortification for bread that is represented as 'organic'. This approach does not require further definition 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.

An exemption for bread represented as organic will allow manufacturers of organic bread to follow existing organic practices and standards in New Zealand and will not impact on organic bread importation and exportation. In addition, the exemption provides an additional element of choice for consumers wishing to avoid fortified bread.

Although a number of submitters 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 Communications and Education Strategy on mandatory iodine fortification at Attachment 10.

15.2.3 'Natural' Bread

Consumers may view what is 'natural' differently to manufacturers and food technologists, making it difficult to classify foods and ingredients. Unlike 'organic' foods, which can be categorised by adherence to an organic certification system, there are no certification criteria for 'all natural' foods.

Given the difficulty in determining an acceptable definition for 'all natural' foods (see Section 11.3.6), FSANZ is not considering an exemption for 'all natural' bread containing iodised salt. This approach is consistent with mandatory fortification with folic acid, which does not allow an exemption for 'all natural' foods. Manufacturers will have the ability to label foods using 'natural ingredients' and add additional qualifications in order to produce a label which is unlikely to mislead the consumer.

15.3 Level of Iodine Fortification in Iodised Salt

In determining the appropriate level of iodisation in salt to address the re-emergence of mild-to-moderate iodine deficiency, the Risk Assessment recommends a level of 45 mg iodine per kg of salt for use in bread. To account for the impact on dietary iodine intakes of removing biscuits and breakfast cereals as food vehicles, this level of salt iodisation is greater than that proposed at Draft Assessment.

The voluntary permission to add iodine to salt will be retained. The Risk Assessment recommends a level of 45 mg iodine per kg of salt in table salt, which is equivalent to the recommended level of iodine in 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 enforce²⁸;
- 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 the Draft Assessment Report 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, at Final Assessment, 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.

15.4 Risk Management Conclusion

During the development of this Proposal, a number of potential risks and issues arising from this mandatory iodine fortification Proposal were identified. These included 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;

²⁸ The proposal for two iodisation levels would create a situation where the potential overlap creates difficulties with ensuring regulatory compliance.

- the identification of the need for an iodine supplement program for pregnant lactating 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.
- by increasing the implementation period from the initial 12 months proposed to align with the commencement of the mandatory fortification of bread with folic acid to help reduce upfront costs of relabelling and label write-offs for industry;
- the development of a specific Communication Strategy for New Zealand (see Section 16.1) to increase awareness of the mandatory iodine fortification standard, including specific messages for:
 - pregnant and breast feeding 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; and
- recognition and contribution to 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 prepared a strategy to guide communication and education initiatives to raise awareness and understanding of the proposed standard and its implementation. The NZFSA and the MoH used this as a basis to develop a specific Communication Strategy for New Zealand at Attachment 10. This Strategy has been developed to facilitate communication between consumers, food industry groups, media, and government departments on the mandatory iodine fortification standard. The Strategy outlines the key messages relevant to each of the target audiences and the suitable channels for communication.

The NZFSA have highlighted that it is their role to communicate with New Zealand industry about implementing standards, to monitor and enforce standards in New Zealand and to communicate to, and inform New Zealand consumers. The Ministry of Health has the leadership role for the New Zealand health sector. This includes monitoring health status, developing nutrition policy, and providing advice to health professionals and the public on population health issues, such as adequate iodine intakes.

17. Consultation

17.1 Initial Assessment

FSANZ received a total of 38 written submissions in response to the Initial Assessment Report for this Proposal during the public consultation period of 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 industries, the majority of industry submitters supported voluntary fortification; extending current iodine permissions, the promotion of voluntary options or a combination of both options to increase iodine intakes.

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

17.2 Draft Assessment

FSANZ received a total of 68 written submissions responding to the Draft Assessment Report for this Proposal 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 so that baseline data can be collected.

Many public health professionals were concerned that the preferred option does ‘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 has 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 at Attachment 12.

17.3 Issues Paper

In May 2007 FSANZ released an Issues Paper outlining the proposed changes under consideration for Final Assessment. 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 on the inability of the Proposal to fully meet the substantially increased iodine requirements of pregnant and lactating women, and breastfed infants. The need to address deficiency in non-bread eaters was also raised.

Some public health stakeholders viewed the current Proposal as an initial step and only part of the solution to the current iodine deficiency, and noted mandatory fortification is preferable to voluntary fortification as it provides greater certainty, sustainability, equity, and reach. However, a number of public health stakeholders believed that USI would provide higher iodine intakes for pregnant and lactating 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 did state 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 the current Proposal is inconsistent with the Australian Government's Best Practice Regulation Requirements and that to meet these requirements, all strategies for addressing iodine deficiency would need to be evaluated.

A full summary of the comments received in response to the Issues Paper is provided in Attachment 13.

17.4 Targeted Consultation

Issues identified from public submissions and consultations with stakeholders formed the basis of further targeted consultation with key stakeholder 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 New Zealand jurisdictions, and consumer and public health organisations. Consultations have 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 whilst progressing work on this Proposal. The Fortification SDAC is comprised of members who have a broad interest in, and knowledge of, fortification-related issues and represent groups from public health nutrition, food manufacturing, enforcement, food policy, health promotion and consumer education.

Information received has 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 this Proposal. 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 the CHERE, to undertake further work on the costs and benefits of the Proposal.

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).

17.5 Outcomes from Targeted Consultations

Issues identified during intensive targeted consultation with key stakeholder groups are addressed in relevant sections of this Report. These issues include:

- relevance of the UL for young children:
- technical issues such as the use of a brining solution to add salt to bread: and
- concerns about costs, compliance, and enforcement.

These findings have influenced and refined FSANZ's approach at Final Assessment.

18. World Trade Organization

As a member of the World Trade Organization (WTO), New Zealand 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 fortification regulations at Draft Assessment, in accordance with the WTO Technical Barriers to Trade Agreement. No responses to the notifications were received by FSANZ.

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 in Australia and New Zealand, 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 New Zealand. 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.

The Decision

The mandatory replacement of non-iodised salt with iodised salt in bread is the preferred option to address the re-emergence of iodine deficiency in New Zealand. The salt iodisation level is to be in the range of 25-65 mg of iodine per kg of salt. Bread represented as organic are to be exempt from this requirement.

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

Reasons for the Decision

Amendments to the Code, outlined in Attachment 1, are approved for the following reasons:

- Replacement of non-iodised salt with iodised salt in bread would address iodine deficiency across much of the New Zealand population, and prevent it from getting even more serious in the future.
- Replacement of non-iodised salt with iodised salt in bread is technological feasible and well tested internationally.
- Use of iodised salt to reduce the prevalence of iodine deficiency is consistent with international guidance and experience.
- The Tasmanian voluntary program using iodised salt in bread, at an average of 45 mg iodine per kg salt, led to an improvement in the iodine status of a mildly deficient population.
- Based on the available evidence, including overseas experience with mandatory fortification, the proposed level of fortification does not pose a risk to general public health and safety. The level has been set to minimise any potential health risks. In groups that are generally more sensitive to increases in iodine intake, e.g. individuals with existing thyroid conditions, the risk of a negative impact on health is still considered to be very low.
- FSANZ considers that this Proposal would deliver net-benefits to New Zealand. Mandatory fortification with iodine will provide important benefits to the New Zealand population. This benefit compares well with a small ongoing cost of fortification of around three cents per person each year
- The Centre for Health Economics Research and Evaluation (CHERE) assessed this Proposal in terms of cost-effectiveness ratios. 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.
- It 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 New Zealand.

20. Implementation and Review

20.1 Transitional Period

Upon approval by the FSANZ Board of the proposed draft variations to the Code, as presented at Final Assessment, the Ministerial Council will be notified of that decision. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code are expected to come into effect 18 months from gazettal. This 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 also allows alignment with the mandatory folic acid fortification requirements, therefore reducing the costs to industry for labelling changes, as noted in Brooke-Taylor & Co's report at Attachment 14.

At Draft Assessment, FSANZ proposed a one-year transitional. However, many industry submissions noted that a longer transitional period would be required to minimise the costs associated with making the necessary label changes. FSANZ commissioned an independent consultant to explore this issue. A two-year transitional period was recommended to help accommodate several future proposed label changes. The cost savings for industry in being able to simultaneously align the various future label changes is also noted in the Access Economic report at Attachment 8.

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. The fortification range of ± 20 mg iodine per kg of salt was established through consultation with salt manufacturers.

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.

21. Monitoring

Monitoring and review is a fundamental component of any mandatory fortification program. The Ministerial Policy Guideline states any agreement to require fortification should require that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.

Monitoring of the impact of mandatory iodine fortification is an important risk management consideration. As noted in the Editorial note to the draft variation of the Code at Attachment 1, this mandatory fortification requirement will be reviewed when sufficient monitoring data become available.

The responsibility for establishing and funding a monitoring system to assess the impact of a mandatory fortification on the population extends beyond FSANZ's responsibilities under the FSANZ Act. In October 2007, AHMAC agreed to fund the Australian Institute of Health and Welfare (AIHW) to coordinate monitoring activities for mandatory fortification standards in both Australia and New Zealand; folic acid and iodine standards were the latter to be approved. However, the funds allocated to the AIHW are for the coordination and reporting of relevant data, not the actual collection and analysis of the data. The monitoring frameworks for Australia and New Zealand for the mandatory fortification of folic acid and iodine developed by FRSC and agreed by the Australian Population Health Development Principal Committee (APHDPC) in August 2007 were accepted by AHMAC at its subsequent meeting in October 2007.

As the main objective of a mandatory iodine fortification program is to reduce the prevalence of iodine deficiency, measurement of iodine status is an essential component of any monitoring system that aims to assess the effectiveness of the fortification measure. It is also highly desirable to collect information on the health effects of improved iodine status, particularly for the vulnerable populations, namely children and pregnant and breastfeeding women, as well as on changes in the food supply and food consumption patterns. As for any monitoring system, the collection of baseline data prior to or just after the implementation of the fortification program and at some time in the future to assess changes in performance measures is essential.

The MoH will be responsible for tracking food composition changes via their national food composition program and for other monitoring activities relevant to the New Zealand population. FSANZ has agreed to collaborate with the AIHW and MoH on the following elements of the monitoring system:

- tracking changes in the food supply for fortified/unfortified foods in key food categories in consultation with the food industry;
- tracking labelling changes on fortified foods;
- tracking changes in food consumption patterns for different demographic groups in key food categories that are likely to be fortified;
- tracking discretionary salt intake, including uptake of iodised table salt; and
- researching changes in consumers' attitudes and behaviour towards fortified foods.

Estimated costings for undertaking the monitoring system for iodine have been proposed by the AIHW, MoH, and the NZFSA and are summarised below in Table 10.

Table 10: Proposed Costs for a New Zealand Iodine Monitoring Program

Agency	Funding per period	Funding per annum	Comments
AIHW	AU\$ 300 000	AU\$ 100 000	Three year period, funds cover the coordination of monitoring programs for iodine and folic acid in Australia and New Zealand, including reporting but not data collection costs
MoH*	\$NZ 1 600 000	\$NZ 320 000	Five year period
Includes:	\$NZ 750 000	\$NZ 150 000	Key monitoring activities, liaison, data collection and analysis
	\$NZ 200 000	\$NZ 40 000	Food composition activities
	\$NZ 400 000	\$NZ 80 000	Extra data collection for target populations
	\$NZ 100 000	\$NZ 20 000	First two years of five year period, industry compliance work, averaged over five years
	\$NZ 60 000	\$NZ 12 000	Last three years of five year period, industry compliance work, averaged over five years
	\$NZ 80 000	\$NZ 16 000	Consumer research
	\$NZ 10 000	\$NZ 2 000	Administrative costs

*Costs may be reduced if there are synergies with a folic acid monitoring system

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ABBREVIATIONS AND ACRONYMS

ABS	Australian Bureau of Statistics
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
APHDPC	Australian Population Health Development Principal Committee
CNS	New Zealand Children's Nutrition Survey
COAG	Council of Australian Governments
DALY	Disability adjusted life year
EAR	Estimated average requirement
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia New Zealand
GDP	Gross domestic product
ICCIDD	International Council for the Control of Iodine Deficiency Disorders
IDD	Iodine deficiency disorder
Ministerial Council	Australia and New Zealand Food Regulation Ministerial Council
MUIC	Median urinary iodine concentration
NHMRC	National Health and Medical Research Council
NNS	National nutrition survey
NOAEL	No observed adverse effect level
NRV	Nutrient reference value
NZFSA	New Zealand Food Safety Authority
MoH	New Zealand Ministry of Health
RDI	Recommended dietary intake
SDAC	Standards Development Advisory Committee
UL	Upper level of intake
UNICEF	United Nations Children's Fund
WHO	World Health Organization
WTO	World Trade Organization
μg	micrograms (1000 th of a milligram)
mg	milligrams (1000 th of a gram)
g	grams

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

Standards or variations to standards are considered to be legislative instruments for the purposes of the Legislative Instruments Act (2003) and are not subject to disallowance or sunseting.

To commence: 27 September 2009

[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 replacement of non-iodised salt with iodised salt in bread (New Zealand only) and the mandatory addition of thiamin and folic acid to wheat flour for making bread (Australia only) in Standard 2.1.1, the addition of vitamin D to table edible oil spreads and margarine in Standard 2.4.2, the addition of vitamins to formulated caffeinated beverages in Standard 2.6.4, the addition of vitamins and minerals to 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 (New Zealand only).

[2.2] *inserting after clause 4 –*

5 Mandatory addition of iodised salt to bread (New Zealand only)

- (1) Subclause 1(2) of Standard 1.1.1 does not apply to this clause.
- (2) Subclause (3) does not apply to bread produced in, or imported into Australia.
- (3) Where salt is added to bread it must be iodised salt.
- (4) Subclause (3) does not apply to bread which is represented as organic.

Editorial note:

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

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

Standard 2.10.2 sets out the compositional requirements for iodised salt.

Policy Guideline - Fortification²⁹ of Food with Vitamins and Minerals

This Policy Guideline provides guidance on development of permissions for the addition of vitamins and minerals to food.

The Policy Guideline does not apply to special purpose foods the formulation and presentation of which are governed by specific standards in Part 2.9 of the Australia New Zealand Food Standards Code (the Food Standards Code).

The policy should only apply to new applications and proposals. There is no intention to review the current permissions.

The policy does not apply to products that should be or are regulated as therapeutic goods. This should not lead to a situation where generally recognised foods, through fortification, become like or are taken to be therapeutic goods.

The policy assumes the continuation of a requirement for an explicit permission for the addition of a particular vitamin or mineral to particular categories of foods to be included within the Food Standards Code. Currently the majority of permissions are contained in Standard 1.3.2 – Vitamins and Minerals.

Regard should be had to the policy in development of regulatory measures applying to the mixing of foods where one, or both of the foods may be fortified.

The policy for regulation of health and nutrition claims on fortified food is covered by the Policy Guideline on Nutrition, Health and Related Claims. Claims should be permitted on fortified foods, providing that all conditions for the claim are met in accordance with the relevant Standard.

‘High Order’ Policy Principles

The Food Standards Australia New Zealand Act 1991 (the Act) establishes a number of objectives for FSANZ in developing or reviewing of food standards.

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
 - (a) the protection of public health and safety
 - (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
 - (c) the prevention of misleading or deceptive conduct.

2. In developing or reviewing food regulatory measures and variations of food regulatory measures the Authority must also have regard to the following:

²⁹ Within the context of this policy Fortification is to be taken to mean all additions of vitamins and minerals to food including for reasons of equivalence or restoration.

- (a) the need for standards to be based on risk analysis using the best available scientific evidence;
- (b) the promotion of consistency between domestic and international food standards;
- (c) the desirability of an efficient and internationally competitive food industry;
- (d) the promotion of fair trading in food; and
- (e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

These objectives apply to the development of standards regulating the addition of vitamins and minerals to food.

A number of other policies are also relevant to the development of food standards including the Council Of Australian Governments document 'Principles and Guidelines for national Standard Setting and Regulatory Action by Australia and New Zealand Food Regulatory Ministerial Council and Standard Setting Bodies(1995, amended 1997)(Australia only), New Zealand Code of Good Regulatory Practice (November 1997), the Agreement between the Government of Australia and the Government of New Zealand concerning a Joint Food Standards System and relevant World Trade Organisation agreements.

Specific Order Policy Principles - Mandatory Fortification

The mandatory addition of vitamins and minerals to food should:

1. Be required only in response to demonstrated significant population health need taking into account both the severity and the prevalence of the health problem to be addressed.
2. Be required only if it is assessed as the most effective public health strategy to address the health problem.
3. Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
4. Ensure that the added vitamins and minerals are present in the food at levels that will not result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.

Ensure that the mandatory fortification delivers effective amounts of added vitamins and minerals with the specific effect to the target population to meet the health objective.

Additional Policy Guidance - Mandatory Fortification

The specified health objective of any mandatory fortification must be clearly articulated prior to any consideration of amendments to the Food Standards Code to require such mandatory fortification.

The Australian Health Ministers Advisory Council, or with respect to a specific New Zealand health issue, an appropriate alternative body, be asked to provide advice to the Australia and New Zealand Food Regulation Ministerial Council with respect to Specific Order Policy Principles 1 and 2, prior to requesting that Food Standards Australia New Zealand raise a proposal to consider mandatory fortification.

The assessment of public health strategies to address the stated health problem must be comprehensive and include an assessment of alternative strategies, such as voluntary fortification and education programs.

Consideration should be given, on a case by case basis, to a requirement to label foods that have been mandatorily fortified by including the information in the Nutrition Information Panel of the food label.

An agreement to require mandatory fortification also requires that it be monitored and formally reviewed to assess the effectiveness of, and continuing need for, the mandating of fortification.

Specific order policy principles – Voluntary fortification

- The voluntary addition of vitamins and minerals to food should be permitted only:

Where there is a need for increasing the intake of a vitamin or mineral in one or more population groups demonstrated by actual clinical or subclinical evidence of deficiency or by data indicating low levels of intake.

or

Where data indicates that deficiencies in the intake of a vitamin or mineral in one or more population groups are likely to develop because of changes taking place in food habits.

or

Where there is generally accepted scientific evidence that an increase in the intake of a vitamin and/or mineral can deliver a health benefit.

or

To enable the nutritional profile of foods to be maintained at pre-processing levels as far as possible after processing (through modified restoration³⁰).

or

- To enable the nutritional profile of specific substitute foods to be aligned with the primary food (through nutritional equivalence).

- The permitted fortification has the potential to address the deficit or deliver the benefit to a population group that consumes the fortified food according to its reasonable intended use.
- Permission to fortify should not promote consumption patterns inconsistent with the nutrition policies and guidelines of Australia and New Zealand.
- Permission to fortify should not promote increased consumption of foods high in salt, sugar or fat.
- Fortification will not be permitted in alcoholic beverages.

³⁰ The principle of Modified Restoration as derived from The FSANZ document *Regulatory principles for the addition of vitamins and minerals to foods*. (Canberra, 2002) is as follows:

Vitamins and minerals may be added, subject to no identified risks to public health and safety, at moderate levels (generally 10-25% Recommended Dietary Intake (RDI) per reference quantity) to some foods providing that the vitamin or mineral is present in the nutrient profile, prior to processing, for a marker food in the food group to which the basic food belongs. The vitamin or mineral must be naturally present at a level which would contribute at least 5% of the RDI in a reference quantity of the food. This regulatory principle is based on the restoration or higher fortification of the vitamin or mineral to at least pre-processed levels in order to improve the nutritional content of some commonly consumed basic foods.

- Permissions to fortify should ensure that the added vitamins and minerals are present in the food at levels which will not have the potential to result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.

The fortification of a food, and the amounts of fortificant in the food, should not mislead the consumer as to the nutritional quality of the fortified food.

Additional Policy Guidance - Voluntary Fortification

Labelling – There should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods. An added vitamin or mineral is required to be listed in the Nutrition Information Panel only if a claim is made about it and the vitamin or mineral is present at a level for which a claim would not be misleading. An added vitamin or mineral must be listed in the ingredient list under current labelling requirements.

Monitoring/Review - A permission to voluntary fortify should require that it be monitored and formally reviewed in terms of adoption by industry and the impact on the general intake of the vitamin/mineral.

International Experience with Iodine Fortification Programs

1. Introduction

Universal salt iodisation, or USI³¹, is the recommended strategy for the control of global iodine deficiency (WHO and UNICEF, 2004). USI, as defined, is rarely achieved and most countries practice a modified version of USI, where either all household salt is iodised and/or particular manufactured foods use iodised salt. Iodisation may be mandatory or voluntary. Many developed countries such as the United States, Canada, Switzerland, Belgium, the Netherlands, Denmark and Germany have introduced legislation allowing and in some cases mandating, the iodisation of household salt and/or use of iodised salt in some processed foods (de Benoist, 2004). The history and practice of iodisation policy and legislation in some countries with economies similar to Australia is outlined below.

2. Background

One third of the world's populations still live in areas with a risk of iodine deficiency (de Benoist, 2004). Since the 1990s, the World Health Organisation (WHO) and UNICEF iodine supplementation programs have successfully eliminated or reduced the risk of iodine deficiency disorders in many developing countries (de Benoist, 2004). Mandatory iodisation of household salt is the most common strategy for iodine fortification in these countries. 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 and Ralph, 1987; Mattes and Donnelly, 1991). The advantages of using salt as a vehicle for iodine fortification are:

- salt production is restricted to a few producers;
- salt iodisation technology is easy to implement;
- in most instances the addition of iodine to salt does not affect colour, odour or taste when added to the food;
- the quality of iodised salt can be monitored at production, household and retail levels; and
- salt iodisation is cost effective (Venkatesh Mannar and Dunn, 2006).

There are other strategies used worldwide to combat iodine deficiency. Iodine oil, taken orally or intravenously, is useful in the short term, where particular populations are severely iodine deficient and do not have access to iodised salt (de Benoist, 2004). However it is expensive and labour intensive to administer. Iodisation of the water supply has been used successfully in iodine deficient regional populations in China, (DeLong, 2002) Malaysia, (West, 2005) and Thailand (Delange *et al.*, 2000a). Iodine has also been used to fortify food. It can be added directly, as in margarine in the Philippines, (Capanzana *et al.*, 2007), or to noodles, bananas and eggs in Thailand (Delange *et al.*, 2000a).

More commonly, iodised salt is substituted for non-iodised salt during food processing. Bread is a popular choice as a vehicle for iodised salt in European countries because it is a staple food with a fairly small variability in salt content.

³¹ Universal salt iodisation (USI) – the iodisation of all salt used for human and animal consumption.

Bread is manufactured using iodised salt in Tasmania, Austria, Belgium, Bulgaria, Denmark, Germany, Italy, Netherlands, and Switzerland (Arbeitskreis Jodmangel, 2006). Several other processed foods have successfully used iodised salt, for example sausages and pickles in Germany (Remer and Neubert, 1998) and cheese and meat products in Switzerland (Als *et al.*, 1995a; UNICEF, 2006).

Milk and dairy foods are a major source of iodine in many developed countries (Great Britain, Denmark, USA, Belgium, Australia, New Zealand) (Eastman, 1999; Delange *et al.*, 2000b; Rasmussen *et al.*, 2002; Merck, 2005; USFDA, 2006). The iodine in milk is often due to iodophors used in the dairy industry or from iodised animal feeds (Dunn, 1998; Eastman 1999; Kreiner, 2006). In many European countries where animal feed is iodised, animal products e.g. milk, eggs and meat provide a considerable amount of dietary iodine (Lee *et al.*, 1994; Arbeitskreis Jodmangel 2006). These sources of iodine are hard to monitor and regulate as there are seasonal differences in the use of animal feed (Pennington, 1990; Pearce *et al.*, 2004) and technological changes occur, for example iodophors are being replaced as equipment sanitisers. The iodine content of milk and dairy products can vary as much as 10 fold (Dunn, 1996).

3. History of iodisation and iodine deficiency disorders

Iodine deficiency disorders (IDD) have been recognised in Europe since the 19th Century. IDD/goitre and cretinism were endemic in the mountainous and remote regions of Europe. Iodising salt was first suggested to treat IDD over 150 years ago by Boussingault and the technology was further developed in the USA in the early 20th Century (WHO and UNICEF, 2004). Switzerland was the first European nation to establish an iodised salt program in 1922 (WHO and UNICEF, 2004). The USA was also a pioneer, first using iodised salt in 1920 (WHO and UNICEF, 2004). Poland introduced iodised salt in the 1930s as did several other European countries; France, Romania, Slovenia and Yugoslavia in the post world war II period (ICCIDD, 2002a). Many of these early programs were not sustainable due to war, political upheaval, and/or changes in trade or industry practices (Gerasimov, 2002; WHO and UNICEF, 2004).

It was thought IDD was under control in mid-20th Century Europe, and as a consequence many health authorities relaxed the constant surveillance and vigilance necessary to maintain adequate iodine status. Iodine deficiency is again a problem in many parts of Europe, which now has the lowest household access to iodised salt of all the WHO regions³² (WHO and UNICEF, 2004). In response to an increasing focus on iodine deficiency by WHO, several European countries have instigated or re-instigated iodine fortification legislation over the last 10 to 15 years. Of the 32 western and central European countries reviewed by the ICCIDD in 2002 (Delange *et al.*, 2000b; ICCIDD, 2002a), 14 had iodine sufficiency (MUIC > 100 µg/L), 12 were iodine deficient (MUIC < 100 µg/L) and 5 had inadequate data available for an assessment. Table 1 summarises details of the iodisation policies of many Western and Central European countries, the United States of America and Canada.

³² Who regions are Africa, America, SE Asia, East Mediterranean, Europe and West Pacific

Table 1: Iodine Fortification Policies of Western and Central European Countries, America and Canada

Country	Y/N	Year	Concentration (ppm)	Salt Iodisation Policy				Monitoring	Iodine nutritional status
				Mandatory/ Voluntary	Household	Food industry	Animal feed		
<i>Austria</i>	yes	1963/90	20	mandatory	yes 95%	no	yes	regular	sufficient
<i>Bosnia</i>	yes	2001		mandatory	yes 100%	yes	yes	regular	sufficient
<i>Bulgaria</i>	yes	1994		mandatory	yes 100%	yes	no	regular	sufficient
<i>Canada</i>	yes	1949	76	mandatory	yes 100%	no	no?	none	sufficient
<i>Croatia</i>	yes	1996	25	mandatory	yes 90%	yes	yes	regular	sufficient
<i>Czech</i>	yes	1950	20-34	mandatory	yes 100%	yes	yes	regular	sufficient
<i>Denmark</i>	yes	2000	13	mandatory	yes >90%	yes, baking	no	yes	sufficient, regional variation
<i>France</i>	yes	1952	10-15	voluntary	yes 55%	no	yes	no	deficient
<i>Germany</i>	yes	1991	20	voluntary	yes 84%	yes 30-35%	yes	yes	some deficient areas
<i>Italy</i>	yes	2005	30	mandatory	yes 3%	no	no	planned	deficient
<i>Macedonia</i>	yes	1999	20-30	mandatory	yes 100%	yes	yes	regular	sufficient
<i>Netherlands</i>	yes	1968	50	voluntary	yes 65%	bread some crackers	no	none	sufficient
<i>Poland</i>	yes	1935/97	20-40	mandatory	yes 90%	recommended	planned	planned	some deficient areas
<i>Romania</i>	yes	1956	15-20	voluntary to be mandatory	yes, only 25%	yes	yes	planned	deficient
<i>Slovak Rep</i>	yes	1966	19	mandatory	yes 85%	yes	no	regular	sufficient
<i>Slovenia</i>	yes	1953	20-30	voluntary	yes ?	yes	no	regular	deficient
<i>Switzerland</i>	yes	1922	20	voluntary	yes 94%	bread, cheese	yes	regular	sufficient
<i>Turkey</i>	yes	1999	40	mandatory, not enforced	yes 20-64%	yes	no	planned	deficient
<i>Yugoslavia</i>	yes	1951	12-18	mandatory	yes 73%	yes	yes	planned	regional variation
<i>USA</i>	no	1920	76	voluntary	yes 70%	some	yes	none	sufficient

(ICCIDD, 2002a; WHO and UNICEF, 2004; Arbeitskreis Jodmangel, 2006)

4. International Experience with Iodisation

4.1 Countries with Voluntary Iodisation

Of the 20 Western and Central European and American countries, listed in Table 1 that have iodine legislation, eight have *voluntary* iodisation of salt. Four of these countries have populations with a mild iodine deficiency, including:

- Romania, which has voluntary fortification of salt for household and industrial use. Due to poor uptake, iodised salt is only 25% of the market, there are plans to make iodisation compulsory (ICCIDD, 2002a).
- In Italy, until mandatory iodisation was introduced in 2005, iodised salt was available, but its use was limited to about 3% of sales (ICCIDD, 2003c).
- Slovenia, where iodisation is universal but voluntary. Data from the last 16 years shows that 79% of 16 year olds have goitre (ICCIDD, 2003e).
- France continues to have a mild iodine deficiency even though iodised salt is used in the home and for animals and market coverage is about 55% (ICCIDD, 2002a).

Iodine deficiency also persists in countries such as Greece, Ireland, Hungary and Spain where there is no specific iodine legislation but *voluntary* iodisation is allowed (ICCIDD, 2006). In Ireland, table salt can be iodised but uptake is only 3.3%. There is evidence that sections of the population are iodine deficient (Narwoor *et al.*, 2005).

4.2 Countries with Mandatory Iodisation

In most countries where iodisation is mandatory, iodine sufficiency has been achieved. Turkey and Belgium are the exceptions. Turkey is unable to adequately enforce their policy of mandatory universal iodisation and iodised salt has only achieved 20-30% of the market share. Iodisation legislation exists in Belgium but has never been implemented. Both countries remain iodine deficient (Delange *et al.*, 2000b).

Some of the central European countries with traditionally high levels of endemic cretinism and goitre, for example Bosnia, Bulgaria, Croatia, Czech Republic and Yugoslavia, have been more aggressive in legislating for universal salt iodisation (ICCIDD, 2002a; Laurberg *et al.*, 2003; WHO and UNICEF, 2004). Other countries with mild to moderate iodine deficiency chose iodisation of household salt only, or selected manufactured foods, for example, Denmark with bakery goods, (Laurberg *et al.*, 2003) and Netherlands with bread (Brussaard *et al.*, 1997). These programs have successfully improved iodine deficiency.

4.3 Switzerland

Switzerland is a prime example of a successful iodisation and monitoring program. Historically the Swiss had high levels of IDD including cretinism and goitre. The country implemented legislation in 1922 to iodise salt for human consumption (WHO and UNICEF, 2004). The potassium iodide content of salt has been gradually increased over the last four decades; from 7.5 mg iodine/kg in 1962 to 15 mg iodine/kg in 1980 and to 20 mg/kg in 1998 (Zimmermann *et al.*, 2005).

In the 1980s, IDD seemed to be resolved when a sufficient UIC (urinary iodine concentration) of 141 µg/day was found in 112 adults from all over Switzerland (Burgi *et al.*, 1990). However, in the 1990s some studies suggested that iodine status was marginally deficient among schoolchildren and pregnant women, (Als *et al.*, 1995b) and moderately deficient (70-90 µg/L) in 266 adults (Als *et al.*, 2000). Several reasons have been suggested for the decline in iodine status during the 1990s, including:

- the population reducing their use of household salt in response to health messages from the government to reduce sodium intake;
- more imported foods being consumed and an increasing number containing non-iodised salt (Zimmermann *et al.*, 2005);
- food habits changing: an increasing proportion of the dietary sodium is coming from manufactured foods and many of these foods are iodised at low levels, (5-10 mg/kg) or not at all (Als *et al.*, 1995a); and
- the manufacturing industry iodising a smaller range of foods (from 80% to less than 70%) (Zimmermann *et al.*, 2005), to facilitate trade (Als *et al.*, 1995a).

In Switzerland the production and trade of iodised and uniodised salt is controlled by a state monopoly (Als *et al.*, 2004). Iodised salt now has a market share of 94% of household salt and 67% of salt used in commercial food production (ICCIDD, 2002a).

There are several reasons for the ongoing sustainability of the Swiss iodisation program. These include:

- state control of salt manufacturing since 1909;
- constant surveillance of iodine levels at production sites;
- government keeping the cost of iodised salt the same as non-iodised salt; and
- monitoring the iodine status of the population every five years by a commission which can increase (or decrease) iodisation levels when necessary .

The Swiss program may be threatened by international trade regulations which could block monopolies and prevent artificial low pricing of iodised salt (Zimmermann *et al.*, 2005).

4.4 United States of America

Endemic goitre was common in Midwest and Northwest America until the 1920s (Hollowell *et al.*, 1998; Dunn, 1998). In 1923, after David Marine demonstrated that iodine treatment could reduce and prevent goitre, health authorities campaigned for the general use of iodised salt as a prophylactic. By the 1930s most table salt was iodised although iodisation remained voluntary (Dunn, 1998). Today, iodised salt constitutes approximately 50-60% of the market and salt is iodised at 100 ppm (ICCIDD, 2002b).

Iodine, in various forms is also used incidentally, (rather than as a prophylactic) as a bread conditioner, in food colouring, as a sanitiser for milking equipment in the dairy industry and in animal feed (Dunn, 1998). This often leads to high but variable amounts of iodine in the food supply (Pennington, 1990; Dunn, 1998). A study examining the iodine content of milk and bread in the Boston area (Pearce *et al.*, 2004) found that the iodine content of the different brands of bread varied from over 300 µg per slice to as low as 2 µg per slice. Reports show variations in the iodine concentration in milk ranging from 16-34 µg /100 ml (Pennington, 1990).

The US population also obtains iodine from vitamin supplements, health foods such as kelp, skin antiseptics and certain medications (Hollowell *et al.*, 1998). Most of these sources are unrecognised and none are regulated (Dunn, 1998).

In the United States urinary iodine levels are monitored regularly, as part of the NHANES Survey and dietary iodine intakes as part of the Total Diet Study (USFDA, 2006). Further monitoring is essential, not least because many sources of iodine are incidental and iodine intake can vary regionally and/or seasonally.

In the late 1970s the Total Diet Study reported up to five times the Recommended Daily Allowance in several foods, but primarily in dairy foods (Taylor, 1981). This resulted in the dairy industry reducing their use of iodophors (Egan and Bailey, 2002).

Between the 1971-74 NHANES I survey and the 1988-94 NHANES III survey urinary iodine levels have decreased considerably (Hollowell *et al.*, 1998). This decrease may be due to:

- the reduction in the use of iodophors in the dairy industry;
- the replacement of iodine by bromine salts as the dough conditioner in commercial bread production (Hollowell *et al.*, 1998); and
- voluntary salt reduction, secondary to concerns about the sodium intake and hypertension (Hollowell *et al.*, 1998).

More recent results from the NHANES 2000 report show no significant change from the 1988-94 NHANES III survey. However the survey showed an increased prevalence of mild iodine deficiency in women of child-bearing age. As incidental iodine use decreases or the population reduces its use of discretionary salt in response to health messages, the possibility of further decreases in iodine status increases (Dunn, 1998).

4.5 Germany

Germany has a history of IDD and in the 1970s goitre prevalence was recorded as 30-60% of the population (ICCIDD, 2003a). In 1996 a nationwide survey of 5,932 people from 32 regions showed a 30% deficit in recommended iodine intake (Gartner, 1999). However, studies after 2000 confirm a marked improvement in the iodine status of the German population (ICCIDD 2003a). (Manz *et al.*, 2002), (Remer *et al.*, 2006). Although mean iodine status appears sufficient, some researchers believe that iodine deficiency continues to exist in particular regions of Germany (Kreiner, 2006).

Iodisation of salt and/or iodine fortification has a complex history in Germany.

East Germany had compulsory iodisation of table salt at 20 ppm and of animal feed at 10 ppm until unification in 1990. Iodisation then became voluntary in both East and West Germany.

In *West* Germany, prior to unification, restrictive regulations on food additives had limited the use of iodised salt in many manufactured foods. The iodisation salt level for household use was low. However in 1981 the salt iodisation level increased from 5 to 20 ppm but this only marginally improved iodine status for West Germans (Remer and Neubert 1998).

In 1989, it became legal in West Germany to add iodised salt to industrially processed foods and canteen meals.

After unification, many more restrictive regulations on food additives were removed. In 1991, when the use of iodised salt in the pickling of meat and sausage was mandated, iodine status improved significantly.

Iodine status improved again after 1993 when new legislation made labelling of iodised manufactured foods unnecessary (Remer and Neubert 1998).

Iodised salt for household use now has 84% (ICCIDD, 2002a) of market share but only 30-35% of salt used in the food industry is iodised (Remer *et al.*, 2006; Kreiner, 2006). The use of iodised salt in manufactured foods has decreased since 1996 (ICCIDD 2003a).

In Germany an important incidental source of iodine is from animal feed which was iodised in 1995 to improve animal health. Iodisation of animal feeds wasn't fully adopted until 2000. The improved iodine status of the German population after 2000 may be due in part to the more widespread use of iodised animal feeds. A longitudinal study of 358 children aged 6-12 years reported that the contribution to iodine status from milk and eggs almost doubled from the period 2000 to 2003 compared with 1996 to 1999 (Remer *et al.*, 2006). This demonstrates the significant 'carry over' effect on iodine status of humans consuming products from animals fed on iodised feed.

4.6 Netherlands

While severe iodine deficiency, for example cretinism, is not prevalent in the Netherlands, goitre is common in the south eastern regions. Iodine supplements have been used since 1935 (Wiersinga *et al.*, 2001). Iodised salt for baking bread or 'bread salt' has also been used as a prophylactic since 1942 (Brussaard *et al.*, 1997). Legislation for the mandatory iodisation of salt used in bread was first enacted in the Netherlands in 1968. A high court case in 1982 found that mandatory iodisation of bread salt was unconstitutional and since then bakeries have been able to choose to use iodised or non iodised salt in their bread (Grit, 2006).

During the time that iodisation was mandatory, the majority of bakers believed that iodine fortification of bread was beneficial to their industry. Due to a widespread education campaign iodisation was also well accepted by the population and iodised bread was considered a healthy basic food. Once the habit of iodine fortification was established in the baking industry most bakers chose to continue using iodised salt in their bread although it is no longer compulsory (Grit, 2006).

Since mandatory fortification was repealed in 1982, several studies from 1987-92 reported inadequate iodine status, especially in women. Surveys conducted in the 1980s found a high prevalence of goitre (35% in women and 18% in men) (ICCIDD, 2003d). In a move to improve the iodine status of the population, the fortification level of bakers' salt was raised in 1999 to 75-85 mg iodine /kg salt. Permission was also given to use bread salt in bread replacers and some meat products. This was in response to a decline in bread consumption in favour of bread replacers like crackers, rusks and breakfast cereals. The use of iodised household salt has also declined since mandatory iodisation was repealed (Grit, 2006).

Several studies since 2000 demonstrate that these measures have been effective in improving the iodine status of the population (Wiersinga *et al.*, 2001).

The Netherlands is now considered iodine replete (ICCIDD, 2003d).

It could be said that voluntary iodisation has been effective in the Netherlands. However, this may be because the Netherlands once had *mandatory* fortification which meant that iodisation was already well established and accepted by industry and consumers.

4.7 Denmark

In Denmark, fortification of food with nutrients is only allowed if:

- the population is deficient in that nutrient;
- the fortification will lead to an effective increase of the nutrient; and
- the effect on the population is monitored (ICCIDD, 2003b).

In 1982 it became illegal to sell iodised salt in Denmark after a working group found iodine enrichment 'nutritionally irrelevant' (Rasmussen *et al.*, 1996).

Several studies had demonstrated an inadequate iodine status and a high incidence and prevalence of iodine related deficiencies in the Danish population (Rasmussen *et al.*, 1996).

In 1994, the Danish Veterinary and Food Administration responded by establishing a working group to evaluate the need for an iodine fortification program in Denmark. The Working Group concluded that iodised salt in bread gives similar coverage as using iodised salt in all manufactured foods. They concluded the majority of the Danish population was iodine deficient and that the benefits of iodine fortification far outweighed the risks. Careful monitoring of iodine levels in foods and the iodine status of the population were integral parts of the implementation of mandatory iodine fortification strategy (Rasmussen *et al.*, 1996).

When salt iodisation was introduced in 1998, it was voluntary. An agreement was made with the salt and food industry with the expectation that iodised salt would cover at least 80% of the market within 2 years. After 18 months, iodised salt covered around 50% of the household market but none for industry. The voluntary approach was found to be ineffective (Laurberg *et al.*, 2003). Consequently, in 2000, salt iodisation was made mandatory for household use and for commercial bread and cake production (Pedersen *et al.*, 2006).

Monitoring was mandatory and the population was monitored carefully for iodine intake and the occurrence of thyroid disorders. Monitoring of the population occurred on two levels:

- Regular monitoring of iodine levels in salt, bread and cakes at retail outlets and sales of iodised salt.
- A long-term study of a cohort of 4649 subjects living in two areas of Denmark with different ground water iodine levels (Aalborg and Copenhagen) was launched to assess the effect of the fortification program on the population (Laurberg *et al.*, 2006).

The legislation has been well supported by industry with 97% of rye bread and 905 other brands of bread using iodised salt (Laurberg *et al.*, 2006). A study assessing the increase in iodine intake after fortification (Rasmussen *et al.*, 2007) found a desirable increase in iodine intake.

4.8 *Canada*

During the first half of the 20th Century, iodine deficiency was common in Canada. Fortification of salt and bread with iodine was voluntary and public health campaigns advised consumers to choose fortified products or take supplements. Unfortunately, this strategy proved ineffective. Iodine deficiency remained a problem because most people still chose to eat the unfortified alternatives (Bowley, 2003).

Mandatory iodisation of table salt was introduced in Canada in 1949. Reports indicate that in spite of this mandatory approach, it took until the 1970s to gain compliance on a broad basis (Bowley, 2003). Mandatory fortification of table salt exists in the whole of Canada. The coverage of iodised table salt in Canada has reached almost 100% (ICCIDD, 2001).

Milk has also been a significant source of iodine for Canadians. From 1987 data, the iodine content of milk ranged from 122 µg/L in Newfoundland to 517 µg/L in Manitoba. (ICCIDD, 2001). This is due to iodophors used in the dairy industry and also to use of animal feeds with added iodine. The use of iodine in animal feed is similar to that in the US and Europe. As in the USA and Europe the iodine levels in milk are higher in winter months because animals are more reliant on being hand feeding, (with iodised animal feed) and less on grazing on natural pasture grasses.

5. **Conclusion**

International experiences with iodine fortification has shown that mandatory fortification is a more reliable and stable method to ensure that the population achieves a safe, predictable and adequate iodine intake. This review of international experience with iodine fortification has shown:

- Of the 20 European countries (also including the USA and Canada) with effective iodine legislation, those with mandatory fortification almost all had achieved 'sufficient' iodine status.
- Of the countries (listed in table 1) with voluntary fortification legislation, only half have achieved an adequate iodine status.
- Many countries with voluntary fortification, for example Switzerland and the USA, which were originally successful in improving iodine status, now find changes in food habits, manufacturing practices and imports/exports, have resulted in decreases in the amount of iodine in the food supply.
- Many countries have found voluntary fortification with or without a public education campaign unsustainable or ineffective in the long term and have introduced mandatory fortification. Denmark, which is similar to Australia in many ways, is a case in point.
- In industrialised countries people obtain more than 75% of their salt and therefore most of their iodine, from processed foods. However, in Switzerland and Germany industry appears to be decreasing the fortification level of processed foods and or the range of foods fortified with iodine.

- Mandatory fortification of bread with iodised salt has been successful in addressing iodine deficiency in populations identified as deficient.
- Mandatory fortification can deliver a predictable and appropriate level of dietary iodine. Dietary iodine from sources such as iodophor use and animal feeds frequently result in erratic, unpredictable and unsustainable amounts of iodine in the food supply.

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Iodine Status in New Zealand: Implications for Health and Performance

1. Assessment of Iodine Status

Assessing iodine intake using dietary assessment methods is recognised as difficult as these are potentially confounded by: 1) the potentially wide variation of iodine contents in similar foods from different regions, and 2) the potential presence of iodine uptake inhibitors often referred to as goitrogens. Population iodine status is more accurately reflected by urinary iodine concentration (ICCIDD *et al.*, 2001). Thyroid volume, as assessed by neck palpation, or preferably ultrasonography, provides a measure of long-term iodine status (Gibson, 2005). Other less direct indicators of iodine status include blood concentrations of thyroid-stimulating hormone (TSH), thyroglobulin, and the thyroid hormones: thyroxine and triiodothyronine (thyronine)

1.1 Enlarged Thyroids and Goitre

Chronically low iodine intakes lead to adaptive responses by the thyroid, including enlargement of the gland (ICCIDD *et al.*, 2001). Thyroid volume is therefore a long-term measure of iodine status. Increased thyroid volume is known as goitre once volume in children exceeds the 97th percentile of age or body surface area specific World Health Organization (WHO) reference values (Gibson, 2005). Raising iodine intake leads to a reduction of goitre size in children, and has historically been used to assess the success of interventions to address iodine deficiency (ICCIDD *et al.*, 2001). The goitres of adults are not similarly reduced by addressing iodine deficiency; therefore, iodine status in populations has historically been assessed by measuring goitre in children.

A number of systems exist to grade goitre assessed by palpitation. One developed by the WHO, International Council for the Control of Iodine Deficiency Disorders (ICCIDD) and UNICEF assigns a grade 0, 1 or 2 to indicate not visible or palpable, palpable but not visible, or visible enlargement respectively (Gibson, 2005).

1.2 Urinary Iodine Concentration

Urinary iodine concentration (UIC) is the preferred measure of iodine status of the ICCIDD and WHO (ICCIDD *et al.*, 2001). It closely reflects iodine intake at lower levels and is a sensitive indicator of recent changes in iodine intake (Gibson, 2005).

1.2.1 World Health Organization Classification of Population Iodine Status

The WHO and ICCIDD have developed a system of classifying populations into categories of iodine status based on their median UIC (MUIC) as shown in Table 1. The median is used in because the distribution of UIC is not normally distributed (ICCIDD, 2001).

The WHO and the ICCIDD state that, in school-aged children, a MUIC of less than 100 µg/L, and more than 20% of the population having a UIC of less than 50 µg/L, together indicate *mild* iodine deficiency; a median concentration of less than 50 µg/L is indicative of *moderate* iodine deficiency (ICCIDD *et al.*, 2001).

In children less than two years old and in lactating women a MUIC below 100 µg/L indicates an *insufficient* iodine intake, whereas in pregnant women, who have higher iodine requirements than children or other adults, an MUIC below 150 µg/L indicates an *insufficient* iodine intake (ICCIDD, 2007). Table 1 provides further details on ICCIDD criteria for the assessment of population iodine status.

Table 1: ICCIDD Criteria for Assessing Iodine Status, Based on Median Urinary Iodine Concentrations in School-Aged Children

Median urinary iodine (µg/L)	Iodine intake	Iodine status
< 20	Insufficient	Severe iodine deficiency
20 – 49	Insufficient	Moderate iodine deficiency
50 – 99	Insufficient	Mild iodine deficiency
100 – 199	Adequate	Optimal
200 – 299	More than adequate	Risk of iodine-induced hyperthyroidism in susceptible groups
>300	Excessive	Risk of adverse health consequences

The latest guidelines from the ICCIDD state that in children less than two years old and in lactating 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 MUIC below 150 µg/L indicates an *insufficient* iodine intake.

These categories of MUIC are not indicative of the iodine status of individuals and should only be used to assess populations. As an individual's urinary iodine concentrations reflect recent iodine intake they can have a high day-to-day variability. Therefore, spot samples cannot be used to diagnose the iodine status of an individual. Thomson *et al.* (1996) have shown that urine samples over a 24-hour period are necessary for diagnosis of iodine deficiency in an individual and for research purposes.

1.3 Neonatal Thyroid Stimulating Hormone

TSH in children and adults is relatively insensitive to mild and moderate iodine deficiency, but is appropriate for the diagnoses of congenital hypothyroidism in newborns (Gibson, 2005). The WHO recommends neonatal TSH be measured in heel-prick blood samples taken 72 hours after birth to avoid confounding by the initial surge of TSH (WHO, 1994).

1.4 Other Potential Markers of Iodine Status

Other indicators of iodine status include thyroglobulin and thyroid hormone i.e. thyroxine and triiodothyronine (thyronine), concentrations (ICCIDD *et al.*, 2001; Gibson, 2005). Of these blood markers, thyroglobulin appears to be the most specific indicator of recent iodine status; this new biomarker is still gaining acceptance amongst the research community (Gibson 2005). The blood concentrations of thyroxine and thyronine are also quite insensitive to milder forms of iodine deficiency.

1.5 Goitrogens

Inadequate intakes of iodine are not the only cause of thyroid dysfunction and goitre. Substances, collectively known as goitrogens, can inhibit the absorption and/or utilisation of iodine by the thyroid, or otherwise interfere with normal thyroid hormone synthesis (Sarne, 2004). These substances can occur as natural food components, in the form of pharmaceuticals, and as environmental contaminants.

In food they are found naturally in vegetables from the Brassicaceae family such as cabbage, in soybeans, cassava, and a range of plant foods specific to some geographic regions, most notably South America (Gibson, 2005, Sarne 2004). Drinking water has also been shown to contain goitrogenic substances in some instances; these have generally been bacterial by-products or inorganic material from sediment (Sarne 2004). High natural fluoride levels have been associated with impaired thyroid hormone production, and in the presence of iodine deficiency may exacerbate the impact of this deficiency (BEST, 2006).

A range of pharmaceutical agents also act as goitrogens (Sarne, 2004). However, goitrogenic substances have only been clearly identified as major contributors to underproduction of thyroid hormone in the absence of iodine deficiency in a small number of instances where consumption of these substances is unusually high (BEST, 2004; Delange and Hetzel, 2005; Sarne, 2004).

2. Evidence of Iodine Deficiency in New Zealand

Over the past decade several studies have assessed the iodine status of a geographically and demographically diverse range of New Zealanders. Information on the iodine status as reflected by the MUIC and thyroid volume have been published. All of these indicate the presence of mild-to-moderate iodine deficiency.

The 2002 Children's Nutrition Survey assessed the iodine status in a demographically and geographically representative sample of the population (Ministry of Health, 2003). The survey assessed the urinary iodine concentration of 1793 children aged 5-14 years from schools around the country. The key findings of the study were a MUIC of 66 µg/L with 28% of children having a urinary iodine concentration of less than 50 µg/L (males 25%; females 31%). Females were most likely to have urinary iodine concentration below 50 µg/L across ethnic groups with 33%, 29% and 24% of New Zealand European/Other, Maori and Pacific respectively falling below this cut-off. Applying the WHO/ICCIDD criteria this indicates mild-to-moderate iodine deficiency across genders and ethnicities in NZ children aged 4-14 years.

Iodine status in New Zealand children has also been assessed by measuring thyroid volume. Skeaff *et al* (2002) measured the thyroid volume of 300 children aged 8-10 years in Wellington and Dunedin. Comparison of the values to the 2001 WHO age/sex specific cut off values resulted in a goitre presence of 11.3%. The WHO values have recently been revised and new cut off values determined (Zimmerman *et al.*, 2004). Applying the new values to the data suggests the goitre rate is actually closer to 30%.

The only published work examining the iodine status in infants and toddlers reported a MUIC in 43 breast-fed infants of 44 µg/L (inter quartile range 23-82 µg/L) (Skeaff *et al.*, 2005).

In the same study, 51 formula-fed infants had a MUIC of 99 µg/L (inter quartile range 86-167). Over half the sample of breast-fed infants (51.2 %) had urinary iodine levels less than 50 µg/L, compared with 13.7% of formula-fed infants.

This is indicative of moderate iodine deficiency amongst breastfed infants. It also indicates low breast milk iodine concentrations and therefore poor iodine status in breast-feeding women. An earlier study reporting the results of 24-hour urine collections from 35 pregnant and 17 non-pregnant women in Dunedin indicated moderate iodine deficiency in this population (Thomson *et al.*, 2001).

The MUIC, measured at several time points throughout the study, ranged from 33-52 µg/L for pregnant women to 49-60 µg/L for non-pregnant women. Fifty-five per cent of all women had a urinary iodine concentration of less than 50 µg/L. A subsequent study in 170 pregnant women from throughout New Zealand reported an MUIC of 38 µg/L with 70% having a urinary iodine concentration below 50 µg/L, and 7% diagnosed with goitre (Pettigrew Porter *et al.*, 2006). These results are in stark contrast to the recommendation that MUIC in pregnant women should be above 150 µg/L (ICCIDD, 2007).

Although no iodine status data are available from nutrition surveys in New Zealand adults, two published studies examined iodine status in the general adult population. The first study reported the MUIC of 51 µg/L for male and 42 µg/L for female participants from both the Waikato and Otago (Thomson *et al.*, 1997). Fifty seven per cent of participants had urinary iodine concentration levels less than 50µg/L indicative of mild to moderate iodine deficiency. A second study by Thomson *et al.* (2001) reported a MUIC of 54 µg/L for 233 study participants from Otago, indicating mild iodine deficiency. The percentage of participants with urinary iodine concentrations less than 50 µg/L was not provided. Twenty-one subjects had thyroid volumes greater than the upper bound of normal as reported for healthy European subjects with sufficient iodine intake.

Table 4: Summary of Recent New Zealand Research and Surveys Assessing Iodine Status

Reference:	Group	n	MUIC (µg/L)	% < 50 µg/L	Iodine Status
Parnell <i>et al.</i> , 2003	Males 5-14 years	970	68	25	mild
	Females 5-14 years	823	62	31	mild
	All	1793	66	28	mild
Skeaff <i>et al.</i> , 2005	Breastfed Infants	43	44	51	moderate
	Formula Fed	51	99	14	mild
Thomson <i>et al.</i> , 2001	Pregnant women	35	33-52	55	insufficient
	Non-pregnant women	17	49-60		insufficient
Pettigrew Porter <i>et al.</i> , 2006	Pregnant women	170	38	70	insufficient
Thomson <i>et al.</i> , 1997	Adult Males	169	49	50	moderate
	Adult Females	164	44		moderate
Thomson <i>et al.</i> , 2001	Adult Males	114	54		mild
	Adult Females	119	52		mild

3. Health Risks of Iodine Deficiency

3.1 Adverse Effects of Iodine Deficiency

The spectrum of iodine deficiency disorders (IDD) is wide, varying according to the severity and duration of the deficiency and the life stage of the populations effected. The term IDD was first coined to provide a collective term to expand on goitre and cretinism; the latter being a form of severe mental retardation (Hetzel, 2000). It encompasses all presentations of the deficiency disease, including the effects of iodine deficiency on neuropsychological development. Table 5 provides WHO's description of the spectrum of effects of IDD focusing on the more obvious and severe forms throughout the life cycle.

Table 5: Iodine Deficiency Disorders throughout the Life Cycle

Foetus	Abortions Still births Congenital abnormalities Increased perinatal mortality Increased infant mortality Neurological cretinism: mental deficiency, deaf mutism, spastic diplegia, squint Myoedematous cretinism: dwarfism, mental deficiency Psychomotor defects
Neonate	Neonatal goitre Neonatal hypothyroidism
Child and Adolescent	Goitre Juvenile hypothyroidism Impaired mental function Retarded physical development
Adult	Goitre with its complications Hypothyroidism Impaired mental function Iodine induced hyperthyroidism

The signs of mild deficiency are not easily discerned in any age group. However, moderate iodine deficiency in both children and adults is associated with a negative effect on motor performances, motor skill, perceptual and neuromotor abilities and reduced intellectual quotients (IQ). IQ is a tool commonly used to measure mental performance. The average IQ is, by definition, 100 with a standard deviation of 15 points. Someone with an IQ of 80 or below is considered to be able to cope with the adult world (Megafoundation, 2005).

3.2 Importance of Iodine in Pregnancy and During Early Development

Iodine deficiency during pregnancy has often been described as the most common cause of intellectual impairment worldwide. While severe iodine deficiency during foetal development can lead to the extreme form of mental retardation known as Cretinism, mild and moderate deficiency may also lead to lesser impairments in mental development, hearing, motor control and reaction time (Delange, 2001). Recent research also indicates mild and moderate deficiency in children can impair their growth (Zimmerman *et al.* 2007).

The ICCIDD suggest that the most critical period of iodine nutrition is from the second trimester of pregnancy to the third year after birth (ICCIDD, 2001). Many of the effects of iodine deficiency shown in adults are usually the result of chronic iodine deficiency rather than of recent deficiency.

The adverse effects of iodine deficiency on the central nervous system can be irreversible, and are compounded by continuing deficiency during infancy (Zoeller and Rovet, 2004).

Iodine is required for the synthesis of thyroid hormones, which are in turn required for brain development. Major human brain development occurs during foetal growth and early years of life so that adequate iodine is important from conception until at least the third year of life (ICCIDD, 2001).

The foetal thyroid does not begin functioning until about the 24th week of gestation and until that time is reliant purely on the transfer of the thyroid hormones thyronine and thyroxine across the placenta. Even at term, 17.5% of neonates' thyroxine comes from the mother (Delange, 2000).

Brain development continues into early childhood, thus iodine nutrition remains a critical factor (Zoeller and Rovet, 2004). Before the introduction of weaning foods, the iodine intake of the infant depends on the iodine content of breast milk or formula. Levels of iodine in breast milk reflect the maternal diet (Dorea, 2002). Because of foetal reliance on maternal thyroid hormones, and the infant's reliance on breast milk, the dietary requirement for iodine intake are higher for pregnant and lactating women than for the rest of the population (Delange, 2004).

3.3.1 Neurological Consequences for Children of Mothers with Mild Iodine Deficiency during Pregnancy

The effect of mild iodine deficiency (MUIC 55-99 µg/L) on neurological development is a matter of current debate. A recent review concluded that there is evidence of delay in reaction time but no evidence of impaired mental development in infants of mothers that were mildly iodine deficient during pregnancy (Delange, 2001). However, a subsequently published study of Chinese children aged 7-13 months suggests that even mild prenatal iodine deficiency, as assessed by cord blood thyroid stimulating hormone concentrations, is associated with reduced performance in some tests of mental development (Choudhury and Gorman, 2003). This study suggested a dose-response relationship where small differences in the severity of iodine deficiency results in small changes in mental development in a linear fashion.

3.3.1 Neurological Consequences for Children of Mothers with Moderate Iodine Deficiency during Pregnancy

A number of publications have shown an association between moderate iodine deficiency (MUIC 25-49 µg /L) and impaired psychoneuromotor and intellectual development in children, including those born to moderately deficient women (Delange, 2001). The findings include low visual-motor performance, impaired motor skill and diminished IQ.

A study investigating the effect of undetected thyroid deficiency during pregnancy on the IQ in offspring found that the children born to women with undetected hypothyroidism, (with thyroid-stimulating hormone concentrations in the 96-99th centile of 25 000 women tested) had an IQ an average of 7 points less than control children when 7-9 years of age (Haddow, *et al.*, 1999). Although the case-control study was not designed to investigate the effects of iodine deficiency the authors suggested that even mild asymptomatic hypothyroidism might have an effect on intelligence.

An Italian cross-sectional study reported that 11 of 16 children born to moderately iodine deficient mothers were diagnosed with attention deficit and hyperactivity disorder (ADHD), whereas none of the 11 children of mothers in an area of adequate iodine intake had ADHD (Vermiglio *et al.*, 2004). Further research in this area is required to draw any firm conclusion about this apparent association. However, an earlier study reporting a significantly increased risk of ADHD in those with generalised resistance to thyroid hormone, and a subsequent work suggesting a link between TSH concentration and ADHD, add support to this possible relationship (Alvarez-Pedrerol *et al.* 2007; Hauser *et al.*, 1993).

3.5 Neurological Consequences of Mild and Moderate Iodine Deficiency in Children

A cross-sectional study of 1,221 school children in southern Europe (Spain) with a MUIC of 90 µg/L showed that IQ was statistically significantly lower in children with urinary iodine concentrations below 100 µg/L than in those with excretions above 100 µg/L (IQ 96.4 ± 17.5 vs. 99.3 ± 15.8) (Santiago-Fernandez *et al.*, 2004). Further, children with urinary iodine concentrations below 100 µg/L were more likely to have an IQ below the 25th centile, i.e. IQ below 87.3.

Moderate iodine deficiency in both children and adults has been linked to a negative effect on motor performances, motor skill, perceptual and neuromotor abilities and diminished IQ (Delange, 2001). These effects were observed in studies of children who were not severely deficient and did not exhibit signs and symptoms of endemic cretinism. When 310 moderately iodine deficient (MUIC 43 µg/L) 10-12 year olds in Albania were randomly assigned to receive iodine supplements or a placebo (Zimmerman *et al.*, 2006). After 24 weeks the children receiving supplements showed statistically significant improvements in tests of information processing, fine motor skills and visual problem solving compared to those receiving placebo. An earlier study in 196 moderately to severely iodine deficient 7-11 year olds in Benin found that those children who had improved iodine status after 11 months also showed statistically significant improvements tests of mental function (van den Briel *et al.*, 2000).

As well as having an impact on children, iodine deficiency has been shown to have an adverse effect on the IQ of older populations, potentially as a result of being born in iodine deficient areas (Delang and Hetzel, 2005). A meta-analysis of 18 studies undertaken by Bleichrodt and Born (1994) calculated that the mean IQ of individuals with moderate to severe iodine status was 13.5 IQ points lower than that of individuals with adequate iodine status.

3.6 Mild and Moderate Iodine Deficiency and Growth

Despite the negative impact of severe iodine deficiency on growth being well established (Delang and Hetzel, 2005), the impact mild or moderate iodine deficiency on growth has until very recently been unclear. Cross-sectional studies have shown either no correlation or a modest positive correlation between iodine intake and growth in children (Zimmerman, 2007). However, in a recent randomised controlled trial in 310 moderately iodine deficient, 10-12 year-olds those given adequate iodine had significantly improved height-for-age and weight-for-age z scores after six months compared to those not receiving additional iodine (Zimmerman *et al.*, 2007).

Correcting mild iodine deficiency, in 100 5-14 year-olds did not result in a significant improvement in growth after six months compared to those not receiving additional iodine.

3.7 Iodine Deficiency, Goitre, and Thyroid Disease

The form and frequency of different types of thyroid disease as well as the average age of onset have been linked to population iodine status. Severe iodine deficiency leads to underproduction of thyroid hormones, i.e. hypothyroidism, as there is insufficient iodine available for the normal production of thyroid hormones (Delange and Hetzel, 2005). However, in mild and moderate iodine deficiency the overproduction of thyroid hormone i.e. hyperthyroidism, is the more common problem (Aghini-Lombardi *et al.*, 1999; Delange and Hetzel, 2005; Laurberg *et al.*, 2000).

Below is a summary of comparisons between populations of different iodine status and thyroid disease, the separate issue of the impact of fortification programs on thyroid health is covered in Attachment 5 of the Final Assessment Report.

3.7.1 Mild and Moderate Iodine Deficiency and Hyperthyroidism

Comparisons of mild with moderately iodine deficient populations in Denmark with populations that have adequate or above adequate iodine intake in Iceland, indicate hyperthyroidism to be more common in iodine deficient populations (Laurberg *et al.*, 2000). Further, in Denmark it was found that hyperthyroidism was more common in the moderately deficient part of the country than in the mildly deficient part (Pedersen *et al.*, 2002).

The iodine status of a population also influences the distribution and age of onset of different forms of hyperthyroidism. In deficient areas the most common form of hyperthyroidism is multinodular toxic goitre (Aghini-Lombardi *et al.*, 1999; Laurberg *et al.*, 2000). In an area of above adequate iodine intake Graves' disease was the most common form of hyperthyroidism, developing earlier in life in an area of deficiency (Laurberg *et al.*, 2000). No such difference in the incidence of subacute thyroiditis have been reported (Laurberg *et al.*, 2000).

3.7.2 Mild and Moderate Iodine Deficiency and Hypothyroidism

Comparison of data from a moderately iodine deficient area of Denmark and an area of adequate/above adequate intake in England suggests that hypothyroidism is more common in areas of adequate or above adequate iodine intake (Laurberg *et al.*, 2000; Vanderpump, *et al.*, 1995). Other comparisons confirm that hypothyroidism is more common in areas of above adequate iodine intake, than those with mild or moderate deficiency; less clear is what can be expected in populations with adequate but not above adequate intakes (Laurberg *et al.*, 2000). In Denmark it has also been shown that hypothyroidism was more common in the area of mild iodine deficiency than in the area of moderate deficiency (Pedersen *et al.*, 2002)

Szabolcs *et al.* (1997) compared thyroid health in groups of nursing home residents over 60 years of age from the same geographic and ethnographic region, the Carpathian basin. Subjects from Northern Hungary, Slovakia, and Eastern Hungary showed deficient, adequate, and abundant iodine intake respectively. The study reports urinary iodine per gram creatinine as opposed to per litre urine, not allowing for direct application of the criteria for the description of iodine nutrition in Table 1.

Eastern Hungary, where subjects' iodine intake was highest, had the highest prevalence of clinical hypothyroidism. Northern Hungary where iodine intake was lowest had the lowest prevalence of clinical hyperthyroidism.

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Safety Assessment and Risk Characterisation Report for P230 – Consideration of Mandatory Fortification with Iodine for New Zealand

Summary

Iodine is an important trace element that is required for the synthesis of the thyroid hormones, thyroxine and triiodothyronine (thyronine). These hormones have a key role in influencing cellular metabolism and metabolic rate. They are also crucial to the development of the brain and nervous system.

Although iodine is an essential component of the diet, intakes in excess of physiological requirements may produce adverse effects, particularly on the thyroid gland (thyroid) and the regulation of thyroid hormone production and secretion.

Ingested iodine, in the form of iodide, is readily absorbed from the gastrointestinal tract into the circulation. The human body contains about 15–20 g iodine in total, the majority of which is stored by the thyroid. The uptake of iodide by the thyroid is controlled by thyroid-stimulating hormone (TSH), which is highly sensitive to dietary iodine intake. At low intakes representing iodine deficiency, uptake of iodide into the thyroid is increased and at very high intakes, iodide uptake into the thyroid decreases. Once the physiological requirements for thyroid hormone synthesis have been met, the thyroid does not accumulate more iodide and any excess is excreted, primarily in the urine.

Safety Assessment and Risk Characterisation

A large number of human experimental, clinical, and epidemiological studies on the effects of excess iodine on human health have been reported and reviewed in detail by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the European Scientific Committee for Food (SCF), and the US Agency for Toxic Substances and Disease Registry (ATSDR). These reviews indicate there are three potential types of adverse response to excess iodine:

- disturbance of thyroid activity, which may alter the size of the thyroid and/or affect the production of thyroid hormones;
- sensitivity reactions to iodine, which are unrelated to thyroid function;
- iodine poisoning, resulting from acute intakes of large quantities (grams) of iodine. Cases of iodine poisoning are only rarely seen.

This review has focused principally on effects on the thyroid, which are regarded as the primary and most sensitive indicators of iodine toxicity. Some consideration has also been given to iodine ‘allergy’ and sensitivity reactions because of the widely held belief that adverse reactions to iodine-containing therapeutic substances can confer a specific cross-reactivity with iodine in foods.

Effects on the Thyroid

Excess iodine can produce an enlargement of the gland (goitre) and/or affect the production of the thyroid hormones. An under production of the thyroid hormones is referred to as hypothyroidism and may be accompanied by goitre. An over production of thyroid hormone is referred to as hyperthyroidism.

The effect on the thyroid depends on the current and previous iodine status of the individual, and any current or previous thyroid dysfunction. For example, individuals with a long history of iodine deficiency may be prone to the development of hyperthyroidism, known as iodine-induced hyperthyroidism when it is triggered by increased iodine exposure.

Particular life stages may also be more vulnerable to excess iodine. For example, the foetus and newborn infants are more susceptible than children and adults to the development of goitre and hypothyroidism. While the foetal and neonatal thyroid has a much higher fractional uptake of iodine compared to the adult thyroid, it is less able to escape the inhibitory effects of excess iodine on thyroid hormone formation, hence the greater susceptibility to goitre and hypothyroidism.

The human response to excess iodine can therefore be quite variable, although in general most people are very tolerant of excess iodine in the diet with many individuals, including young children, being able to tolerate large intakes up to 50 µg/kg/day and above. In contrast, others may respond adversely to levels close to recommended intakes (3-7 µg/kg/day). Individuals responding adversely to relatively low intake levels typically have an underlying thyroid disorder, and, in many cases, a long history of iodine deficiency.

For the majority of healthy individuals, the most sensitive endpoint for iodine toxicity is sub-clinical hypothyroidism. Sub-clinical hypothyroidism is defined as an elevated TSH concentration in the presence of thyroid hormone concentrations within the normal range of values for healthy individuals. The effect is usually transient, even if excess iodine intake continues. While not clinically adverse, such an effect, if persistent, may be regarded as an indicator of an existing risk of overt or clinical hypothyroidism.

Although there is potential for progression to clinical hypothyroidism in certain susceptible individuals, it remains uncertain as to whether a persistent state of sub-clinical hypothyroidism would, in practice, have any clinical consequences in otherwise healthy individuals.

In healthy adults, sub-clinical hypothyroidism has been associated with acute intakes of 1700-1800 µg/day (24-25 µg/kg body weight/day for a 71 kg person), and for children, has been associated with chronic intakes of 1150 µg/day (29 µg/kg/day for a 40 kg child). Chronic iodine intakes of approximately 1000 µg/day however appear to be well tolerated by healthy adults.

In the *Nutrient Reference Values for Australia and New Zealand*³³, the National Health and Medical Research Council specified an Upper Level of Intake (UL)³⁴ for iodine of 1100 µg/day in adults.

³³ This document is available online at <http://www.nhmrc.gov.au/publications/synopses/n35syn.htm>

³⁴ 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.

The UL is based on the endpoint of sub-clinical hyperthyroidism. The value for the UL has been adjusted for different age groups on a bodyweight basis. FSANZ has adopted this UL for the purpose of risk assessment for the general healthy population.

The dietary intake assessment (Attachment 7 to the Final Assessment Report) indicates that while estimated mean population intakes will remain well below the UL for iodine following the introduction of mandatory fortification, a small percentage of young children, in particular 1-3 year olds, have the potential to 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. Furthermore, evidence exists which indicates that young children are able to exceed their respective ULs by 2-3 fold without apparent adverse consequences. This, and the reversible nature of the endpoint (sub-clinical hypothyroidism), means such intakes are unlikely to represent a health and safety risk to young children, though a reduced margin of safety exists. Overall, the potential for adverse effects in the small number of young children that are estimated to exceed the UL for iodine is considered low.

For those individuals with thyroid disorders or a long history of iodine deficiency, the UL may not be applicable since these individuals may respond adversely at lower levels of intake. It has been reported that intakes in the range 3-7 µg/kg/day may be sufficient to precipitate or aggravate hyperthyroidism in these individuals. Iodine-induced hyperthyroidism typically occurs in individuals with an underlying autonomously functioning thyroid caused by either multinodular goitre or by Graves' disease. The health risk for these individuals needs to be considered separately from the general population.

An increased incidence of iodine-induced hyperthyroidism is reported to be the most common adverse effect encountered following the introduction of iodine fortification. Once iodine deficiency has been corrected however the incidence of iodine-induced hyperthyroidism typically reverts to normal levels or even below normal levels after several years. The incidence of iodine-induced hyperthyroidism is said to be significantly reduced or avoided by appropriate quality control and monitoring of the fortification programme.

In terms of the risk to the New Zealand population, the evidence indicates that widespread moderate iodine deficiency has only emerged in recent years. As a consequence, the number of individuals with autonomous multinodular goitres is expected to be quite small. Therefore, while an increase in the detectable occurrence of iodine-induced hyperthyroidism is a recognised risk following the introduction of iodine fortification, in the New Zealand context it is likely to be a rare event.

A small but finite risk exists for individuals with Graves' disease, however, such individuals will typically be under the care of a medical professional, therefore should there be any exacerbation of the condition this should be detected quickly and remedial action taken.

Iodine 'Allergy' and Sensitivity Reactions

Exposure to iodine (in the form of iodide), and certain iodine-containing therapeutic/diagnostic substances, can produce a range of adverse reactions in certain sensitive individuals that are unrelated to thyroid function.

Although the reactions observed appear to have an immunological basis, they are rarely IgE-mediated, therefore they cannot be regarded as true allergic reactions.

In certain sensitive individuals, oral exposure to very large doses of free iodide (>300 mg/day) has been associated with a range of adverse reactions including hives, skin lesions, oedema, and fevers. The symptoms usually cease once the excess intake is discontinued. In many cases, pre-existing disease and related drug therapy are believed to have contributed to the reaction. While these reactions appear to be a true sensitivity to iodine, they occur at very high dose levels that would not be typical from the diet, even with mandatory fortification.

A variety of mild to very severe reactions (including rare cases of anaphylactic reactions) have also been observed in certain individuals following exposure to particular iodine-containing therapeutic/diagnostic substances, such as iodinated contrast material (ICM) and iodine-based antiseptics (e.g. povidone-iodine). Despite iodine being common to both types of substances, testing has shown that the adverse reactions observed are almost certainly a reaction to the iodine-containing molecule as a whole, and not to iodine itself.

It has been suggested that a cross reactivity may exist between contrast material sensitivity and seafood allergy as a consequence of the presence of iodine. Little scientific evidence is available however to support this hypothesis. When investigated, the vast majority of adverse reactions to seafood are allergic (IgE-mediated) reactions to specific proteins, and are completely unrelated to the presence of iodine.

In conclusion, increased dietary iodine intake as a result of mandatory iodine fortification is highly unlikely to increase the risk of iodine sensitivity reactions occurring, and nor is it likely to provoke cross-reactions in people who are sensitive to iodinated contrast materials or iodine-based antiseptics or who are allergic to seafood.

1. Introduction

Although iodine is an essential component of the diet, intakes in excess of physiological requirements may produce adverse effects, particularly on the thyroid gland (thyroid) and the regulation of thyroid hormone production and secretion. This in turn can have downstream impacts on a wide variety of other organ systems, producing an array of debilitating effects in the affected individual.

The purpose of this review is to examine the potential adverse effects associated with an increased iodine intake and to identify vulnerable groups.

2. Physical and Chemical Properties

Iodine (I) is a non-metallic element belonging to the halogen family and has a molecular mass of 126.9. Iodine is a bluish-black, lustrous solid, which sublimes at room temperature into a blue-violet gas with a sharp characteristic odour. Iodine dissolves readily in alcohol, benzene, chloroform, carbon tetrachloride, ether or carbon disulfide but is only slightly soluble in water (0.03 g/100 ml at 20°C).

The chemistry of iodine can be quite complex as it can exist in a number of different valence states, is chemically reactive (although less so than other halogens) and forms various organic and inorganic compounds. The most common compounds formed are the iodides (I^-) and iodates (IO_3^-).

Thirty-six isotopes are recognised with fourteen of these yielding significant radiation. The only naturally occurring isotopes are ^{127}I , which is stable, and ^{129}I , which is radioactive. This report will concentrate on adverse effects associated with increased intake of stable iodine.

3. Toxicokinetics

3.1 Absorption

Gastrointestinal absorption of iodine is generally considered to be close to 100% after an ingested dose of soluble iodide salts, such as potassium or sodium iodide. This conclusion is based on several studies in human subjects receiving oral doses of radioiodine compounds (Fisher *et al.*, 1965; Ramsden *et al.*, 1967).

Although some absorption occurs in the stomach, the small intestine appears to be the principal site of absorption in both humans and rats (Riggs 1952, Small *et al.* 1961). The mechanism by which iodide is transported across the intestinal epithelium is not known.

Gastrointestinal absorption appears to be similar in children, adolescents and adults, as assessed from measurements of 24-hour thyroid uptakes of radioiodine administered orally (Cuddihy, 1966; Oliner *et al.*, 1957; Van Dilla and Fulwyler, 1963). Absorption in infants however may be lower than in children and adults. Suggestive evidence for this comes from studies in which thyroid uptake of radioiodine was measured and compared in neonates who received tracer doses of radioiodine orally or by injection.

The very rapid changes in iodine status and biokinetics in the first few weeks of postnatal life however generates some uncertainty with the interpretation of these study findings (ATSDR, 2004).

Iodine incorporated into food is said to be nearly completely absorbed, however most of the dietary balance studies have only been undertaken with milk (ATSDR, 2004). Assessments of gastrointestinal absorption of iodine in other foods are not available. Little information is available on the gastrointestinal absorption of forms of iodine other than iodide. Iodine compounds such as I_2 and iodates (such as $NaIO_3$) may undergo reduction to iodide before being absorbed in the small intestine and absorption may not be complete (ATSDR, 2004).

3.2 Distribution

Once absorbed, iodide enters the circulation and is distributed throughout the extracellular fluid where it is taken up by those tissues with specialised transport mechanisms for iodide (Cavalieri, 1980). The human body contains about 15-20 g iodine in total, the majority of which (>90 %) is stored by the thyroid (Cavalieri, 1997). The concentration of iodine in serum is about 50-100 $\mu\text{g/L}$ under normal circumstances, with about 5% being in the inorganic form as iodide and the remaining 95% consisting of various organic forms of iodine, principally protein complexes of the thyroid hormones.

Other tissues that accumulate iodide include the salivary glands, gastric mucosa, choroid plexus, mammary glands, placenta, and sweat glands. The tissue distribution of iodide and organic iodine are very different and are interrelated by metabolic pathways that lead to the iodination and de-iodination of proteins and thyroid hormones.

The uptake of iodide by the thyroid is controlled by thyroid-stimulating hormone (TSH), which is secreted from the anterior lobe of the pituitary gland. In addition to stimulating iodide transport from the blood into thyroid cells, thyroid-stimulating hormone is also responsible for stimulating the oxidation of iodide to iodine, and iodine binding to tyrosine.

Iodide taken up by the thyroid is used for the production of the thyroid hormones, which are stored in the gland. Approximately 90% of the thyroid iodine content is in the organic form and includes iodinated tyrosine residues comprising the thyroid hormones thyroxine and thyronine, and their various synthesis intermediates and degradation products.

Once requirements for thyroid hormone synthesis have been met, the thyroid does not accumulate more iodide and any excess is excreted in the urine (Bender and Bender, 1997).

Children (1 and 10 year olds) appear to have a similar fractional uptake of iodide in the thyroid gland compared to adults (ATSDR, 2004). This contrasts to the situation with neonates, who have much greater fractional uptakes, although this quickly declines to the levels of adults by 5 days of age. After the first few weeks, uptake changes very little with age.

The percent turnover rates of iodine in the thyroid however does change with age, with 0-4 year olds having an apparent half-life of 20 days compared to 33 days in 4-8 year olds and 83 days in 8-12 year olds. Iodine concentration in the thyroid also increases with age with 1-2 year olds having between 95-130 μg iodine/g thyroid tissue compared to 400 $\mu\text{g}/\text{g}$ in adults (Stather & Greenhalgh, 1983).

Iodide uptake into the thyroid gland is highly sensitive to iodide intake. At low intakes representing iodine deficiency, uptake of iodide into the thyroid gland is increased (Delange and Ermans, 1996). At very high intakes, iodide uptake into the thyroid gland decreases, primarily as a result of decreased iodothyronine synthesis (the Wolff-Chaikoff effect) and iodide transport into the gland (Nagataki and Yokoyama, 1996; Saller, 1998).

3.3 Metabolism

Once in the thyroid, iodide is oxidised to elemental iodine by the enzyme thyroid peroxidase (Saller, 1998). This reaction is the rate-limiting step for protein iodination and hormone synthesis. Once oxidised, iodine enters the biosynthetic pathway for thyroid hormone synthesis.

Initially iodine is incorporated into monoiodotyrosine and diiodotyrosine, which are then coupled together to form the thyroid hormones thyronine (coupling of a monoiodotyrosine and diiodotyrosine residue) and thyroxine (coupling of two diiodotyrosine residues). These reactions occur within a large glycoprotein called thyroglobulin, which is synthesised only in the thyroid gland.

TSH regulates every step in the biosynthesis of the thyroid hormones, from the concentration of iodide to the proteolysis of thyroglobulin (Cavalieri, 1980).

There is a sensitive feedback mechanism between the thyroid and the pituitary gland to maintain the levels of thyroid hormones. This is influenced by the hypothalamus, with thyrotropin-releasing hormone mediating the secretion of TSH from the pituitary.

De-iodination reactions are carried out by a family of selenoproteins. Iodotyrosine dehalogenase regenerates iodide from monoiodotyrosine and diiodotyrosine for re-use within the thyroid or release into blood, accounting for the iodide leak in the state of chronic iodine excess or certain thyroid conditions (Cavalieri, 1997). The liver contains a considerable amount of thyroxine, some of which is converted into thyronine and some excreted into the bile, and ultimately reabsorbed or excreted (Cavalieri, 1980).

3.4 Excretion

All absorbed iodine is excreted primarily in the urine and faeces, but is also excreted in breast milk, exhaled air, sweat and tears (Cavalieri, 1997). Urinary excretion normally accounts for 97% of the elimination of absorbed iodine, while faecal excretion accounts for about 1-2% (Larsen *et al.*, 1998).

The fraction of the absorbed iodide dose excreted in breast milk varies with functional status of the thyroid.

A larger fraction of the absorbed dose is excreted in breast milk in the hypothyroid state compared to the hyperthyroid state. In the hypothyroid state, uptake of absorbed iodide into the thyroid is depressed, resulting in greater availability of the absorbed iodide for distribution to the mammary gland and breast milk.

4. Toxicity of Iodine

A large number of human experimental, clinical, and epidemiological studies on the effects of excess iodine on human health have been reported. These studies will not be reviewed again in detail as they have already been subject to significant reviews by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (WHO, 1989), the European Scientific Committee for Food (SCF, 2002) and the Agency for Toxic Substances and Disease Registry (ATSDR, 2004).

JECFA concluded there are three potential types of adverse response to excess iodine. The first is disturbance of thyroid activity, which may alter the size of the gland and/or affect the production of thyroid hormones. There is also evidence to indicate that iodine (or the lack of it) may alter the pattern of thyroid malignancy. The second type of response involves sensitivity reactions, which are unrelated to thyroid gland function. The third type of response results from acute intakes of large quantities (grams) of iodine (iodine poisoning). Cases of iodine poisoning are only rarely seen.

This review will largely focus on effects on the thyroid gland, which is regarded as the primary and most sensitive indicator of iodine toxicity (ATSDR, 2004).

4.1 Disturbance of Thyroid Function

The primary effects of excessive stable iodine ingestion are on the thyroid gland and regulation of thyroid hormone production and secretion. Adverse effects on the pituitary and adrenal glands are secondary to disorders of the thyroid gland. Excess iodine can result in goitre, hypothyroidism (with or without goitre), or hyperthyroidism (thyrotoxicosis) (see Box 1 for definitions of the various terms used). The effect produced depends on the current and previous iodine status of the individual and any current or previous thyroid dysfunction (WHO, 1989).

For example, individuals exposed to low levels of iodine early in life may be prone to the development of iodine-induced hyperthyroidism if iodine exposure increases later in life. Those with underlying thyroid disease also respond more to increased iodine intake, and it appears that females are more likely to respond to excess iodine than males. The foetus and neonates are also more susceptible to excess iodine than other life-stage groups.

The most common cause of hyperthyroidism is Graves' disease (diffuse toxic goitre), an autoimmune disease where the immune system produces antibodies that stimulate the thyroid-stimulating hormone receptors of the thyroid gland resulting in the non-suppressible overproduction of thyroid hormone. This causes the thyroid gland to become enlarged. In the elderly, a condition called toxic nodular goitre may cause hyperthyroidism.

Toxic nodular goitre occurs when one or more small benign tumours in the thyroid gland produce excess thyroid hormones.

Terminology

Goitre refers to an enlargement of the thyroid that is usually visible as a swelling in the anterior portion of the neck. A number of different types of goitres are known to occur.

Simple or non-toxic goitre is an enlargement of the thyroid gland that is not associated with overproduction of thyroid hormone, inflammation or malignancy, whereas *toxic goitre* is one involving excessive production of thyroid hormone. Thyroid enlargement can be uniform (diffuse goitre) or the gland can become enlarged as a result of the occurrence of one or more nodules (nodular goitre).

The two most common causes of simple or non-toxic goitre are iodine deficiency or the ingestion of large quantities of goitrogenic foods or drugs, i.e. substances that inhibit the absorption and/or utilisation of iodine by the thyroid, or otherwise interfere with normal thyroid hormone synthesis. In these cases, the thyroid gland is unable to meet the demands of the body (i.e., because of an inadequate supply of iodine) and enlarges to compensate. Enlargement of the gland is usually sufficient to overcome mild impairment to hormone production.

Goitre can also be associated with both **hypothyroidism** and **hyperthyroidism**.

Hypothyroidism refers to the diminished production of thyroid hormone leading to clinical manifestations of thyroid insufficiency and can occur with or without goitre. Typical biomarkers of hypothyroidism are a depression in the circulating levels of thyroxine and/or thyronine below their normal ranges. This is usually, but not always, accompanied by an elevation of TSH above the normal range.

The most common cause of hypothyroidism is Hashimoto's disease (or lymphocytic thyroiditis). Hashimoto's disease is an autoimmune disease in which abnormal antibodies are produced that impair the ability of the thyroid to produce thyroid hormone. The pituitary gland responds by producing more TSH; this may cause the thyroid gland to enlarge.

Hyperthyroidism is where accelerated thyroid hormone biosynthesis and secretion by the thyroid gland produce thyrotoxicosis. The term *thyrotoxicosis* refers to the hypermetabolic clinical syndrome resulting from serum elevations in thyroid hormone levels, specifically free thyroxine, triiodothyronine, or both.

The terms hyperthyroidism and thyrotoxicosis are often used interchangeably but are not synonymous. That is, while many patients have thyrotoxicosis caused by hyperthyroidism, other patients may have thyrotoxicosis caused by inflammation of the thyroid gland, which causes release of stored thyroid hormone but not accelerated thyroid hormone synthesis. Thyrotoxicosis may also be caused by ingestion of exogenous thyroid hormone.

4.1.1 Iodine-Induced Hypothyroidism

The human body has a number of adaptive mechanisms for dealing with excess iodine. These mechanisms tend to be inhibitory in nature and generally do not significantly affect thyroid function.

The most well known of these is the *Wolff-Chaikoff effect* (Wolff *et al.*, 1949), where large dietary or therapeutic intakes of iodine can inhibit organic iodine formation (the binding of iodine to tyrosine in the thyroid), producing a decrease in the circulating thyroid hormone levels, and a subsequent increase in TSH.

The effect is typically transient, even if the excess intake continues, with most people being able to escape from the inhibition without a clinically significant change to circulating hormone levels. Escape is thought to be the result of the down regulation of the sodium-iodide symport, i.e. the iodide transport mechanism in the thyroid gland, leading to a decrease in intrathyroidal iodine and the resumption of normal thyroid hormone synthesis (ATSDR, 2004). Most individuals are therefore able to adapt to excess iodine.

Some individuals fail to escape from the Wolff-Chaikoff effect and typically develop goitre and may also become hypothyroid. These effects result from a persistent inhibition of thyroid hormone synthesis and release. A failure to escape the Wolff-Chaikoff effect is thought to occur primarily in susceptible individuals (ATSDR, 2004). Susceptible individuals include: fetuses and neonates; patients who have autoimmune thyroiditis; patients with Grave's disease previously treated with iodine; women who have post-partum thyroiditis; or those who have subacute thyroiditis. The hypothyroidism resolves once the excess iodine intake is discontinued. Spontaneous recovery usually occurs within 2-3 weeks, although some individuals may develop primary hypothyroidism.

4.1.1.1 Effects in Adults

A number of studies have examined the acute effects of increased intakes of iodine on the thyroid hormone status of adults (Gardner *et al.*, 1988; Georgitis, *et al.*; 1993; Namba *et al.*, 1993; Paul *et al.*, 1988; Robison *et al.*, 1998).

These studies suggest that acute (14 days) iodine exposures of 1500 µg/day (21 µg/kg/day) above the pre-existing dietary intake can be tolerated without producing a clinically adverse change in thyroid hormone levels, although such doses may produce a reversible depression in serum thyroxine concentration and a small rise in serum TSH concentrations, both within the normal range for healthy individuals.

Changes in thyroid hormone levels within normal ranges are not considered to be clinically adverse; however, they are indicative of a subtle suppression in thyroid hormone release. Based on estimates of the background dietary intakes of the subjects in these studies, in most cases estimated from measurements of urinary iodide excretion, the total iodide intakes producing sub-clinical hypothyroidism in healthy adults were around 1700-1800 µg/day (24-25 µg/kg/day) (Gardner *et al.*, 1988; Paul *et al.*, 1988).

Acute intakes of approximately 700 µg/day (10 µg/kg/day) had no detectable effect on thyroid hormone status in healthy individuals. One study also found no evidence of disturbances in thyroid hormone status in 6 healthy euthyroid³⁵ males who received doses of 20 mg/day (0.3 mg/kg/day) (Robison *et al.*, 1998), suggesting that, at least under certain conditions, exposure levels >10-24 µg/kg/day may be tolerated by some individuals.

Two studies have been conducted in prison populations exposed to iodine through iodination of the water supply. In a study by Freund *et al.*, (1966), the health and thyroid function of representative subjects of a prison population were assessed before and during usage of iodinated water for nine months. Water containing 1000 µg/L iodine induced a marked decrease in the uptake of radioactive iodine but protein bound iodine levels did not increase significantly until the iodine concentration was increased to 5000 µg/L. No information on actual intake is provided but it has been assumed that water consumption would have been about 1-2 litres/day (WHO, 1989). In another study, iodination of a prison water supply at a concentration of 500-750 µg/L (estimated intake 1000-2000 µg/day) for up to 15 years did not result in any change to serum thyroxine levels (Thomas *et al.*, 1978).

These studies suggest that 1000 µg iodine/day is safe for the majority of the population and support the findings from short-term studies. On the basis of these long-term studies, JECFA set a provisional maximum tolerable daily intake (PTDI) of 17 µg/kg bodyweight for iodine from all sources (WHO, 1989).

A study was initiated in China in 1999 to investigate iodine-induced thyroid dysfunction following the introduction of salt iodisation in 1996 (Teng *et al.*, 2006). The introduction of salt iodisation had resulted in median urinary iodine excretion increasing from 165 µg/L in 1995 to 306 µg/L in 1999. Cohorts in three regions with different levels of iodine intake were investigated: a region regarded as mildly iodine deficient with a median urinary iodine excretion of 84 µg/L (Panshan); a region with more than adequate iodine intake having a median urinary iodine excretion of 243 µg/L (Zhangwu); and a region with excessive iodine intake, having a median urinary iodine excretion of 651 µg/L (Huanghua). The study examined the prevalence and cumulative incidence of various thyroid disorders within each cohort.

³⁵ Where thyroid-stimulating hormone levels are in the normal range and the thyroid is neither hypothyroid nor hyperthyroid and considered 'normal'.

The investigators found that more than adequate or excessive iodine intake was associated with a slightly increased cumulative five-year incidence of sub-clinical hypothyroidism and autoimmune thyroiditis, but not of overt hypothyroidism or hyperthyroidism. For the majority, the sub-clinical hypothyroidism and autoimmune thyroiditis were not sustained.

4.1.1.2 Effects in the Elderly

Very little data are available for the elderly. Sub-clinical hypothyroidism has been shown to be induced by an acute increase of 500 µg/day (7 µg/kg/day) (Chow *et al.*, 1991) and in epidemiological studies has been associated with chronic intakes of 160-800 µg/day (4-12 µg/kg/day) (Laurberg *et al.*, 1998). This possibly suggests that the elderly may be less tolerant of excess iodide than younger adults.

4.1.1.3 Effects in Children

Some data are available on adverse effects of chronic exposure to high iodine intakes in school-age children but very little data are available for younger children.

Very large iodine intakes have been reported in children residing in certain coastal areas of Japan (Suzuki *et al.*, 1965). In coastal Hokkaido in Japan the traditional local diet is high in iodine-rich seaweed. Urinary iodide excretion in children consuming the local diet was approximately 23,000 µg/day, estimated to be equivalent to an iodine intake of >10,000 µg/day. The overall prevalence of visible goitre in the children was 3-9%, although in some villages, about 25% of the children had visible goitre.

Most of the goitres responded to the administration of thyroid hormone, restriction of dietary iodine intake, or both. TSH assays were not available, but it was suggested that the increase in serum TSH was involved in the generation of goitre. No cases of clinical hypothyroidism were reported.

Results from an epidemiological study of children in China suggest that chronic exposure to excess iodine (1150 µg/day, 29 µg/kg/day) can result in or contribute to the development of sub-clinical hypothyroidism (Li *et al.*, 1987; Mu *et al.*, 1987; Boyages *et al.*, 1989). The study compared thyroid status in groups of children, aged 7-15 years, who resided in two areas of China with different drinking water iodine concentrations, providing estimated iodine intakes of 29 and 10 µg/kg/day. Both groups were euthyroid with normal values for serum thyroid hormones and TSH concentrations; although TSH was significantly higher in the high iodine group. These chronic intake levels therefore did not induce clinical hypothyroidism. The high iodine intake group had a 65% prevalence of goitre compared to 15% in the low iodine intake group. This study was used by the ATSDR to establish a chronic-duration minimal risk level (MRL)³⁶ for iodine of 10 µg/kg/day (about 400 µg/day for a 40 kg child) based on a no-observed-adverse-effect level (NOAEL)³⁷ of 10 µg/kg/day and a lowest-observed-adverse-effect-level (LOAEL)³⁸ of 29 µg/kg/day for sub-clinical hypothyroidism in healthy human children (ATSDR, 2004).

³⁶ An MRL is an estimate of the daily human exposure to a hazardous substance that is likely to be without appreciable risk of adverse non-cancer health effects over a specified duration of exposure.

³⁷ The highest tested dose of a substance that has been reported to have no harmful (adverse) health effects on people or animals.

³⁸ The lowest tested dose of a substance that has been reported to cause harmful (adverse) health effects in people or animals.

In their evaluation, the ATSDR noted that the thyroid gland enlargement can be considered a 'less-serious' LOAEL and is not indicative of significant functional impairment.

In the United States, which is iodine replete, very high iodine intakes – such as estimated intakes of up to 980 µg/day in infants (7 kg bodyweight) and 1350 µg/day for toddlers (15 kg bodyweight) – have been observed in young children without any apparent adverse effects (Park *et al.*, 1981).

A recent study of an international sample of 6-12 year old children (n = 3319) from five continents was undertaken to determine whether chronic high iodine intakes are associated with greater thyroid size in school age children (Zimmermann *et al.*, 2005). The MUIC ranged from 115 µg/L (range 2 – 450 µg/L) in central Switzerland (equivalent to an estimated iodine intake of 120 µg/day) to 728 µg/L (range 38 – 11,100 µg/L) in coastal Hokkaido, Japan (equivalent to an estimated iodine intake of 740 µg/day). In the entire sample, 31% of children had urinary iodine concentrations (UIC) >300 µg/L, with 11% being >500 µg/day. This contrasts to figures for children from coastal Hokkaido, where 59% had UIC >500 µg/L, and 39% had UIC >1000 µg/L. The study found that chronic intakes of approximately twice those recommended, indicated by UI concentrations in the 300-500 µg/L, do not increase thyroid volume in children.

UIC ≥500 µg/L were associated with increasing thyroid volume in children from coastal Hokkaido but not in children from central Hokkaido or the United States (the two other sites with a high prevalence of UI concentrations >500 µg/L).

The authors concluded that moderately high dietary iodine intakes in the range 300-500 µg/day appear to be well tolerated by healthy children, although such intakes are of no benefit. Uncertainty still remains regarding higher intakes.

Therefore, while chronically high iodine intakes have been associated with an increased prevalence of thyroid enlargement and goitre, as well as an increased prevalence of sub-clinical hypothyroidism, in children residing in coastal areas of Japan or certain regions of China, this is not true for all populations with chronically high iodine intake, for example in the United States. Such effects have also not been observed in children following the introduction of iodine fortification programmes (Delange and Hetzel, 2005).

4.1.1.4 Effects in Pregnant Women

Maternal exposures to excess iodine, generally in the order of several hundred milligrams of iodine/day, during pregnancy have been shown to produce goitre and hypothyroidism in the foetus and neonates.

The susceptibility of the foetus and neonates to the development of goitre and hypothyroidism has a toxicokinetic basis. Iodine uptake into the foetal thyroid commences at approximately 70-80 days of gestation and generally reaches its peak at approximately 6 months of gestation (Aboul-Khair *et al.*, 1966; Book & Goldman, 1975; Evans *et al.*, 1967). The foetal and neonatal thyroid has a much higher fractional uptake of iodine compared to the adult thyroid, although the fractional uptake generally declines to that of adults 5 days after birth. The foetal thyroid is also less able to escape the inhibitory effects of iodine on thyroid hormone formation.

In one clinical case, hypothyroidism and life-threatening goitre occurred in an infant born to a woman who consumed approximately 200 mg iodine/day (2.8 mg/kg/day) as sodium iodide for two years, including during pregnancy (Iancu *et al.*, 1974). The infant was treated with levothyroxine and reverted to normal gland and thyroid status within three weeks after birth and did not require further hormone therapy. In another case, a woman ingested approximately 260-390 mg iodine/day (4.6 mg/kg/day) during pregnancy resulting in the foetus developing goitre *in utero*. (Vicens-Calvet *et al.*, 1998). The foetus was subsequently successfully treated *in utero* with levothyroxine and was born with a normal gland and thyroid status.

Such doses, however, are atypical and clinical experience with lower doses of iodine supplementation given during pregnancy for the purpose of correcting or preventing iodine deficiency and for the management of Grave's disease indicates that oral doses of 4-5 µg/kg/day can be tolerated without any indication of thyroid dysfunction in the newborn (Pedersen *et al.*, 1993, Liesenkötter *et al.*, 1996).

During the course of a study conducted in prison populations (described above), where the prison water supply was iodinated at a concentration of 500 to 750 µg/L (estimated intake 1000-2000 µg/day) for up to 15 years, 177 women in the prison gave birth to 181 full-term infants without any enlargement of the thyroid in the infants being noted (Stockton and Thomas, 1978).

4.1.1.5 Effects on Individuals with Thyroid Disorders

In individuals with thyroiditis, frequently caused by Graves' or Hashimoto's disease, high intakes of iodine may exacerbate the condition, producing either sub-clinical or clinical hypothyroidism. The hypothyroidism is usually transient with thyroid function returning to normal in 2-3 weeks once the iodine intake is discontinued, although transient thyroxine replacement therapy may be required in some individuals (Markou *et al.*, 2001).

The impact of large scale iodine supplementation programmes on the occurrence of clinically significant iodine-induced thyroiditis does not appear to have been systematically or extensively studied, however, there is little evidence from the epidemiological surveys done to date that iodine supplementation per se is associated with a significant risk of autoimmune thyroiditis (Delange and Lecomte, 2000), although a recent study by Teng *et al* (2006) (discussed above) suggests that increasing iodine intakes from mildly deficient to more than adequate may increase the incidence and prevalence of autoimmune thyroiditis.

4.1.2 Iodine-Induced Hyperthyroidism

Oral exposure to excess iodine can, under certain circumstances, lead to hyperthyroidism. This condition is referred to as 'jodbasedow' although it is not thought to be a single aetiological entity (Fradkin and Wolff, 1983). The occurrence of iodine-induced hyperthyroidism is most common in iodine deficient populations following the introduction of iodine supplementation programs. The degree of vulnerability depends on the duration of the deficiency, with the most vulnerable being those over 40 years of age who have been iodine deficient since birth (Hetzel and Clugston, 1998). Other vulnerable groups include those with thyroid diseases such as Graves' disease or postpartum thyroiditis.

The clinical features of iodine-induced hyperthyroidism are said to be similar to that of Graves' disease, however, in contrast to the diffuse goitres associated with Grave's disease, iodine-induced hyperthyroidism is generally associated with nodular goitres. Nodular goitres are fairly common in elderly people and are the result of longstanding iodine deficiency. Many of these nodules are autonomous, meaning they are independent of regulation by thyroid-stimulating hormone and produce thyroid hormone in direct response to dietary iodine. Thus excess iodine may precipitate or aggravate hyperthyroidism in these subjects.

Frequently, iodine-induced hyperthyroidism is mild and follows a self-limited course, but in some cases it is more severe, even lethal. Iodine-induced hyperthyroidism can be prevented in the next and subsequent generations by correction of iodine deficiency (Delange and Lecomte, 2000).

4.1.2.1 Iodine Deficient populations

A number of epidemiological studies have been conducted in Europe and Africa to monitor the incidence of iodine-induced hyperthyroidism in iodine deficient populations following the introduction of iodine supplementation programs (DeLange *et al.*, 1999; Mostbeck *et al.*, 1998, Lind *et al.*, 1998; Stanbury *et al.*, 1998). A review of these studies indicates that iodine intakes in the range of 3-7 µg/kg/day may be sufficient to produce an increase in hyperthyroidism in iodine deficient populations (ATSDR, 2004). In countries with long-standing iodine deficiency it has been recommended that iodine intake not exceed 500 µg/day to avoid the occurrence of iodine-induced hyperthyroidism (SCF, 2002).

Iodine-induced hyperthyroidism has been reported in almost all iodine supplementation programmes (Stanbury *et al.*, 1998) but is said to be rare in cases where the supplementation programme is well executed (Delange and Hetzel, 2005). For example, in Iran the incidence of hyperthyroidism 4 years after the commencement of iodine fortification was very similar to the incidence of spontaneous thyrotoxicosis in the population prior to the intervention (Azizi and Daftarian 2001; Azizi *et al.*, 2005). In a recent study by Teng *et al.* (2006) (discussed in section 4.1.1), there were no significant differences in the cumulative incidence of either overt hyperthyroidism or Graves' disease in the cohorts studied following the introduction of salt iodisation.

One of the most well documented cases of iodine-induced hyperthyroidism occurred in Tasmania, Australia, following the introduction of iodised bread in 1966 and the addition of iodophors to milk by the dairy industry (Connolly *et al.*, 1970). Milk iodine (from the seasonal use of feed supplements) has also been a factor in outbreaks of hyperthyroidism in Europe (Barker and Phillips 1984; Phillips, 1983).

In the Tasmanian case, a 2- to 4-fold increase in hyperthyroidism occurred within a few months after diets were supplemented with iodide for the prevention of endemic goitre from iodine deficiency (Connolly *et al.*, 1970). The supplemental dose was 80-200 µg/day from the addition of potassium iodate to bread, but mean urinary iodide excretion rates suggested a total post-supplementation iodide intake of about 230 µg/day (range 94-398), equivalent to 3.3 µg/kg/day, some of which came from other sources such as milk (Connolly 1971a, 1971b).

The highest incidence of hyperthyroidism after the iodine supplementation began occurred in people over 40 years of age (Stewart 1975, Stewart & Vidor 1976). Stewart (1975) noted that the small increase in the incidence of hyperthyroidism that occurred in people under 40 years of age was largely due to Graves' disease.

While an increased incidence of iodine-induced hyperthyroidism is a common finding following iodine supplementation, its occurrence is said to be almost entirely avoided by adequate and sustained quality control and monitoring of the supplementation programme, which should also confirm adequate iodine intake (Delange and Lecomte, 2000). If an increase in the incidence of iodine-induced hyperthyroidism does occur, it typically reverts to normal or even below normal after one to ten years of iodine supplementation (Delange and Hetzel, 2005). A decline in the number of cases of hyperthyroidism, following an initial increase in their number after the introduction of iodine fortification, has been observed in a number of separate studies.

In a prospective epidemiological study conducted in Denmark, all new cases of overt hyperthyroidism in two areas with previously mild and moderate iodine deficiency were recorded prior to and during voluntary and subsequent mandatory fortification, which were introduced in 1998 and 2000, respectively (Pederson *et al.*, 2006). There was an initial rise in the incidence of hyperthyroidism after the introduction of voluntary fortification from 102.8 to 122.8 cases/100,000 people/year, a further rise to 140.7/100,000/year following mandatory fortification, and a small decline to 138.7/100,000/year 3-4 years following the introduction of mandatory fortification. Hyperthyroidism increased in both sexes and in all age groups, with the most pronounced increase being observed in young adults aged 20-39 years.

The increase in occurrence of hyperthyroidism was more pronounced in the area with previously moderate iodine deficiency.

In an epidemiological study conducted in Austria, the annual incidence of hyperthyroidism was evaluated in 392,820 patients examined at nuclear medicine centres before and after the level of table salt iodisation was increased from 7.5 to 15 mg/kg in 1991 to address persistent mild iodine deficiency (Mostbeck *et al.*, 1998). The mean urinary iodide concentration before the adjustment was 42-78 µg/g creatinine and after the adjustment was 120-140 µg/g creatinine. The monitoring revealed an initial 53% increase in the annual incidence of hyperthyroidism which then declined to 21% above baseline after five years.

An epidemiological study in Switzerland examined the incidence of hyperthyroidism before and after the iodine content of salt was increased from 7.5 to 15 mg/kg to address persisting mild iodine deficiency in the population (Baltisberger *et al.* 1995, Bürgi *et al.* 1998). The study population consisted of 109,000 people. The intervention proved to be successful, with the mean urinary iodine concentration increasing from 90 µg/g creatinine to 150 µg/g creatinine. During the first year after the increased salt level, the combined annual incidence of hyperthyroidism, diagnosed as either Graves' disease or toxic nodular goitre, increased by 27% (from 62.3/100,000 to approximately 80/100,000). However, over the next eight years, the total incidence of hyperthyroidism steadily declined to 44% of the pre-supplementation rates, with most of the decrease resulting from a decline in the incidence of toxic nodular goitre.

Healthy Individuals

Cases of iodine-induced hyperthyroidism in people who were euthyroid and without apparent thyroid disease have been reported (Rajatanavin *et al.*, 1984; Savoie *et al.*, 1975; Shilo and Hirsch, 1986; O'Connell *et al.*, 2005); however only a few have provided dose information. The most recent case, reported by O'Connell *et al.* (2005), occurred in New Zealand and consisted of a cluster of thyrotoxicosis in adult men as a result of the consumption of a soy milk product with very high iodine concentrations (9.14 mg/kg) from added kelp. In cases reporting dose information, effects were observed following doses in the range 0.05–23 mg/kg/day.

4.1.3 *Thyroid Cancer*

In humans, the only well established cause of thyroid cancer is external radiation of the thyroid gland (NNT, 2002).

The relationship between iodine intake and thyroid cancer has been examined in several large-scale epidemiology studies. The results of these studies suggest that increased iodine intake may be a risk factor for thyroid cancer in certain populations, particularly populations in iodine deficient, endemic goitre regions (ATSDR, 2004). Not all the studies have found an increased risk of cancer; however, a recurrent observation in these studies is an apparent shift in histopathology toward a higher prevalence of papillary cancers, relative to follicular cancers, after increased iodine intake in otherwise iodine-deficient populations. Papillary carcinomas are said to be less aggressive, tend to be diagnosed at earlier stages and have a better prognosis than follicular cancers (Delange and Lecomte, 2000; SCF, 2002).

Therefore, increased iodine intake may alter the pattern of thyroid cancer in iodine deficient, endemic goitre regions; resulting in a trend towards less aggressive forms of thyroid cancer.

There is little evidence to indicate that either the pattern or incidence of thyroid cancer is affected by iodine intake in regions exhibiting only mild or moderate iodine deficiency (Sehestedt *et al.*, 2006). Likewise, studies of populations in which iodine intakes are sufficient have not found significant associations between iodine intake and thyroid cancer (Horn-Ross *et al.*, 2001; Kolonel *et al.*, 1990).

4.2 **Sensitivity Reactions**

Exposure to iodine, and certain iodine-containing substances, can produce a range of adverse reactions in certain sensitive individuals.

While there is a tendency for such reactions to be referred to as 'iodine allergy', in most cases, these reactions, which are unrelated to thyroid function, do not appear to be true allergic reactions (i.e. they are not IgE-mediated), although they do seem to have an immunological basis, with both humoral and cell-mediated responses being involved (Curd *et al.*, 1979; Rosenberg *et al.*, 1972; Stone, 1985).

Sensitivity reactions have been observed following oral exposure to iodide, dermal application of iodine-based antiseptics and administration of iodinated contrast materials (ICM). This review will largely focus on sensitivity reactions following oral exposure to free iodide, as this is the most relevant exposure route.

However, because of the widely held belief that adverse reactions to iodine-containing substances such as ICM and iodine-based antiseptics can confer a specific cross-reactivity with iodine in foods, some consideration will also be given to these reactions, and their causes.

4.2.1 Reactions to Free Iodide

In certain individuals, oral exposure to excess iodine can produce urticaria (hives), acneiform skin lesions (iododerma), and fevers (Kubota *et al.*, 2000; Kurtz and Aber, 1982; Rosenberg *et al.*, 1972; Stone, 1985). Cases of more serious reactions involve angioedema (localised oedema), vasculitis, peritonitis and pneumonitis, and complement activation (Curd *et al.*, 1979; Rosenberg *et al.*, 1972; Stone, 1985). In general, such reactions have occurred in association with repeated oral doses of iodide exceeding 300 mg/day. Such doses are vastly in excess of typical dietary iodine intake.

Iododerma is thought to be a form of cell-mediated hypersensitivity (Rosenburg *et al.*, 1972; Stone, 1985). Characteristic symptoms include acneiform pustules, which can coalesce to form vegetative nodular lesions on the face, extremities, trunk, and mucous membranes. The lesions regress and heal when the excess iodide intake is discontinued. The literature reports cases of iododerma occurring following oral doses of iodide 300-1000 mg/day (5-14 mg/kg bw/day) (Baumgartner, 1976; Khan *et al.*, 1973; Kint and Van Herpe 1977; Rosenberg *et al.*, 1972; Shelly, 1967; Soria *et al.*, 1990).

However, in many of these cases, pre-existing disease and related drug therapy may have contributed to the reaction to iodide; the dose-response relationship for iododerma in healthy people remains highly uncertain (ATSDR, 2004).

Oral exposures to iodide >1000 mg/day have been associated with the occurrence of fevers, which cease once exposure to the excessive iodide intake is discontinued (Horn and Kabins, 1972; Kurtz and Aber, 1982). Reported clinical cases have almost always involved a pre-existing disease, usually pneumonia or obstructive lung disease in which potassium iodide was administered along with other drugs, such as antibiotics, barbiturates and methylxanthines; therefore the dose-response relationship for healthy people is highly uncertain (ATSDR, 2004).

4.2.2 Reactions to Iodine-Containing Substances

The administration of ICM has been associated with both immediate and delayed reactions. The immediate reactions, which can vary from mild to severe and life threatening, are primarily anaphylactoid³⁹ in nature, although rare cases of anaphylactic reactions have also been documented (Laroche *et al.*, 1999). Delayed reactions are mainly mild to moderate in nature, typically manifesting as various types of skin reactions. The delayed reactions appear to be T-cell mediated (Christiansen *et al.*, 2000).

The contrast materials used are tri-iodinated benzoic acid derivatives that in solution contain a small amount of free iodide.

³⁹ Immediate systemic reactions that mimic anaphylaxis but are not caused by an IgE-mediated immune response. Anaphylaxis and anaphylactoid reactions are clinically indistinguishable.

Studies have shown that individuals who have reacted to ICM fail to react to free iodide following subsequent testing, indicating that the sensitivity reactions observed are almost certainly a response to the contrast molecule as a whole, and not to free iodide (Coakley and Panicek, 1997).

Dermal exposures to iodine-based antiseptics, such as povidone-iodine (polyvinylpyrrolidone-iodine, or PVP-I), have produced both localised and systemic reactions in humans.

Several case reports exist describing contact dermatitis in individuals treated with topical applications of povidone-iodine (Nishioka *et al.*, 2000; Okano, 1989; Tosti *et al.*, 1990). The vast majority of these reactions appear to be the result of skin irritation (manifesting as irritant contact dermatitis) rather than an allergic response (Coakley and Panicek, 1997). Systemic effects are rare and have only been reported in instances of intravaginal applications of povidone-iodine (Moneret-Vautrin *et al.*, 1989; Waran and Munsick, 1995).

In cases of both systemic and localised reactions, patients typically react to subsequent skin challenge tests to povidone-iodine, but not to potassium iodide (Van Ketel and Van den Berg, 1990), indicating the response is caused either by povidone-iodine as a whole, or by povidone itself.

Often, individuals who have a history of a previous reaction to ICM or a topical solution of povidone-iodine or other iodine-based antiseptics and who have subsequently developed an allergy to shellfish or other seafood, or conversely who are allergic to seafood and have subsequently reacted to iodine-containing substances such as ICM, are described as having 'iodine allergy' (Kubota *et al.*, 2000). While it is true that iodine is a common component in these cases, the term 'iodine allergy' is misleading because it implies that the reactions observed are directly in response to the presence of iodine, and also that they are IgE-mediated.

At present, there is little evidence that iodine is able to provoke an IgE response, either by itself or by acting as a hapten and there is also little evidence that the sensitivity reactions to ICM or povidone-iodine are provoked by the iodine component (Coakley and Panicek, 1997). In addition, when adverse reactions to seafood, such as shellfish, are investigated, they are invariably the result of an IgE-mediated reaction to a specific protein (Daul *et al.*, 1993), and are unrelated to the presence of iodine (Huang, 2005).

There is therefore little available evidence to support the belief that adverse reactions to iodine-containing substances can confer a specific cross-reactivity with iodine in foods, or vice versa. Such cross-reactions, should they exist, would be extremely rare.

4.3 Iodine Poisoning

The effects from acute exposure to high iodine concentrations are largely due to the strong oxidising effect of iodine on the gastrointestinal tract and resultant shock. It is these properties of iodine that make it effective as a topical antiseptic and antimicrobial disinfectant. The mechanism of toxicity is not understood although direct chemical injury to the gastrointestinal tract and related secondary consequences including fluid and electrolyte loss, massive acute extracellular fluid volume contraction and cardiovascular shock may contribute to the widespread systemic effects that have been observed in lethal and near lethal poisonings.

Cases of iodine poisoning are rare however and are typically associated with intakes of many grams. Symptoms observed in lethal or near-lethal poisonings have included abdominal cramps, bloody diarrhoea and gastrointestinal ulcerations, oedema of the face and neck, pneumonitis, haemolytic anaemia, metabolic acidosis, fatty degeneration of the liver, and renal failure (Clark, 1981; Dyck *et al.*, 1979; Finkelstein and Jacobi, 1937; Tresch *et al.*, 1974).

Death has occurred from 30 minutes to 52 days after ingestion, although death generally occurs within 48 hours. Where the dose was known, it ranged from 1.1 to 9 g iodine (18-150 mg/kg for a 60 kg adult), although there is a single case report of a 54-year-old male surviving the accidental ingestion of 15 g iodine (Tresch *et al.*, 1974).

5. Upper Level for Oral Intake

A number of adverse health effects have been associated with increased iodine intakes (WHO, 1989). The most relevant of these in the context of the expected increase in iodine intake following fortification of the food supply is the potential for disturbance of normal thyroid activity.

The effect produced – iodine induced hyperthyroidism or iodine induced hypothyroidism – depends on the current and previous iodine status of the individual and any current or previous thyroid dysfunction.

For the majority of healthy individuals, the most sensitive endpoint for iodine toxicity is sub-clinical hypothyroidism. Sub-clinical hypothyroidism is defined as an elevation in thyroid-stimulating hormone concentration while serum thyroid hormone concentration is maintained within the normal range of values for healthy individuals. The effect is usually transient, even if excess iodine intake continues.

While not clinically adverse, such an effect, if persistent, may lead to thyroid gland enlargement, which is an indicator of an existing risk of clinical or overt hypothyroidism (SCF, 2002).

In healthy adults, sub-clinical hypothyroidism has been associated with acute intakes of 1700 and 1800 µg/day (24-25 µg/kg body weight/day for a 71 kg person), and for children, has been associated with chronic intakes of 1150 µg/day (29 µg/kg/day for a 40 kg child).

The level of 1700 µg/day for sub-clinical hypothyroidism has been used by the Institute of Medicine as a lowest-observable-adverse-effect level (LOAEL) (Institute of Medicine, 2001). There was considered to be little uncertainty regarding the range of iodine intakes that are likely to induce elevated thyroid-stimulating hormone concentrations above baseline, therefore an uncertainty factor of 1.5 was considered sufficient to derive an Upper Intake Level (UL)⁴⁰.

A higher uncertainty factor was not considered necessary because of the mild and reversible nature of the endpoint on which the UL is based.

⁴⁰ The tolerable upper intake level is the highest level of daily nutrient intake that is likely to pose no risks of adverse health effects in almost all individuals. The UL is not intended to apply to individuals who are receiving iodine under medical supervision.

The LOAEL of 1700 µg/day was divided by the uncertainty factor of 1.5 to obtain a UL of 1133 µg/day of iodine, which was rounded down to 1100 µg/day.

The ULs for other age groups were derived by adjustment of the adult UL on a bodyweight basis, as follows:

1-3 years	200 µg/day
4-8 years	300 µg/day
9-13 years	600 µg/day
14-18 years	900 µg/day
≥19 years	1,100 µg/day

There is also no evidence to indicate altered susceptibility of pregnant or lactating women to excess iodine, therefore the UL is the same as that for non-pregnant and non-lactating females. For infants, a UL was judged not determinable because of insufficient data on adverse effects in this age group and concern about the infant's susceptibility to excess iodine intake.

FSANZ has adopted these ULs for the purpose of risk assessment for the general healthy population. The National Health and Medical Research Council also subsequently adopted these levels in Australia as part of their recent review of nutrient reference values (NHMRC, 2006).

While the occurrence of sub-clinical hypothyroidism may lead to progression to clinical hypothyroidism in certain susceptible individuals, it remains uncertain as to whether a persistent state of sub-clinical hypothyroidism would, in practice, have any clinical consequences in otherwise healthy individuals. A body of evidence exists which indicates that healthy adult individuals are able to tolerate quite large intakes (up to 50 µg/kg bw/day) (ATSDR 2004) and in some cases intakes as high as 138 µg/kg bw/day in young children have been reported with no evidence of any adverse consequences (Park et al 1981). These levels of intake are vastly in excess of the ULs described above and suggest that healthy individuals, including young children, may exceed their respective ULs by 2-3 fold without any apparent adverse consequences.

For those individuals with thyroid disorders or a long history of iodine deficiency, the UL may not be applicable since these individuals may respond adversely at levels of intake below the UL. It has been reported that intakes in the range 3-7 µg/kg/day may be sufficient to produce an increase in hyperthyroidism in chronically iodine deficient individuals. The health risk for these individuals needs to be considered separately from the general population.

6. Risk Characterisation

6.1 Implications of Exceeding the Upper Level of Intake

Following introduction of mandatory iodine fortification, it is estimated that a small percentage of young children may exceed the UL (see Dietary Intake Assessment in Attachment 7 to the Final Assessment Report). The level of exceedance is greatest for 1-3 year old children but disappears in later childhood (>8 years). No other age groups are estimated to exceed their respective ULs. The magnitude of the exceedance is influenced by the amount of discretionary iodised salt in the diet.

In considering if the estimated intakes for young children are likely to represent a health and safety risk, a number of factors need to be taken into account.

The age-specific ULs for iodine are not absolute thresholds for toxicity but rather represent intake limits, which provide a comfortable margin of safety. While it is not desirable to routinely exceed the UL, such occurrences do not automatically mean an adverse effect will result because of the safety margin that is incorporated when ULs are derived. In the case of iodine, the UL includes an uncertainty factor of 1.5. Intakes above the UL, while reducing the margin of safety, may be considered acceptable providing they remain within the safety margin.

The toxicological 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 (ATSDR, 2004). Usually, this state does not persist, even if the excess intake continues.

In some populations however an excessively high iodine intake has been shown to result in a persistent state of sub-clinical hypothyroidism, leading to an increased prevalence of thyroid gland enlargement (goitre) (Zimmerman, *et al.*, 2005). In certain susceptible individuals, (e.g. the foetus, neonates) there may also be progression to clinical hypothyroidism (SCF, 2002; ATSDR, 2004).

While the foetus and newborn infants are considered to have increased susceptibility to excess iodine, due to the immaturity of their thyroid, this is not believed to extend beyond a few weeks of age (ATSDR, 2004). Young children therefore are only more vulnerable than adults to excess iodine as a result of their lower body weight. Differences in bodyweight are taken into account in the derivation of ULs for different age groups. The UL for 4-8 year olds is 300 µg/day and for 1-3 year olds is 200 µg/day.

The effects of chronic high iodine intakes on young children appear to be variable. Some groups of children with excessively high chronic intakes of >10 mg/day (in some coastal areas of Japan) have shown an increased prevalence of thyroid enlargement, but no evidence of clinical hypothyroidism (Suzuki *et al.*, 1965; Zimmermann *et al.*, 2005). Whereas others with intakes up to 1.35 mg/day (e.g., in toddlers in the United States) do not appear to be adversely affected (Park *et al.*, 1981). It therefore remains uncertain whether chronically high iodine intakes would, in practice, have any clinical consequences in otherwise healthy children.

Although a small number of young children are estimated to exceed the UL following the introduction of mandatory iodine fortification, the estimated intakes are still below a level at which adverse effects might be observed. Therefore, while the estimated intake level for young children exceeds the UL, the maximum estimated intake still remains within the margin of safety.

The addition of discretionary iodised salt to the diet, such as in cooking and added to food at the table, has the potential to significantly increase the estimated iodine intakes. Considerable uncertainty exists regarding the extent of discretionary salt use by the population, including by young children. However, added salt is generally not recommended for young children. It also seems unlikely that a young child would add the same amount of salt to food at the table as an adult, if at all.

Because of this, the estimated iodine intakes for the majority of young children are expected to be closer to the lower end of the range of estimated intakes. The estimated intakes at the high end of the range would represent a worst-case situation that in reality is unlikely to be realised in the vast majority of young children. Even so, these worst-case estimates are still below an intake level where adverse effects might be observed.

Overall, the potential for adverse effects in the small number of young children that are estimated to exceed the UL for iodine is considered low. While 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, means such intakes are unlikely to represent a health and safety risk to young children, though a reduced margin of safety exists.

6.2 Vulnerable Groups

The UL may not be applicable to individuals with thyroid disorders or a long history of iodine deficiency, therefore the health risk for these individuals needs to be considered separately from the general population. The main health risk for these individuals is the occurrence of iodine-induced hyperthyroidism.

Iodine-induced hyperthyroidism typically occurs in individuals with an underlying autonomously functioning thyroid caused by either multinodular goitre or by Graves' disease.

An increased incidence of iodine-induced hyperthyroidism is reported to be the most common adverse effect encountered following the introduction of iodine fortification (Stanbury *et al.*, 1998). Because of this clear link with iodine deficiency, iodine-induced hyperthyroidism is regarded as one of the Iodine Deficiency Disorders (Delange and Hetzel, 2005).

It affects principally the elderly, who are the population group most likely to have developed multinodular goitres as a result of long-standing iodine deficiency (Hetzel & Clugston 1998). Many of the nodules are autonomous, meaning they are independent of regulation by TSH and produce thyroid hormone in direct response to dietary iodine (ATSDR, 2004). Thus, excess iodine may precipitate or aggravate hyperthyroidism in these subjects.

While the highest incidence of hyperthyroidism following the introduction of iodine fortification is usually found in the elderly population, small increases in incidence have also been documented in people under 40 years of age due largely to Graves' disease (Stewart, 1975).

Graves' disease is an autoimmune disease caused by the stimulation of the thyroid by antibodies, which bind to TSH receptors resulting in the non-suppressible overproduction of thyroid hormone. Excess iodine can precipitate active Graves' disease by providing more substrate for thyroid hormone synthesis and possibly also by disturbing immune function (Topliss and Eastman, 2004).

While an increase in the incidence of iodine-induced hyperthyroidism is regarded as a unavoidable consequence of the correction of iodine deficiency, it has been demonstrated that its incidence can be significantly reduced or even avoided by appropriate quality control and monitoring of the fortification programme (Delange and Lecomte 2000).

The incidence of iodine-induced hyperthyroidism is said to revert to normal or even below normal after 1-10 years of iodine supplementation (Delange and Hetzel, 2005).

In terms of the risk to the New Zealand population, the evidence indicates that widespread moderate iodine deficiency has only emerged in the last 10 to 15 years. As a consequence, the number of individuals with autonomous multinodular goitres is expected to be quite small. Therefore, while an increase in the detectable occurrence of iodine-induced hyperthyroidism is a recognised risk following the introduction of iodine fortification, in the New Zealand context it is likely to be a rare event.

A small but manageable risk exists for individuals with Graves' disease, however, such individuals will typically be under the care of a medical professional, therefore should there be any exacerbation of the condition this should be detected quickly and remedial action taken.

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Food Technology Report

1 Introduction

Food Standards Australia New Zealand is considering mandatory fortification of the food supply in Australia and New Zealand with iodine.

Generally, the addition of iodine to foods is technologically feasible. However, in some instances the addition of iodine can lead to quality changes in food products such as appearance, taste, odour, texture and shelf life. These changes will depend on the chemical form of iodine used as a fortificant, the chemistry of the food that is being fortified, the food processes involved in manufacture and possible processing interactions that could occur during distribution and storage.

Many foods have been fortified with iodine and the potassium salts of iodine compounds have been used as the preferred form.

2 Forms of Iodine

Iodine is normally introduced, or supplemented, as the iodide or iodate of potassium, calcium or sodium. The following table lists different chemical forms of iodine along with their important physical properties.

Table 1: Physical Properties of Iodine and its Compounds

Name	Chemical Formula	% Iodine	Solubility in water (g/L)				
			0°C	20°C	30°C	40°C	60°C
Iodine	I ₂	100	-	-	0.3	0.4	0.6
Calcium iodide	CaI ₂	86.5	646	676	690	708	740
Calcium iodate	Ca(IO ₃) ₂ ·6H ₂ O	65.0	-	1.0	4.2	6.1	13.6
Potassium iodide	KI	76.5	1280	1440	1520	1600	1760
Potassium iodate	KIO ₃	59.5	47.3	81.3	117	128	185
Sodium iodide	NaI·2H ₂ O	85.0	1590	1790	1900	2050	2570
Sodium iodate	NaIO ₃	64.0	-	25.0	90.0	150	210

Adapted from Mannar and Dunn (1995)

2.1 Potassium Iodide

Potassium iodide (KI) is highly soluble in water. In most impure salts potassium iodide is not very stable due to both oxidation, and migration and then subsequent evaporation. Oxidation to iodine occurs if storage conditions are either humid or highly aerated, involve exposure to sunlight or heat, the presence of impurities or moisture in the salt or an acidic environment. Loss of iodine is decreased when salt that is iodised with potassium iodide is very pure (refined) (>99.5%) and dry (<0.1% moisture), as well as with the addition of stabilisers and drying agents (Mannar and Dunn, 1995).

Potassium iodide is cheaper than potassium iodate and the percentage of iodine by weight is also greater. However, overall cost may be higher if used in an impure salt due to its instability in comparison to potassium iodate. Due to its solubility in water, potassium iodide is more readily dispersed by addition as a liquid to the salt slurry before drying.

2.2 Potassium Iodate

Potassium iodate (KIO_3) is more stable in unrefined salt than the iodide, removing the need for extra stabilisers or carrier agents. It is also more stable in unfavourable atmospheric conditions such as in high humidity. This is the form that is currently used in Australia and New Zealand for the iodisation of salt. Although potassium iodate is less soluble in water than potassium iodide, losses are greatly reduced as it is less likely to migrate from packaging, and solutions of sufficient concentrations up to 4%, are still easily prepared (Mannar and Dunn, 1995). Iodates can be added to dried salt in powder form.

Potassium iodate has been evaluated by the Joint Food and Agriculture/World Health Organization Expert Committee on Food Additives (JECFA) as a flour treatment agent. Potassium iodate has been assigned the International Numbering System number (INS) 917 and is specified by JECFA.

2.3 Sodium Iodide and Iodate

Sodium iodide (NaI) is even more soluble than potassium iodide (KI). Similarly the sodium salt of iodate is more soluble than the potassium salt. The sodium salts provide higher percentages of iodine compared to the potassium salts but they are also more reactive and therefore less stable than the potassium salts. Sodium salts of iodine are suitable alternatives to the potassium salts.

2.4 Calcium Iodide and Iodate

In comparison to the potassium and sodium compounds, calcium is much less soluble in water, limiting its applicability. Calcium iodate ($Ca(IO_3)_2$) is not used to a great extent for this reason, even though it is also stable in impure salts (Mannar and Dunn, 1995). There have also been some reports of off-flavours when calcium salts are used, due to the calcium ions, (Kuhajek and Fiedelman 1973 cited in FAO, 1996).

2.5 Permitted Forms

Voluntary addition of iodine is currently permitted to salt at a concentration range from 25-65 mg /kg in Australia and New Zealand in Standard 2.10.2 – Salt and Salt Products. The permitted forms listed are sodium and potassium salts of iodide and iodate. Iodised salt and foods produced with iodised salt are required to be appropriately labelled.

Both iodide and iodate are relatively strong oxidizing agents in comparison to other inorganic anions in foods (Fennema, 1985). There has been concern from industry that the fortification of food with iodine may therefore lead to technical challenges associated with food processing and quality changes in food products in terms of appearance, taste, odour, texture and shelf life. However, the amount of additional iodine in food resulting from most fortification scenarios is typically small.

3 Potential Food Vehicles

3.1 Sugar

The use of sugar as a carrier for iodine was studied in Sudan for use in endemic iodine deficiency cases. Sugar was assessed as a suitable carrier to increase iodine levels across the population. Improvements including decreases in the rates of goitre, and increases in the level of urinary iodine and thyroid hormone values were recorded with no side effects noted.

The iodised sugar was produced by adding iodine to a sugar solution before it was crystallised in an evaporator-crystalliser, or it was sprayed over the cured sugar before being dried (Eltom *et al.*, 1995).

3.2 Oil

Lipiodol is the brand name of iodised poppyseed oil. It is the major alternative to iodised salt for correcting endemic iodine deficiency used in some developing countries, such as Algeria. Single oral doses containing 240 mg of iodine will cover a child for 6 months (Benmiloud, *et al.*, 1994). Lipiodol has also been given during pregnancy to normalise thyroid function of both mothers and newborn babies, increase placental weight and reduce the frequency of iodine deficiency disorders in Algeria (Chaouki and Benmiloud, 1994 cited in Delange and Hetzel, 2004).

Lipiodol has also been used as a single iodised oil injection (4 mL) in treating iodine deficiency in Papua New Guinea, and was found by Buttfield and Hetzel (1967) to remain effective for four and a half years. Iodised oil has a great advantage in that it does not require refrigeration (Delange and Hetzel, 2004).

Untoro *et al* (1998, p 753) reported that iodised peanut oil, which has been used in Indonesia since 1993, has higher iodine retention than Lipiodol due to its higher proportion of monounsaturated fatty acids.

The applications involving iodisation of oils are as supplements rather than as iodisation of oils for use in cooking.

3.3 Liquid Milk

The use of iodophors as equipment sanitisers in the dairy industry contributed to the iodine intake of the human population in the past (Joerin and Bowering, 1972; Sutcliffe, 1990 cited in Grace and Waghorn, 2004). The decline in use of iodophors subsequently lowered the iodine intake of the population (Thomson, *et al.*, 1997). Adding iodine to milk as a direct fortificant poses some technological problems as milk is a single ingredient food with no mixing step. The effects of different pasteurisation times, heat treatments and storage conditions may also affect iodine levels in different liquid milk products.

Two on-farm methods of increasing iodine levels in milk are mentioned in the literature. The first involved supplementing feed with iodine and the second used an intramuscular injection of iodised oil.

Kaufmann and Rambeck (1997) reported that the concentration of iodine in milk increases with the increasing level of supplementation in the feed of the animal, as iodine is readily transported across membranes of the digestive tract. Supplementation with iodine at up to 100 mg produced iodine levels in the milk of 493 +/- 125.3 µg/L and did not change the fundamental sensory properties of the milk.

To avoid large variations in iodine concentrations in milk due to seasonal and regional factors, as well as providing a practical alternative to pasture-fed supplementation, it has been suggested that a long-acting injectable supplement of iodised oil is a viable option (Knowles *et al.*, 2004). Treatment schemes for this method have been outlined by Grace and Waghorn (2004), with a general finding being that multiple injections could maintain iodine concentrations of 60 µg/L for the entire lactation.

Problems associated with increasing iodine levels in milk via supplementation of the animal can include increased costs to the primary producer and the inability to maintain consistent levels between farms. Batches are almost always blended in transport and at the dairy processing plant. The possible variation in iodine levels in different milk products such as whole milk, 2% fat and skim milk may also warrant investigation as iodine salts will dissolve in the aqueous phase but are more likely to promote organoleptic changes in the milk fat.

Milk consumption is not uniform across the population. With some consumers, particularly lactose intolerant individuals, using alternatives to cow's milk, tandem fortification of these products may also need to be considered.

3.4 Rice and Other Grains

Rice has been fortified with other vitamins and minerals such as iron, calcium and B vitamins. Fortification of rice can be problematic as it is most commonly consumed as the whole grain and is often rinsed prior to cooking (FAO, 1996).

Techniques used for addition of nutrients to milled rice products include application of an enrichment 'premix' of vitamins and minerals directly after milling of parboiled rice to aid in adherence of the powder to the grain due to the residual heat and moisture from milling. A major drawback of this method is that subsequent washing prior to cooking leads to losses of 20-100% of nutrients (Hoffpauer, 1992; Hoffpauer and Wright, 1994 cited in FAO, 1996).

There is another method mentioned in literature that involved milled rice soaked in the water-soluble vitamins and an acidic medium. The subsequent cross linking of starch granules lead to initial significant vitamin loss, but increased retention of vitamins during rinsing and cooking (Joseph *et al.*, 1990 cited in FAO, 1996).

Techniques for enrichment of cereals can involve application of powdered premixes or spraying of nutrient solutions followed by drying to the milled grains followed by a coating of a water-insoluble substance as a sealant (Cort *et al.*, 1976; Hoffpauer, 1992 cited in FAO 1996). These methods for fortification have been used in the USA for nutrients including thiamine, riboflavin, niacin, iron, vitamin D and calcium. This sort of application method has been found to be much more stable to rinsing, with vitamin losses of 0.2-1.1%. Problems have been encountered due to discolouration of the grain due to the presence of some vitamins including riboflavin.

Fortification of whole grain cereals with iodine may be problematic as iodine may be present in foods as iodide or iodate, and these are both relatively strong oxidizing agents. As has been found with soluble iron compounds they may reduce shelf life by promoting oxidation of the lipid component of the grain (FAO, 1996). Iodine fortification may also be problematic due to discolouration of fairly neutral-coloured grains such as white rice.

3.5 Salt

Almost all the research, to date, to increase the iodine content of the food supply has involved the use of iodised salt in processed foods rather than direct addition of iodine in its various forms to food. Mannar (1988) as cited in FAO (1996) describes four technologies used in the addition of iodine to salt – Spray mixing, dry mixing, drip feed addition and submersion.

Most commonly, potassium compounds are used to produce iodised salts. Potassium iodide is suitable for use in refined salts, while potassium iodate is suitable for both refined and unrefined (impure) salts without the addition of extra stabilisers and drying agents.

Studies of the stability of iodised salt using potassium iodate showed that on storage in polyethylene bags for two years there was no significant loss of iodine, as well as negligible iodine loss after boiling of the salt solutions (Chauhan *et al.*, 1992; Silveira, 1993 cited in FAO, 1996).

Cheetham Salt Ltd estimated that production related costs, i.e. the costs of iodine and associated analytical testing, would add approximately 5% to the cost of salt to the food industry.

3.5.1 Margarine

An investigation into the use of iodised salt in the manufacturing of processed foods in South Africa by Harris, Jooste and Charlton (2003) found that iodised salt was being used by a proportion of food companies unknowingly in the manufacturing of common processed foods. This provides an indication that iodised salt may not always cause the adverse effects on products such as changes to stability, colour, flavour and taste suggested by manufacturers. This included two margarine manufacturers with a countrywide scale of distribution. The iodine content of the salt used at one manufacturer was found to be, on average, 39 mg/kg which is within the current voluntary iodine fortification levels used in Australia for table salt of 25-65 mg iodine/kg salt.

3.5.2 Cheese

Iodised salt is used in the production of cheese in Switzerland. Hostettler (1953) cited in West *et al* (1995) concluded that iodised salt in cheese production did not affect the quality. Two previous studies involved Emmenthaler and Gruyère cheese in which no difference in quality could be detected. This could be due to the low concentration of iodine effectively present in the product as well as the lack of reporting of differences in cheese quality between different areas of Switzerland that did and did not use iodised salt as a cheese ingredient. Iodine could also be introduced into cheeses by inoculation into cheese milk (Kammerlehner, 1995).

Technological problems can arise when iodine is added to cheeses that are cooked and stretched, for example when used in pizza type cheeses such as mozzarella (*personal communication* Dairy Australia).

3.5.3 Cereals

Cereals and flours are good candidates for iodine fortification as they are used in the preparation of many mixed foods reaching a wide cross section of the population. However, one case has been sited where an off-flavour was produced in a cake mix prepared with iodised salt using potassium iodide. The cresol from the lemon flavouring reacted with the iodide to form iodocresol which has a very low odour threshold (Sevenants and Sanders, 1984 cited in West, de Koning and Merx, 1995).

Many industries report the successful addition of small amounts of iodine to cereals without any significant technical difficulties (Winger *et al.*, 2005). As products such as breakfast cereals, become more complicated and contain a more diverse array of ingredients, the likeliness of an adverse reaction occurring is increased. The type of processing for many different products will also influence the retention of iodine levels in the food and quality. Further studies are needed to confirm the expected iodine losses in specific breakfast cereals as a result of different processing methods.

3.5.4 Bread

Iodine may be delivered into bread by the addition of iodised salt as an ingredient, as a component of the improver mix or by incorporation into the flour. Iodisation of bread has been carried out in the Netherlands and Tasmania by the addition of 2-4 ppm potassium iodate to the bread improver mix which was already in general use. Iodate has been used in bread production in the past, not as a fortificant but to oxidise the sulphhydryl groups of cysteine residues in the protein to disulphide bridges, thus improving dough quality (West, de Koning and Merx, 1995).

The effect of iodised salt on processing characteristics and quality of white bread was investigated by Kuhajek and Fiedelman (1973) cited in FAO (1996). No abnormalities were reported and retention of iodine throughout processing and storage was 50-80%. There were no reported effects on food quality aspects in relation to sensory characteristics.

There is currently a memorandum of understanding between the Tasmanian Department of Health and Human Services with bakeries for the use of iodised salt in bread making in that State. Salt is usually added to bread at 1-2% of the formulation for taste and for technological reasons as salt interacts with cereal proteins. No technical problems with the baking process, including changes to taste, texture or product quality were reported.

There will be losses of iodine during bread processing steps, especially baking. Limited data exists 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 (Winger *et al.*, 2005). 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).

3.5.6 Canned, Cured, Pickled, and Fermented Products.

Wirth and Kühne (1991), as cited by West, *et al* (1995) investigated the effect of iodised salt on quality of meat products in Germany. Table salt in Germany has contained 15-25 mg of iodine/kg from potassium iodate since 1982.

No effects on processing and sensory characteristics of the products tested were reported. These products included pasteurised sausages, fresh sausage (bratwurst), dry cured ham (Rohschinken) and fermented sausage, prepared using iodised table salt. Iodised nitrite curing salt was used in the production of fresh sausage, cooked cured ham, cooked sausage and fermented sausage (salami), with no effect on sensory characteristics or nitrite content noted. The iodised salt had no reported effect on the formation of nitrosamines in those products studied. Losses of iodine during cooking and storage were noted as varying from 25% for bratwurst to 7% for fermented sausage.

Differences in the characteristics of smoked, salted and cured fermented foods produced using iodised salt and those using unfortified salt were investigated by Azanza *et al* (1998) in the Philippines. In general it was found that iodised salt had no effect on the sensory properties of the products as well as no significant effect on pH, water activity or salt levels. Iodine content increased in all products following salting, ranging from 15.89-755.0%. Consequent processing steps including boiling, heating, drying, smoking, curing/fermenting reduced iodine content by 32.75-93.04%. The only exception to this was nitrite-cured pork, where due to the low temperature during curing and gradual salt uptake, the iodine content was reported to continue to increase.

As there is a significant variation in losses and uptake during processing and storage, the use of iodised salt in processed meat products would require substantial shelf life testing of each individual variety. Processed meat products are not consumed uniformly by all Australians and therefore this may not be a very effective vehicle, in terms of cost to industry or in terms of increasing iodine status in the general population.

3.5.7 *Pickled Vegetables*

Amr and Jabay (2004) reported that iodization was seen to have no effect on the flavour of pickles, but the form of iodine used affects the appearance in terms of darkening and discolouration, as well as the degree of softening. These negative effects occurred with most pickled vegetables when potassium iodate (KIO₃) was used but none were noted when potassium iodide (KI) was used. The final concentration of iodine in the pickled vegetables was the same regardless of the type of salt or form of iodine used. The source of the salt used in pickling vegetables, from the Dead Sea or a natural brine well and whether refined or crude salt was added resulted in minimal effects on the sensory evaluation results.

Doman *et al* (1999) reported on the effect on quality of fermented cabbage using different concentrations of potassium iodide in iodised salt. There was no reported change in quality with potassium iodide used in concentrations up to 6.0 mg/kg. Quality was found to be no different in terms of microflora composition, lactic acid production and sensory properties after seven days of production and ninety days storage.

Therefore, if iodisation of pickled vegetables was to be used as a tool to increase the iodine status of the population, potassium iodide would probably be the preferred form as there would be lesser detrimental effects on the quality of the product.

3.5.8 *Canned Products*

The effect of iodised salt used in some canned products is discussed by West, de Koning and Merx (1995).

Experiments using canned vegetables, soup and baby food showed there to be no effect on the product or the can itself. One exception reported the initial production of an objectionable flavour in canned pork and beans that receded during extended storage.

A previous study by Kojima and Brown (1955) cited in West, de Koning and Merx (1995) on the effect of iodised salt using potassium iodate and iodide on canned fruit and vegetables also concluded that there was no effect on sensory characteristics, colour, flavour, odour or texture.

The use of iodised salt in canned products may be an effective vehicle for iodine, but the effectiveness of delivery of canned foods to the iodine deficient population is not known.

4.0 Iodine Fortification and the Food Industry

4.1 Storage

Studies of the stability of iodised salt using potassium iodate showed that on storage in polyethylene bags for two years there was no significant loss of iodine (Chauhan *et al.*, 1992; Silveira, 1993 cited in FAO, 1996). The stability of iodine in salt is determined by the form of iodine used. Iodate is more stable than iodide, without the addition of extra stabilisers and drying agents. The purity of the salt and the climatic conditions it is stored in can also affect storage. Oxidation of iodine occurs if storage conditions are either humid or highly aerated; involve exposure to sunlight or heat; allow for the presence of impurities or moisture in the salt; or if there is an acidic environment.

4.2 Processing Interactions

It is important to consider the interaction of iodine with other constituents of food, including the role that any naturally-occurring goitrogens may play in the bio-availability of the iodine once digested.

A manufacturer may be required to spend time and money investigating the levels of iodine retention in a product throughout processing and the complete shelf life. The effect of certain processing techniques, including different times and temperatures to achieve pasteurisation, may affect iodine levels.

4.3 Analytical Testing and Quality Control

Manufacturers would be responsible for the validation of levels of iodine in their products to ensure accuracy and consistency. This would be an on-going additional cost. The establishment of quality control procedures in relation to both natural iodine concentration and added iodine salts will also be required within quality assurance programs.

Many different analytical testing methods have been used in different studies with different food products, such as the potentiometric titration method used to quantify the amount of iodine in salt. Standard methods would be required as well as the establishment of monitoring programs by regulatory bodies.

4.4 Labelling Requirements

There will be labelling costs associated with iodine fortification of processed foods. There has been some concern expressed by the food industry in relation to the requirement to include 'iodised' in the product name which may prove problematic considering definitions of products in food legislation. Increased costs to industry in relation to modification of labels / packaging to include fortificant in ingredients list and name of product would not be an on-going cost after the initial change.

5.0 Conclusion

There has been some concern expressed by industry about the effect that the addition of iodine will have on product quality. From this review of literature there have been many cases of successful fortification of foods with iodine with few reported effects on organoleptic qualities.

Salt has been extensively used as a vehicle for iodine fortification. With the widened use of iodised salt in food processing a variety of foods could provide a source of iodine, and may prove beneficial in improving the iodine status of the population. The use of iodised salt in a number of processed foods has been considered in this review, with almost all studies reporting no effect on product quality dependant on source of iodine used.

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Summary of Submissions to Draft Assessment Report

In September 2006, FSANZ received **68** submissions in response to the Draft Assessment Report for Proposal P230 – Consideration of Mandatory Fortification with Iodine. Seventeen submissions were from New Zealand, 45 from Australia, two from the United States, two bi-national, one German and one unknown. A summary of submitter comments is provided in the table below.

The two options proposed at Draft Assessment to reduce the prevalence of iodine deficiency in Australia and New Zealand included:

Option 1 – Maintaining the *status quo*; and

Option 2 – The mandatory replacement of salt with iodised salt in bread, breakfast cereals and biscuits, with a salt iodisation level of 20-45 mg of iodine per kg of salt.

Key Issues Identified from Submissions

1. Regulatory options

1.1 *Maintaining the Status Quo*

Those in favour of maintaining the *status quo* expressed concern about a range of issues associated with mandatory fortification, including:

- the proposed fortification scenario uses a population-wide approach for the benefit of a small sub-group of the population;
- adverse effects resulting from increased amounts of iodine in the food supply, especially for those with a history of thyroid disorders;
- iodine supplements will still be required by pregnant and lactating women;
- consumer choice is reduced; and
- the impact on organic bread as the addition of synthetic substances is not permitted.

Those against maintaining the *status quo* noted the urgent need to address the re-emergence of iodine deficiency in the population and the limited effectiveness of the current voluntary iodine permissions.

1.2 *Proposed Mandatory Fortification Scenario*

Those supporting the mandatory fortification scenario acknowledged the significance of health effects associated with mild to moderate iodine deficiency in parts of Australia and New Zealand. Mandatory fortification was considered to be more effective than voluntary fortification in reaching a broad spectrum of the population, particularly disadvantaged groups which may not respond to education and supplementation.

Some submitters were aware that the proposed mandatory scenario may create small manageable risks, but believed the risks would be outweighed by the public good.

It was also noted this fortification scenario would not reach the 1% of the population with coeliac disease and would be insufficient to meet the needs of pregnant and breastfeeding women.

Several submissions were opposed to mandatory fortification, due to the restriction of consumer choice, and considerable trade impacts, especially for biscuits. Industry submitters noted that the success of the Tasmanian iodine supplementation program and other overseas voluntary iodine fortification programs highlighted that voluntary fortification is a viable alternative. Opponents to mandatory fortification suggested it was not an appropriate response, given the variable prevalence of iodine deficiency in Australia. Technological issues were raised, including the impact of iodised salt on products with a long shelf life and different processing methods. The consequence of using iodised salt in products classified as 'natural' and 'organic' was also raised.

2. Alternative Suggestions for Addressing Iodine Deficiency

2.1 Extension of Current Voluntary Fortification Permissions with a Memorandum of Understanding with Industry

Industry submitters favoured this voluntary approach, stating it had been effective in Tasmania, allowed for consumer choice, had no WTO implications and is consistent with national policies and guidelines. It was suggested this could be applied regionally, and added to products most suited to the target group. There was also support for appropriate education and awareness campaigns for industry and consumers and a Trans-Tasman monitoring program for urinary iodine status in the target population.

2.2 Universal Salt Iodisation

A number of public health submitters believed that the proposed mandatory fortification scenario delivered insufficient amounts of additional iodine and that FSANZ had been overly constrained by not wishing to exceed the UL for young children. Submitters recommended Universal Salt Iodisation (USI) believing it to be more effective than the proposed scenario and consistent with the WHO position on iodine fortification.

3. Food Vehicles

There was a range of views concerning the appropriateness of using iodised salt in bread, breakfast cereals and biscuits. As salt is widely consumed by the population, several submitters recognised iodised salt as an effective source of iodine. Some submitters noted the large variation in salt content, and hence iodine content, in the three different food vehicle categories, for example 25% of breakfast cereals do not contain salt and there are large variations in the salt content of biscuits.

Others expressed concern that promoting iodised salt conflicts with national and international nutrition guidelines to reduce salt intakes and introduces conflicting health messages. There was considerable support for bread as a suitable vehicle, with research showing that < 3% of people don't eat bread.

Many who supported mandatory fortification questioned the inclusion of products with a high fat, sugar or salt content (e.g. biscuits), which are not in line with nutritional guidelines, especially with the current increase in obesity. In addition, dietary modelling showed that biscuits contributed only a minimal amount of iodine and removal would resolve the problem of requiring all imported biscuits to be fortified with iodine.

Those against mandatory fortification recommended extending voluntary permissions to all processed foods and developing a MOU with industry. Several industry submitters called for other core food vehicles to be considered or the extension of voluntary permissions to other foods, for example milk and milk products, bread improvers or bread making flour. Some questioned the suitability of bread as the best vehicle, citing a recent Newspoll survey which showed that not all women regularly consume bread.

4. Safety and Efficacy

There was general recognition for the potential adverse health outcomes associated with mild and moderate iodine deficiency in unborn babies, children 1-3 years and adults. The difficulties of obtaining adequate iodine from the food supply alone without fortification was noted and there was support for replacing non-iodised salt with iodised salt. Some acknowledged that any possible adverse effects associated with fortification could be addressed through monitoring, community education and medical management.

Those against mandatory fortification questioned the need to subject the whole population to mandatory fortification when some states already have an adequate iodine status. A number of submitters believed that this proposal would be insufficient to meet the needs of pregnant and lactating women.

A number of submissions noted health concerns relating to increasing iodine intake in individuals with a pre-existing thyroid conditions and the risk of young children exceeding the UL for iodine. Others believe that FSANZ's use of the UL for young children is too conservative and should be based on the higher FAO/WHO recommendation.

5. Level of Fortification

There was support for a single level of fortification for table salt and commercial salt to avoid complexity and confusion in manufacturing, monitoring and enforcement. Several submissions noted the need for higher levels of salt iodisation to address overall trends to reduce salt intakes, especially in some sections of the population.

Public health submitters noted the wide variability in the salt content of bread, breakfast cereals and biscuits. They noted that individuals choosing low salt products, in line with health recommendations, would receive less iodine. They also commented that lower cost products typically contain higher levels of salt. An outcome-based standard was suggested to minimise this discrepancy, or to mandate a higher level of salt iodisation for use in low salt bread.

6. Consumer Choice

There was strong opposition to mandatory fortification in New Zealand due to the removal of consumer choice. It was thought that mandatory fortification of bread would alter the perception of bread as a wholesome health product.

Unleavened bread and salt-free bread, biscuits and cereal were not considered to be appropriate alternatives due to their increased cost. New Zealand submitters considered exempting heavy health bread from the fortification scenario would offer a more appropriate alternative to fortified bread than unleavened bread and salt-free cereal.

In contrast, some submitters considered that consumer choice is less vital when fortifying a food supply to restore a nutrient to adequate levels and correct deficiency in the population.

7. Impact of Fortification on Industry

Those in support of mandatory fortification believed the benefits far outweighed the small cost to substitute iodised salt for non-iodised salt in bread, breakfast cereals and biscuits. Preliminary advice from the bread industry confirms that the use of iodised salt does not pose any technical difficulties. However, storage trials have not been conducted to determine the stability of using iodised salt in products with a long shelf life, for example breakfast cereals.

Industry concerns raised in submissions included:

- cost involved and time required to make labelling changes;
- cost of maintaining two salt supplies to meet requirements for export to Japan;
- barriers to export markets and potential loss of export earnings due to consumer preference for unfortified products;
- potential product liability issues for manufacturers should there be any adverse health outcomes for consumers;
- one breakfast cereal manufacturer identified technical issues in using iodised salt due to their specific manufacturing practice; and
- technical difficulties with iodisation of coarse salts used for toppings and coatings.

8. Trade

Those opposed to mandatory fortification considered that this Proposal would be seen as a technical barrier to trade and may result in a breach of the WTO. The level of salt iodisation proposed was also considered to be trade restrictive, as various countries have different levels of salt iodisation. The complexities for companies that produce products for the domestic market and Japan were noted, as any product containing iodised salt is not permitted to be imported into Japan.

The impact on trade is likely to be greater for New Zealand as it is a larger importer of biscuits and exporter of cereal-based products than Australia. If challenged under the WTO, New Zealand would need to demonstrate that it is the least trade restrictive measure to address iodine deficiency.

9. Labelling and Claims

Several submitters were concerned that salt as a food vehicle creates conflicting health messages and encourages manufacturers to maintain or increase salt levels. Many were opposed to the use of an iodine claim but some wanted the iodine content to be included in the Nutrition Information Panel (NIP). Industry submitters supported a review of current prohibitions on making iodine content claims on a wider range of products containing at least 10% of the RDI for iodine.

Baking industry submissions expressed concern about the status of the descriptors of 'organic' and 'natural' with respect to fair trading legislation and the impact of mandatory fortification on the 'perception' of bread as 'wholesome' and 'healthy'.

10. Current Salt Permissions

The majority of submissions supported retaining the current voluntary permission to use iodised salt in the manufacture of foods. Consumers may be confused if iodised table salt is no longer available but present in bread. The voluntary permissions may also provide iodised alternatives for those who are unable to or who choose not to consume bread, breakfast cereals and biscuits. It would also assist manufacturers of bread, biscuits and breakfast cereals who co-process multiple food items with a single supply of salt.

The New Zealand dietary guidelines would need to be changed if the voluntary permissions for salt iodisation were removed.

11. Use of Salt in Non-Mandated Foods

Industry submitters advised that small to medium-sized businesses may encounter difficulties in handling more than one supply of salt. Iodised salt may be used in place of normal salt in all products at a particular production site where there is a mandatory requirement to use iodised salt. This could result in higher population intakes of iodine than anticipated under the fortification scenario.

12. Implementation and Transition Period

Industry submitters considered that 12 months is not achievable for labelling and packaging changes to be implemented. A transition period of at least 24 months was recommended to minimise costs and to allow alignment with other regulatory changes.

Submitters suggested consulting with industry prior to developing an Implementation Guide. It was recommended that the Guide be available well in advance of changes to the Code coming into effect. It should include clear definitions for bread and biscuits, and clarification of other products e.g. bread crumbs, coatings and sprinkles. A number of submitters considered that gluten-free products should be included in the definition for mandatory fortification.

New Zealand recommended that consideration be given to the inclusion of separate, but mirror standards in the Code to ensure that New Zealand can proceed, in the event that further work is required by Australian jurisdictions.

New Zealand also noted the requirement for the transitional period to extend until July 2008 when the legislation requiring food exports to comply with the Code will be amended.

13. Cost/Benefit Analysis

Industry submitters noted uncertainties around the economic benefits of mandatory fortification. They considered that their alternative voluntary approach would deliver the desired outcome without incurring excessive costs to all parties and would maintain consumer choice. Submitters noted the conclusion of the Cost Benefit Analysis (CBA), which suggested exploring an alternative proposal which embraces all the potential benefits or finding another vehicle which better targets those in need, including those in geographic areas of Australia where iodine deficiency was identified. Other submitters disagreed with this conclusion and considered the mandatory fortification is the most effective option at this time.

A number of submitters identified the following issues relating to the CBA:

- the cost of reduced consumer choice was not included;
- the cost to industry if consumers avoid fortified products was not incorporated;
- the costs to industry are grossly underestimated in relation to label changes and potential write off of packaging with the 12 month framework;
- the government costs for health promotion, education, monitoring and surveillance are underestimated; and
- the costs of anti-discrimination action by those who are adversely affected by mandatory fortification are not included.

14. Monitoring and Compliance

The majority of submitters considered a Trans-Tasman coordinated monitoring program a fundamental component of any mandatory fortification proposal. This should include monitoring of health outcomes, nutritional status, food composition and industry compliance. Submitters supported a coordinated commitment from relevant agencies to allocate funding, collect baseline data and review current food composition databases before implementation. Monitoring of iodine status and iodine intake should be integrated into a broader nutrition monitoring and surveillance system to ensure that monitoring is ongoing and sustainable.

Some opponents to mandatory fortification considered that the geographic diversity in iodine status has the potential to produce inconsistent implementation, compliance and enforcement outcomes. A number of submitters believed there should be an evaluation of thiamin fortification to ascertain effectiveness, benefits and costs before implementing mandatory fortification with iodised salt.

15. Communication and Education

The majority of submitters acknowledged the need for a coordinated, ongoing education and communication campaign.

Several submitters noted the lack of awareness amongst consumers as to the need for additional iodine. Key messages need to be developed to ensure that pregnant and lactating women take supplements in addition to iodine fortified food. Some submitters suggested a combined health promotion strategy for folic acid and iodine fortification.

A variety of mediums appropriate to the target audience would be required to reach key medical and other health professional organisations, and women who consume few or no iodine fortified foods. Public health and consumer submitters noted the importance of clear, relevant and positive messages to ensure that some groups do not lose trust in food quality with mandatory fortification. Submitters suggested working with specific cultural groups to ensure messages, resources and distribution strategies are culturally appropriate to reach at risk groups. Targeted education is also required for those with iodine related health conditions, their medical practitioners and relevant community support groups.

Industry submitters supported an awareness campaign to raise and maintain awareness with industry of the need to use iodised salt in food manufacture. Industry groups believe they should be permitted to support government initiatives by communicating the benefits of iodine on food labels.

16. Dietary Intake Assessment

A number of submissions considered that uncertain, inadequate and out of date data had been presented as evidence of iodine deficiency in Australia and New Zealand. They believed further evidence of urinary iodine excretion tests is required before considering mandatory fortification. The lack of food consumption data on regions within states was noted, for example for indigenous groups, and for specific groups who may consume quantities of high iodine foods e.g. seafood/bread/salt e. Several submitters questioned the dietary modelling undertaken by FSANZ to select the most appropriate food vehicles and the level of fortification.

The New Zealand Ministry of Health raised a number of concerns regarding the iodine intakes of 1-3 year olds which are inconsistent with New Zealand data for South Island children aged 6 – 24 months. Their submission also questioned the dietary exposure assessment of iodine in formulated supplementary foods for young children.

17. Consistency with Policy Guidelines

Several submitters considered that the proposed mandatory fortification scenario was not consistent with the Ministerial Policy Guideline as the health need had only been demonstrated in two States, not for the whole Australian population. In addition, mandatory fortification with iodine had not been demonstrated to be the most effective public health strategy. Some submitters considered the inclusion of biscuits and all breakfast cereals as suitable food vehicles to be contrary to the national nutrition guidelines. They also considered that the proposed scenario would result in excess or imbalance for some population groups and that it is impossible to assess whether sufficient amounts of iodine will be delivered to the target population.

Those against mandatory fortification recommended a sunset clause be included to ensure the effectiveness of the intended initiative based on formal monitoring of dietary intakes and health effects.

SUBMITTER	SUBMISSION COMMENTS
<p>Australian Consumers' Association (ACA) Australia Clare Hughes</p>	<p>Provisional Support for Option 2 - does not support changes to iodine permissions without a firm commitment to monitoring and evaluation.</p> <ul style="list-style-type: none"> If the health implications from iodine deficiency are significant to warrant fortification, ACA prefers mandatory rather than voluntary fortification as this allows a more strategic approach to increasing consumption. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Considers mandatory fortification is more appropriate than voluntary. Success with voluntary fortification depends on the food industry, whereas mandatory fortification will be driven through careful consideration by health experts. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Believes bread-making flour is appropriate, but is concerned that fortification of cereals and biscuits could allow foods high in sugar, saturated fat and kilojoules to be fortified. This could legitimise the consumption of these foods. Need to ensure manufacturers do not increase the use of salt in processed foods in order to increase iodine levels. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Considers the word 'iodised' should appear on the product description, and be listed in the ingredient list. Foods fortified with iodine should not be permitted to carry health claims. <p><i>Implementation</i></p> <ul style="list-style-type: none"> Supports an incremental increase in the amount of iodine added to minimise effects of immediate increases in iodine consumption for susceptible individuals. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> ACA is not aware of a firm commitment of funding or other resources for monitoring and their support for Option 2 is dependant on this. Monitoring of iodine in the food supply, iodine consumption including excess consumption, and the impact on public health will be needed. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Any intervention to fortify the food supply must be accompanied by an awareness campaign including health benefits, food sources and the rationale for fortification.
<p>The Coeliac Society of Australia Inc Australia Graham Price</p>	<p>Supports Option 2 – Mandatory iodine fortification</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Supports mandatory fortification of bread, breakfast cereals and biscuits. Seeks clarification of whether definition of bread, cereals and biscuits includes all products or just mainstream products? Recommends gluten-free specialty products be included in definition as one in 100 people in Australia may have coeliac disease and would benefit from a mandatory fortification standard.
<p>Consumers Institute New Zealand Belinda Allen</p>	<p>Supports Option 2 - Mandatory iodine fortification</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Considers the significant iodine deficiency in NZ and parts of Australia will only be addressed by mandatory fortification of the food supply.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Supports the requirement that manufacturers must list iodised salt in the ingredient list to ensure consumers are informed about what is in food. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> • Considers the current voluntary iodine permission for salt should be retained. Believes there will be confusion for consumers if it was no longer available. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Essential that there is a well funded monitoring system in place which includes monitoring the food supply as well as iodine levels in the population. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Notes the Draft Assessment Report suggests iodine supplements be recommended for pregnant women. There needs to be a consistent message from the Ministry of Health and health professionals around the need for supplements in pregnancy. • The communication strategy should carefully consider the impact of mandatory iodine fortification alongside mandatory folic acid fortification, especially among pregnant women who are a key target group for both strategies.
<p>FSANZ Consumer Liaison Committee Australia Brenda Cook</p>	<p>Supports Option 2 – Mandatory iodine fortification (Member of the FSANZ Consumer Liaison Committee)</p> <ul style="list-style-type: none"> • Believes high acceptance of Proposal by consumers. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports mandatory fortification of bread, breakfast cereals and biscuits. • Selected food vehicles are in line with Australian Guidelines for Healthy Eating (except sweet biscuits and sugar-based breakfast cereals). • Notes difficulty to obtain adequate iodine from food supply alone without supplementation. • Not all consumers eat seafood, dairy or seaweed and use of iodised salt is low (approx 10%) (main food sources of iodine). • Notes dairy products no longer contain iodine based sanitisers. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Is aware of results of the National Iodine Nutrition Study and acknowledges mild to moderate iodine deficiency in Australia and NZ. • Notes far reaching affect of iodine deficiency in the unborn, children 1-3 years and thyroid function/disease in adults. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Notes importance of consumer choice for those who need to avoid high levels of iodine or who wish to avoid fortified or ‘unnatural’ food. • Consumer choice is maintained through salt-free options. • Concern consumer choice compromised if all bread making flour contains folic acid and iodised salt is used. • Concern about the perception of organic or ‘natural’ products and the possibility of obtaining an ‘exemption’ from mandatory fortification requirements. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Can manufacturers exporting products to Japan apply for an exemption?

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Suggests a combined health promotion strategy for folic acid and iodine fortification to highlight importance in the diet. • Incorporate a strategy to replace salt with iodised salt in cooking and at the table without increasing salt intake. • Supports ongoing health promotion and education strategies targeted at pregnant / breast feeding women and young children. • Seeks clarification whether nutrition is included in ante-natal classes and whether the importance of folic acid and iodine in the diet is discussed. <p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • Encourages further voluntary fortification of dairy products aimed at children e.g. cheese sticks.
<p>Kahui Kounga Kai (FSANZ Maori Reference Group) New Zealand</p>	<p>Supports Option 2 – Mandatory iodine fortification</p> <ul style="list-style-type: none"> • Considers the benefits of mandatory fortification far outweigh any disadvantages for Maori. • Kahui Kounga Kai wish to have ongoing input into the Proposal to ensure the iodine message reaches Maori in an appropriate way. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Notes there is very little Maori specific data available which will limit ability to determine the impact on the Maori population. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Notes the importance of including input from the Maori reference group when planning monitoring. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Considers the 12-month transition period will allow time for consumers to be informed. • Provides advice for communicating with Maori : <ul style="list-style-type: none"> – need to emphasis that salt is already widely used in bread, cereals and biscuits and fortification with iodised salt will not increase salt intake, or alter taste; – presentation of information and language used should be kept simple to avoid mixed messages; and – current FSANZ format, language and presentation could raise suspicion and question whether other additives are also being added to food. • Kahui Kounga Kai offer assistance with determining resources for communicating with Maori and advise: <ul style="list-style-type: none"> – messages should equate to something tangible Maori can identify with; – the use of current networks with facilitators to reach Maori stakeholders; and – the word deficiency be changed to a more positive term to focus on wellness. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Notes the adult nutrition survey has no breakdown of the Maori population. • Raises two points: <ul style="list-style-type: none"> – has any research been undertaken on what is an excessive level of iodine given the large intake of kaimoana (seafood), bread and salt by Maori?

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> - there is a need for more data on Maori consumption patterns and statistics.
<p>National Council of Women of New Zealand New Zealand Lynda Sutherland</p>	<p>Appears to support Option 2 – Mandatory iodine fortification, (though not stated)</p> <ul style="list-style-type: none"> • Stated ‘Many were shocked at the results of plain salt usage that are starting to reappear’ and reference to ‘the ‘bad old days of elder relatives with horrible goitres’. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Notes the damage to infants due to iodine depletion. • Concern expressed about the re-emergence of goitres with usage of plain salt. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports fortification of all processed food to reach sections of the population who mainly eat prepared food e.g. takeaway, tinned or frozen. • Supports fortification of tinned infant food as a priority. • Suggests that ‘biscuits’ are too inclusive a name and should be replaced with ‘and other bakery items’. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Supports the importance of labelling and noted that not all consumers are literate. • One group suggested using a ‘heart tick’ though not all agreed which may have been related to ethnicity. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Suggests governments should address if non-iodised foods should be imported into Aust and NZ. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • A small rural group noted that small companies used iodised salt while larger companies used non-iodised salt. • Majority support removing voluntary iodine permissions, but some expressed concern about the availability of un-iodised salt for home preserving and pickling. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Support health promotion for general population. • Suggest special consideration when dealing with Pacific Island groups. • Concern that many younger people are not aware of this issue. • Need to address the trendy fashion of food gurus advocating sea salt. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Concern re additional cost to consumers, but that health issues are more important.
<p>Patricia Abbott Private Australia</p>	<p>Supports Option 1 - Maintaining the <i>Status Quo</i></p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned that mandatory fortification with iodine will seriously impact on the health of those with thyroid cancer as many foods will have to be avoided. Advises consultation with cancer specialists to assess the impact on this group. • Notes others can add iodised salt, but thyroid cancer patients cannot take iodine out.

SUBMITTER	SUBMISSION COMMENTS
Keith Beatty Private USA (Biochemist)	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> States <i>Don't mess with nature's food supply</i> Family has congenital hyperthyroidism with variable expression and so have concerns about adverse effects from increasing iodine. Self reported adverse effects after consuming one teaspoon of kelp, for example, hands perspired, increased tremors, and increased bruit. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> Suggests congenital hyperthyroidism with low protein bound iodine is normal for some genetic groups and could be a genetic response to cold adaptation (higher BMR in absence of iodine for land locked populations in cold climates).
Patricia Berry Private Australia	<p>Preferred option not stated</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerned that for those taking thyroxine the suggested change will affect their medication dosage. If the Proposal is implemented this must be well advertised so that those taking thyroxine are aware they may have to adjust medication as a small amount can adversely affect health. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Questions why iodine needs to be added to biscuits – considers this unnecessary. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Would like to maintain a choice whether to eat food fortified with iodine; would prefer unfortified bread to be available. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Targeted education would be necessary for those taking thyroxine medication.
Catherine Dart Private Australia	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Expressed concern that iodine can increase metabolic rate that can cause a whole new set of problems. Iodine levels in Australian population not sufficiently deficient to take this action. Dangers of iodine toxicity should be outlined. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> People have the right to make informed choices about their diets and their lives. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Supports education as the preferred approach. <p><i>Other issues - claims</i></p> <ul style="list-style-type: none"> Believes iodised products would just be used as a new marketing hype.

SUBMITTER	SUBMISSION COMMENTS
Leonie Huntsman Private Australia	<p>Supports Option 2 – Mandatory iodine fortification</p> <ul style="list-style-type: none"> States ‘I strongly support this Proposal which will cost so little and prevent so much misery’.
Patricia Li Private	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <ul style="list-style-type: none"> Not entirely opposed to the proposal but considers voluntary use of iodised or non-iodised salt by manufacturers a better option. <p><i>Consumer choice/food vehicle</i></p> <ul style="list-style-type: none"> Believes it will be very difficult for consumers to select salt free options to avoid iodine as choices will be limited. Considers voluntary use by manufacturers of iodised or non-iodised salt would provide non-iodised options for the consumer. There could be greater advertising of high iodine foods such as seafood.
Eileen McEwan Private Australia	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <ul style="list-style-type: none"> Considers mandatory fortification an ‘overkill’ given not all parts of Australia suffer from iodine deficiency. Noted a total of 44% overall supported mandatory fortification at the Initial Assessment Report, with support primarily from health professionals. Considers the preferred option is inconsistent with a participatory democracy and where high literacy levels mean consumer education can be effective, if costly. Considers mandatory fortification sets an unhealthy precedent. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerned at the scant attention in the Draft Assessment Report given to the effects of over-consumption, particularly iodine induced hyperthyroidism for sufferers of Grave’s disease. Considers mandatory fortification creates dangers for those at risk of hyperthyroidism and marginalises them as member as of society by limiting healthy food choices and requiring them to scrutinise food labels. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Concerned with the limited and inferior choice, limited distribution and potentially inflated price of foods that will be available for those needing to avoid iodine fortified products e.g. those with Grave’s disease. Considers insufficient consideration has been given to those with Grave’s disease. <p><i>Implementation</i></p> <ul style="list-style-type: none"> There is too little detail provided on implementation e.g. some States and Territories do not need iodine supplementation. <p><i>Other issues</i></p> <ul style="list-style-type: none"> Considers an education programme on iodine deficiency, combined with funding for industry to modify their equipment would allow industry to develop iodine fortified options in a variety of food.
Patricia St John Private New Zealand	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <ul style="list-style-type: none"> Objects to mandatory fortification with iodine. Has a direct interest in the issue as was diagnosed with autoimmune thyroid disease 11 years ago.

SUBMITTER	SUBMISSION COMMENTS
	<p data-bbox="389 232 568 259"><i>Safety and efficacy</i></p> <p data-bbox="389 273 628 300">Expresses concern about:</p> <ul data-bbox="389 313 1206 1321" style="list-style-type: none"> <li data-bbox="389 313 1206 577">• the uncertain and inadequate data presented as evidence of a mild to moderate deficiency of dietary iodine in NZ and Australia. Notes the Access Economics report refers to lack of relevant data making assessment difficult. Considers further evidence such as urine iodine excretion tests is needed before any mandatory fortification is even considered. Refers to the limitations in dietary surveys noted by FSANZ. Understands more recent surveys have been undertaken but are not included. Considers no evidence has been presented for the existence of iodine deficiency in either country. Considers the experience cited in poor and undeveloped countries is not applicable to NZ or Australia. Considers severe and long lasting iodine deprivation is required before thyroid function is compromised. <li data-bbox="389 591 1206 694">• the lack of investigation into the cause of iodine insufficiency over the last 10-15 years. Suggests the increase in soy products may be a potential cause, as soy is goitrogenic and has adverse effects on thyroid function. Notes many breads and margarines contain soy. Also notes the use of soy based infant formula. <li data-bbox="389 707 1206 842">• the considerable health risk with the proposal, noting a large increase in mainly transient iodine induced hyperthyroidism and hypothyroidism is expected. Notes Access Economics has not been able to include associated costs in its cost benefit analysis (CBA). Notes only two countries have attempted fortification and monitoring has proved difficult. <li data-bbox="389 855 1206 904">• Concerned at the number of people in NZ and Australia who are likely to be affected by mandatory fortification. <li data-bbox="389 918 1206 1187">• Believes the impact on those with existing autoimmune thyroid diseases will be considerable as iodine exacerbates these diseases. Considers the proposal unsatisfactory and often misleading in this area. Provides figures on incidence of autoimmune thyroid disease. Most thyroid diseases in the developed world are caused by an autoimmune disorder. Notes the underlying mechanisms for the disease process are not understood. Notes the prevalence of such disease is more frequent in countries where dietary iodine is high. Discusses chronic autoimmune thyroiditis. This condition is exacerbated by high iodine intake and by foods such as soy which have an adverse effect on thyroid function, making it difficult to maintain the steady state which is the aim of treatment. <li data-bbox="389 1200 1206 1249">• Considers young children and adults in some areas of Australia will be in danger of exceeding the safety limits for iodine intake. <li data-bbox="389 1263 1206 1321">• Notes pregnant women may be at increased risk of thyroid dysfunction and there may be a risk to the foetus and neonates. <p data-bbox="389 1335 555 1361"><i>Consumer choice</i></p> <ul data-bbox="389 1375 1206 1559" style="list-style-type: none"> <li data-bbox="389 1375 1206 1402">• Does not believe NZ manufacturers will provide alternative product lines. <li data-bbox="389 1415 1206 1464">• Believes the supply of unfortified breads and cereals is likely to be inadequate and very expensive. <li data-bbox="389 1478 1206 1559">• Recommends that if mandatory fortification proceeds, niche breads and unwrapped breads from small bakeries be exempt from fortification as they usually do not use soy flour and are therefore important for those affected by both soy and iodine. <p data-bbox="389 1572 660 1599"><i>Monitoring and enforcement</i></p> <ul data-bbox="389 1612 1206 1662" style="list-style-type: none"> <li data-bbox="389 1612 1206 1662">• Information is lacking on how monitoring will be carried out. Difficulties experienced in Denmark are not encouraging.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Other issues</i></p> <ul style="list-style-type: none"> • Before any mandatory fortification is undertaken, a deficiency sufficient to warrant fortification of all basic cereal based food stuffs should be established. • Random sampling and testing of school children is considered an adequate marker of iodine status of any given population. If deficiency is detected then ultrasonography and blood tests should follow. • If a significant deficiency is established, voluntary fortification of some cereal foods might be a more sensible and less costly approach.
<p>Liz Sanzaro Private Australia</p>	<p>Appears to support Option 2 – Mandatory iodine fortification</p> <ul style="list-style-type: none"> • States ‘I am not one for the notion of fiddling with our food’ but also states ‘I am far more likely to be persuaded that the fortification of our regular food items with iodine is necessary.’ • Does not support mandatory fortification of cereals with folic acid or calcium in fruit juice or other manipulation of food in general. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Family predisposition for the reduced TSH synthesis (submitter and both parents on thyroid replacement therapy) • States that iodine deficiency is a reality for many Australians. • Notes that recorded incidence has increased recently. • Notes that a significant number of females in mid to later years are affected by hypothyroidism, possibly caused by low dietary iodine intake. • Is aware of a disproportionate number of people in her community with swollen thyroid glands, or thyroid gland nodules (needing surgical removal) or pregnancy induced goitre.
<p>Lai Ho Seet Private Australia</p>	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <ul style="list-style-type: none"> • Supports enhanced education on food choices to increase iodine intake. • Submits from personal experience of Grave’s disease. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considers it ‘fruitless’ to add iodine when data does not indicate a local deficiency e.g. Perth / Western Australia. • Concerned as Grave’s disease worsens with excessive iodine. Considers the risk of hidden iodine in food for those with hyperthyroidism is too great compared with the prevention of potential cretinism, which is not seen in developed countries with good education and low poverty. • Concerned that excessive iodine supplementation may lead to hypothyroidism and thyroiditis. • Concerned those with hyperthyroidism will worsen with excess iodine. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Freedom of choice important. Considers it unfair to be forced to have different food to the family. Notes salt-free bread, biscuits and cereals from specialty stores are more expensive. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Education of the target group would be more useful than the addition of iodine to bread, cereals and biscuits e.g. potential mothers and parents of toddlers.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Other issues</i></p> <ul style="list-style-type: none"> • There is more iodine in many diets than ever before with cultural diversity and more people consuming a southeast Asian diet. • Notes the role of soy products as a possible modern cause of hypothyroidism rather than lack of iodine. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Considers WHO data outdated and limited. Believes Australia cannot be compared to third world countries with high rates of poverty.
<p>Leah Voysey Private Australia</p>	<p>Support option not stated - but concerned about mandatory iodine fortification</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned at ‘medicating’ the whole community when this could be harmful to those with autoimmune hyperthyroidism, especially as it is well documented that women in pregnancy or following childbirth can develop hyperthyroidism. • Refers to adverse reactions to supplements containing iodine and foods containing high levels of iodine in those with Grave’s disease. • Queries whether education has been considered fully as a viable part of an alternative strategy.
<p>Francine Worboys Private Australia</p>	<p>Preferred option not specified.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned about the effect of adding extra iodine to the diet for those with hyperthyroidism. Asks if this has been considered when proposing mandatory fortification.
<p>Australian Food and Grocery Council (AFGC) Australia David Roberts</p>	<p>Supports a modified Option 1 - with a Memorandum of Understanding (MoU) with industry for the voluntary use of iodised salt in food manufacture.</p> <p>This would be combined with:</p> <ul style="list-style-type: none"> • an industry awareness campaign promoting the need for iodised salt in food manufacture; • a consumer education campaign aimed at the target population; and • Trans-Tasman monitoring programme for urinary iodine status in the target population. <p><i>Features of the alternative approach (above):</i></p> <ul style="list-style-type: none"> • Shown to be effective in Tasmania and internationally; • Promotes consumer choice; • Has no WTO implications; • Allows those with coeliac disease to be reached; • Is consistent with the policies of COAG, ANZFRMC and FSANZ. • Recommends the approach could be applied regionally, and adjusted from time to time on a regional basis. <p><i>Disadvantages of the preferred mandatory approach:</i></p> <ul style="list-style-type: none"> • Is not the most effective strategy; • Does not meet policy requirements for mandatory fortification; • Removes consumer choice;

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Is not an effective solution for those with coeliac disease who do not consume wheat-based products; • Creates unjustified trade restrictions for imported foods causing potential WTO action; and • Mandatory fortification is not supported by the best available evidence, which supports voluntary use of iodised salt. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • AFGC notes that milk and milk products are major contributors to iodine intakes for both the target groups and all Australians aged two years and above, and for New Zealanders aged 15 years and above. However, these have not been included in the modelling scenarios as possible food vehicles. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Proposal fails to consider consumer views in Australia, and relies on the outcome of the voluntary program for iodine fortification in Tasmania. Assumes there has been no consumer concern at the mandated addition of thiamine 17 years ago. • Rejects the ‘choice’ of unleavened bread and salt free cereals for consumers as these are entirely different products and cannot be compared to the regular products. • Notes the consumer research in New Zealand by NZFSA indicating strong opposition to the mandating of folic acid addition to the food supply because it removed consumer choice. • Refers to a recent survey of consumers undertaken by a business likely to be affected by the proposed mandatory fortification with folic acid and iodine in September 2006. This survey showed 84% of respondents thought voluntary fortification was preferable to mandatory fortification, and 62% respondents were concerned that mandatory fortification shows a trend to making staple foods such as bread act like medicine. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • A 12 month implementation period will cause unnecessary costs to industry and is not achievable due to the volume of labels and relatively small size of the label change and printing industries. • An acceptable time frame to allow for labelling changes is two years for short shelf life products and four years for long life shelf life. • The current Standard 1.3.2 limits food companies from using labels as an effective way of helping to support the communication and education strategy that FSANZ indicates is critical to the success of the proposal. • Recommends a pre-approved iodine health claim for foods fortified with iodised salt in order to enhance communication and education about the importance of iodine in the diet. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Mandatory fortification could be seen as a technical barrier to trade, and therefore will require careful handling by FSANZ to avoid WTO intervention. For example, Australian businesses manufacturing in China for export to Australia will not conform to Australian requirements as China has a different iodisation level for salt from that proposed in P230. Exports to the Japanese market are not permitted to utilise iodised salt in manufacture, and manufacturers may not be able to remain competitive due to additional costs of maintaining two salt supplies and associated costs – this has been noted as a problem for a cereal manufacturer.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • The MoU will allow the necessary flexibility to meet the needs of the Australian market and export markets. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • AFGC recommends FSANZ exempt imported food from the requirement to use iodised salt and focus on agreements via MoU with Australian based manufacturers. This will require further modelling to determine the impact of the proposed exemption. • The four week consultation period has prevented AFGC from obtaining sufficient details on imported foods for this submission. AFGC will however continue to provide FSANZ with such information after the close of submissions to assist the FSANZ modelling and decision making. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> • Supports the retention of current permission for iodised salt for discretionary use. • Recommends promoting the substitution of iodised salt for un-iodised salt. • Australian data indicates that salt use has remained stable over the past 5 years, while iodised salt intake has risen, indicating consumers are choosing to use iodised salt over un-iodised. <p><i>Use of salt in non-mandated foods</i></p> <ul style="list-style-type: none"> • At production sites where foods other than the proposed mandated products are produced, it is likely that all foods would use iodised salt because of the difficulty of sourcing two supplies, maintaining separate storage areas, and additional quality control measures. • At production sites where products are physically separated (different plant) from mandatory products then continued use of un-iodised salt would occur. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Does not believe the proposal meets policy guidelines. • The proposed MoU does meet policy guidelines. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Recommends a Trans-Tasman monitoring program be developed and maintained for urinary iodine status in the target population. <p><i>Communication and education strategies</i></p> <ul style="list-style-type: none"> • Recommends industry awareness campaign to raise and maintain awareness of the need to use iodised salt in food manufacture. • Recommends ongoing consumer education campaign aimed at target population at risk promoting the importance of iodine in the diet. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Notes uncertainties around the economic value of the benefits from mandatory fortification, but no corresponding uncertainty regarding costs to industry and to government. • Compliments Access Economics on their full use of industry supplied data in their report. • Suggests that the AFGC solution of a MoU will deliver the desired outcome without incurring excessive costs to all parties, and will maintain consumer choice.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> Notes the lack of up to date data on current intake of iodine for Australia which hampers risk assessment. Believes that FSANZ should seek further information from stakeholders at each stage of consultation, and in the event that it is necessary to use patterns from 1995 consumption, FSANZ should model a wider range of consumptions to ensure they capture upper and lower intake levels. FSANZ should check outlier results with relevant industry stakeholders for validation. It is incorrect to presume that all sodium reported on a label is derived from sodium chloride. This is incorrect for many foods e.g. biscuits contain sodium bicarbonate as a raising agent. This has the effect of overestimating the iodine contribution modelled in scenario one. The effect is lesser in scenario two. Aztec data (scanned sales data for the total retail salt market) indicates the true figure for discretionary salt is closer to 18% (17.7%) for Australia and 75% for New Zealand. FSANZ should utilise the updated figures for iodised salt in future baseline modelling. Notes that no comprehensive survey of Australian consumer attitudes to fortification has been undertaken. <p><i>Attachments:</i></p> <p>Draft Memorandum of Understanding and membership of AFGC attached to submission.</p>
<p>Bayer HealthCare Australia Ayumi Uyeda</p>	<p>Supports Option 2 – Preferred approach for mandatory iodine fortification and commends the salt industry for their encouraging approach.</p> <p>A pharmaceutical company.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Questions the evidence for selecting the proposed fortification level of 25 – 40 mg/kg iodine in salt and the timeline for expecting an improvement in the mean urinary iodine concentrations. Notes that the level of iodisation of salt in the USA is 100 mg/kg and questions whether this level has shown adverse effects or would be of benefit in Australia. Also questions the need for a higher level of iodine to be added to salt to address the trend to reduce overall salt intake by society in general, and especially by some sections of the population, e.g. patients with high blood pressure and pregnant women. Acknowledges that the implications of iodine are well documented and well understood. <p><i>Implementation</i></p> <ul style="list-style-type: none"> Questions whether the fortification period could be implemented earlier than one year to address those in the Eastern States at greatest risk of iodine deficiency. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Supports increasing awareness within specific groups at risk of iodine deficiency.
<p>Campbell Arnott's Australia Michael Depalo</p>	<p>Supports a Modified Option 1 – Maintaining the <i>status quo</i></p> <ul style="list-style-type: none"> Supports expanded voluntary iodine fortification of foods targeted to the at risk population groups, with consumer education. Fortification could be through iodised salt or other sources of iodine.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Recommends the development of a MOU with industry enabling a targeted application of voluntary fortification with iodised salt to targeted foods. • Campbell Arnott's would be willing to participate in a MoU. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Notes potential risk to those with hyperthyroidism. Mandatory iodine fortification in Denmark created side effects from increasing iodine intakes too quickly in a marginally deficient population. In Tasmania Connolly notes unacceptable high rates of thyrotoxicosis following implementation of universal iodine supplementation in the late 1960s. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Refers to a NZFSA report indicating 84% of consumers were not in favour of mandatory fortification of foods. More than 75% of participants stressed the desire for choice. • Considers salt free varieties of bread, breakfast cereals and biscuits are not acceptable alternatives and there are technical hurdles to producing salt free bread. • Application of a MOU to a large company would allow smaller independent bakeries to produce iodine free bread and biscuits ensuring choice. <p><i>Trade/impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Concerned the application of iodised salt in the production of products in other countries at the same level as in Australia will be complex to manage and impact on imports e.g. Arnott's imports several biscuit products from Indonesia. Monitoring of will be costly and time consuming. Requiring imported foods to meet the requirements could be a barrier to trade. • Recommends FSANZ consider exempting imported foods and focus on a MOU with Australian based manufacturing across a range of products. This will require further modelling – the shortened consultation period had not allowed Arnott's to obtain sufficient detail of imported goods by close of submissions, but can provide this to assist FSANZ analysis. • Considers export is also impacted by the proposal e.g. Japan maintains an absolute ban on fortification with iodine in all foods. This would require alternative formulations of major brands solely for export. Voluntary fortification would offer flexibility. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Technical issues: notes iodine is a known oxidant and there is some evidence that iodising salt significantly increases the risk of oxidative rancidity. This could pose a risk for the shelf-life of products such as biscuits and cereals. Considers issues affecting the provision of safe and high quality products to consumers must be addressed before progressing with the proposal. • Transition period: recommends concessions be made to allow product labels to be updated in line with the normal cycle of reviews by industry to keep costs to a minimum. Recommends a 3 year transition period with the provision of an additional year for stock in trade. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Considers the proposal does not meet the Ministerial Council Policy Guideline which requires fortification to be monitored and reviewed. Concerned agreement on the exact nature of the monitoring system has yet to be reached with other agencies and that there is no indication of commitment to the required levels of monitoring.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Recommends the need to consider both urinary iodine content and frequency of hyperthyroidism. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports an education campaign that is consistent with the national nutrition guidelines of both Australia and NZ. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Concerned iodine intakes are based on NNS data that is more than 10 years old. Supports the commissioning of a new NNS to provide contemporary and robust data as there have been significant changes to the food supply. • Believes the model used by FSANZ assumes all sodium on the NIP is from sodium chloride. Notes many foods especially biscuits use sodium bicarbonate as a raising agent which contributes up to 75% of the sodium content. As biscuits are a target food this could overestimate the iodine contribution. • Notes also that in mixed foods such as biscuits and cereals salt may be added as a component of composite ingredients such as seasoning and salted butter – understands this does not need to be iodised but could result in overestimation of the iodine contribution from these foods. Recommends appropriate modelling be carried out with industry supplied data to confirm potential iodine load.
<p>Cerebos Foods Australia & New Zealand Patricia Verhoeven (Member of AFGC)</p>	<p>Supports Option 1 – Maintaining the <i>status quo</i> with MoUs with industry. Supports the AFGC submission as an alternative effective and economical source of iodine.</p> <p>Does NOT support Option 2 - preferred approach for mandatory iodine fortification as the most effective solution as:</p> <ul style="list-style-type: none"> • it denies consumer choice; • introduces trade restrictions for imported foods. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Recognises that iodisation of salt is an effective way of increasing the iodine intake of populations at risk of IDD. • Supports voluntary use of iodised salt as has been demonstrated as an effective solution in Germany, Switzerland, Netherlands and USA. • Also supported by Tasmanian experience which showed a decrease in iodine deficiency from 21% to 10.9% in 4 years. • Supports voluntary MoU with industry which would allow industry to select those products most suited to the target population to contain iodised salt e.g. avoid using indulgent biscuits as a vehicle for promoting a public health solution. • Recognises the medical evidence linking reduced iodine intake with adverse health outcomes such as Iodine Deficiency Disorders (IDD). • Expressed concern that population groups with Graves' disease would have their dietary choices severely restricted by mandatory fortification. • Believes that mandatory fortification is not an effective mechanism to reach those with Coeliac disease who are required to restrict gluten containing cereals, notably wheat which is the primary ingredient of bread and biscuits. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Iodised salt is recognised locally and internationally as an effective source of iodine.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Included data which showed that consumers are choosing to select iodised salt over non-iodised salt with no growth in total discretionary salt volumes. • Noted that estimated percentages for discretionary salt used in the Draft Assessment Report are incorrect and should be updated and the data remodelled to assess the impact on dietary exposure and upper limits (17.7% instead of 15% in Australia and 74.5% instead of 50% in New Zealand). <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Notes that there would be no alternatives to leavened bread for consumers who do not wish to consume iodine fortified bread under mandatory fortification. • Voluntary MoU retains consumer choice across food categories – especially through small retail businesses such as independent bakeries. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Encourages FSANZ to review current prohibitions on making iodine content claims on food labels. Under current prohibitions in Standard 1.3.2 - Vitamins and minerals and Standard 1.1A.2 - Transitional Standard for Health Claims, iodine claims are either prohibited or severely restricted on products (Iodine content claims are currently permitted under Standard 1.3.2 when certain criteria are met, but are limited to cereal, dairy, fruit and vegetable juice and analogue products) • Supports provisions to allow content claims on a wider range of products containing at least 10% of the RDI for iodine. • Believes allowing manufacturers who voluntarily add iodised salt to products to promote the awareness of the importance of iodine on their products may result in greater industry adoption of voluntary addition of iodine to manufactured foods. • Believes that iodised salt should be permitted to carry iodine content claims to enable consumers to monitor their iodine intake via their use of discretionary salt and to obtain information from the label. (Salt manufacturers are prohibited from making any claims regarding iodine content in packaging thereby preventing assistance with communication, education and awareness messages on salt products) which are a common • Requests FSANZ pre-approve an iodine health claim based on cause and effect evidence used as the basis for recommending mandatory fortification. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Expressed concern about restrictions and complexity for businesses that supply local biscuits to both domestic and export countries where the use of iodised salt is not permitted. • Voluntary solution would remove any potential trade restrictions for both import and export markets. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Believes mandatory fortification can create trade restrictions for imported foods therefore triggering WTO notification. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Strongly supports retaining the current voluntary permission for iodised salt as an alternative, effective and economical source of iodine. • Believes removal of voluntary permission would further restrict consumer choice and iodine intake and create consumer confusion by removing a well established source of iodine in the food supply.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Currently, 74.5% of New Zealand discretionary salt is iodised. Removal of this source of iodine is contrary to health outcome seeking to increase iodine status. • Noted that the NZ dietary guideline would need to be changed if voluntary permission is removed. • Noted that iodised salt is a source of iodine for those with celiac disease. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Believes 12 month implementation period is insufficient due to the volume of labelling changes that would be required and the ability of the label change and printing industries to accommodate these demands within the timeframe. • Recommends a minimum implementation period of 24 months. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports importance of communication and education strategy to raise awareness and understanding of the need to increase iodine status of the population. • Believes that allowing industry to communicate the benefits associated with iodine on food labels would enable labels to be used effectively as part of the education and communication strategy.
<p>Cheetham Salt Australia Wally Rickard</p>	<p>Support Option 2 – Mandatory fortification</p> <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Encourage FSANZ to discuss the use of descriptors such as ‘natural food’ and ‘organic foods’ with The Australian Competition and Consumer Commission and the New Zealand Commerce Commission to clarify the status of foods using iodised salt with regards to fair trading labelling requirements. • Believes it is an overreaction to remove such descriptors because: <ul style="list-style-type: none"> – fortification with iodine is a mandatory requirement; – fortification benefits public health; and – products will contain only a minute amount of iodine. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Suggests voluntary permission not be removed. It would be a backward step in reducing iodine deficiency in the community. • It would prevent manufacturers from using iodised salt in any other food product. • Might be an impediment to manufacturers who co-process multiple food items with a single supply of salt. • Voluntary permission will allow manufacturers to add iodised salt to other processed foods, which could increase iodine in commercial foods.
<p>Complementary Healthcare Council of Australia Australia Allan Crosthwaite</p>	<p>Appears to support Option 2 – Preferred approach for mandatory iodine fortification. (Provides in principle support to the Draft Assessment Report). Peak industry body representing therapeutic product sponsors, raw material suppliers, manufacturers, food manufacturers, wholesalers, distributors, Importers and retailers of complementary healthcare and healthfood products. Also represents consultants, practitioner associations, practitioners and consumers.</p> <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports monitoring as an essential component of mandatory fortification.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Monitoring program should include tracking of changes in iodine supplement usage and consumer attitudes to supplementation as well as fortified foods. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Considers supplement usage to be an integral message when raising awareness of fortification. • Supports communication and education, particularly to those target groups who will not increase their iodine levels through the consumption of bread etc. This is particularly important in light of other contradictory messages to reduce salt and refined carbohydrates in the diet. • The Complementary Healthcare industry would welcome a collaborative relationship with FSANZ to ensure that public awareness is raised regarding the need for supplement use by at risk individuals and groups to achieve an optimum lifestyle in conjunction with a healthy diet.
<p>Dairy Australia Australia Jacinta Orr</p>	<p>Supports neither Option</p> <p>Supports extending the voluntary fortification of foods with iodine, supported by region-specific public education programs as most effective strategy to address regional suboptimal iodine status in Australia.</p> <p>Mandatory fortification may result in unnecessary consumption of iodine across large areas of Australia. Baseline data is not sufficiently robust to support mandatory fortification. With more thorough investigation of the issue it may be that quite different strategies are more appropriate to provide a safe level of dietary intake of iodine for the Australian population.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Acknowledges that increased iodine intakes will improve the iodine status of deficient populations. • However the current prevalence of iodine deficiency in Australia indicates a non-uniform distribution of iodine insufficiency across Australia. • Before mandatory iodine fortification is considered there should be a broader study of all population groups in all regions of Australia. • It appears that iodine fortification is not necessary in Western Australia or Queensland and the need in the Northern Territory is undetermined. • Mandatory fortification would apply to the entire population, rather than targeting problem areas. The iodine studies FSANZ cites have been done on 'at risk' sections of the population, such as schoolchildren and pregnant women. • Re-emergence of iodine insufficiency in some areas of Australia coincides with changes in practices in cleaning of milking equipment. A large number of iodophors were used as teat disinfectants in the dairy industry but tighter controls were introduced in the 1970s. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Welcomes the suggestion that all dietary sources of iodine should be monitored. • Believes adequate monitoring is fundamental and important for risk management and to inform future policy and strongly supports monitoring as part of food fortification. • The Draft Assessment provides a good theoretical outline of the important components of a monitoring program including the need for baseline data. • There is insufficient information regarding which agencies would be responsible for what and about review periods.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • It is important to monitor iodine intake because there may be industry changes that effect iodine intake similar to those of the dairy industry in the 1970s. • A lack of regular monitoring has hampered the appropriate assessment of the impact of iodine fortification in other countries. <p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • The dairy industry is interested in voluntary fortification of dairy foods with iodine however fortifying may pose technical difficulties for some dairy foods. • Extending voluntary fortification would encourage the industry to invest in research and overcome some of the technical difficulties. • The dairy uses salt in cheese production but would not choose to use iodised salt in cheese as it might be a barrier to trade. • The Australian Dietary Guidelines encourage Australians to reduce their intake of salt. While increased attention on the status of iodine is important, need to ensure that this does not obstruct the need for a lower salt intake. • Removing salt iodisation permissions would provide greater certainty in estimating salt intake. • Dairy Australia does not believe that this is an adequate reason to decrease the variety of food in which iodine is available. Reducing the variety of food sources of a nutrient is ill advised. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Public education, particularly in iodine deficient areas, would allow consumers to choose iodised products according to their needs. • Supports continuous national education strategies that use a variety of mediums appropriate to the target audience. • Dairy Australia distributes educational material as part of their Nutrition Program. Resources could emphasise that iodine is a natural constituent of dairy foods and support any government nutrition education initiatives.
<p>Dominion Salt Limited</p> <p>New Zealand</p> <p>Brett Hobson</p>	<p>Does not directly state support for mandatory fortification, but is willing to work with FSANZ to implement the proposal.</p> <p>Commends FSANZ’s work on the proposal which it hopes will address this concerning health issue for New Zealanders.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Is willing to work with FSANZ to implement the proposal. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Recommends clarification of definitions for cereal product salt and whether coatings and sprinkles will require iodisation as well as salt used in the primary dough mix. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Notes reduction of consumer choice with mandatory iodine fortification. • Raises concern regarding organic status of ‘organic’ bread which contain iodised salt. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Considers 12-month transition period to be workable.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Supports a single level of iodine input for discretionary (Table salt) and cereal salt to avoid complexity and confusion in manufacturing and complicating monitoring and enforcement. • Support iodine fortification level of 20-45 mg/kg salt. • Identifies technical difficulties with iodisation of coarse grain salts used for toppings and coatings e.g. on focaccia bread. • Also notes a reduced choice for cereal producers as it will not be practical to supply full range of salt grades in an iodised version – there may be 2-3 iodised grades vs. the +10 currently available. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Support monitoring across several fronts e.g. is willing to supply data on iodised salt usage updates for New Zealand produced salt (proposed on an annual basis.)
<p>Flour Millers Council of Australia Australia Graeme Lukey</p>	<p>Appears to Support Option 1 – Maintaining the <i>status quo</i> Represents companies engaged in flour milling in Australia Does NOT support Option 2. <i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Acknowledges that substitution of non-iodised salt with iodised salt can raise the dietary intake of iodine and therefore address iodine deficiency in affected populations. • States that they ‘do not accept that mandatory fortification is the most effective public health strategy to address a health problem not demonstrated to be shared by the population at large’. • Believes the Tasmanian trial using bread with iodised salt demonstrates that specific strategies developed with the food industry can meet objectives for target populations. • Expressed concern about mandatory fortification of the food supply, impacting on the whole population, when only certain segments of the population are identified to be at risk e.g. Tasmania and New Zealand are of particular concern and warrant special attention. • Raised awareness about the discontinuation of a previous program of iodine supplementation in Tasmania due to high rates of thyrotoxicosis (Connolly RJ et al. (1977) Increase in thyrotoxicosis in endemic goitre area after iodation of bread. <i>Lancet</i>). <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Acknowledges reasons for iodine deficiency are not fully understood. • Supports government research to make best decision to determine effective public health policy e.g. whether by modifying agricultural practice or using processed food. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Supports availability of iodised salt and products manufactured with iodised salt so consumers can consume or avoid as they choose. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Raised concern that discontinuation of previous iodine supplementation in Tasmania demonstrates that Australian government has not met its responsibility to public health in the past.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Upholds the 'Ministerial Council Policy Guideline for Fortification of food with vitamins and minerals' that requires that 'any agreement to require fortification should require that it be monitored and formally reviewed to assess the effectiveness of and continued need for mandating of fortification'. • Suggests that any legislation for mandatory fortification should include a sunset clause to provide for review of effectiveness of the intended initiative based on formal monitoring of dietary intakes and health effects. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Ongoing monitoring programs of dietary intake patterns aligned to health trends is a key element for creditable public health policy. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Considers ongoing public communication and education initiatives through schools, medical practitioners and consumers to enable informed decision making is a key element for creditable public health policy.
<p>The Food Technology Association of Australia (Formerly the Food Technology Association Victoria) David Gill</p>	<p>Accepts Option 2 – Mandatory fortification Made no further comment</p>
<p>Food and Beverage Importers Australia Australia Tony Beaver</p>	<p>Supports Option 1 – status quo Believes the case for mandatory fortification has not been clearly established. Considers alternatives to mandatory fortification should be investigated first.</p> <p><i>Trade</i></p> <ul style="list-style-type: none"> • Biscuits are imported in significant quantities into Australia (excluding imports from New Zealand \$130 million in 2003/4 and \$140 million in 2004/5). • The major sources were the United Kingdom (12%), China (12%), and the United States (10%). • It would be unlikely that any imported biscuits would currently comply with the Standard. • In terms of world trade, Australia is not a major importer of cereal products (importing less than 1%). It is unlikely that products would be reformulated for the Australian market. Although there may be some imports, where the brand is owned by the importer which could be reformulated if an iodine source could be found. • The impact of the proposal would be to significantly curtail trade in biscuits and would lead to the majority of imported biscuits being withdrawn from the Australian market. • It would be simpler to adopt a voluntary program that would encourage customers to use iodised salt and manufacturers to replace salt in their products with iodised salt. • An education program to raise awareness of the importance of iodine and problems associated with iodine deficiency could be initiated.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Australia already has a mandatory fortification for thiamine and before implementing another mandatory fortification measure there should be an evaluation of thiamine fortification to ascertain its effectiveness, benefits and costs. • A 12 month transition period is far too short a period for industry to prepare for the change.
<p>George Weston Foods Limited (GWF)</p> <p>Australia and New Zealand</p> <p>Fiona Fleming</p>	<p>Fully supports Modified Option 1 – Maintaining the <i>status quo</i> plus (as per the AFGC's recommendation)</p> <ul style="list-style-type: none"> • Recommends an agreed MoU with industry to voluntarily use iodised salt in food manufacture; and education campaign that encourages consumers to seek out products fortified with iodine. <p>Does NOT support Option 2 as it:</p> <ul style="list-style-type: none"> • fails to meet the policy requirements for mandatory fortification; • removes consumer choice from those products; • fails to be an effective solution for those with coeliac disease and/or those who are wheat intolerant, or who do not consume wheat based products; • creates unjustified trade restrictions for imported foods causing potential WTO action; and • is not mandatory in most countries where the salt has been adopted as the delivery vehicle for iodine. <p>Supports AFGC's recommendation for a modified option for voluntary fortification involving MoUs with industry as it:</p> <ul style="list-style-type: none"> • has evidence of effectiveness in the Australian market; • retains consumer choice; • has no WTO implications; • through use in non-wheat based products, it allows those with coeliac disease to be reached; • has been shown to be effective internationally; <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Expresses concern that mandatory fortification will fail to reach all parts of the population – e.g. those people who avoid wheat based products due to wheat intolerance or coeliac disease. • Majority of international iodine fortification programs use voluntary fortification rather than mandatory fortification. • Notes the success of the Tasmanian experience of developing MoUs with industry, in increasing the iodine status and its broad acceptance by the general population. With 80% of bread currently fortified, consumers were offered choice in relation to bread and other products. • Believes that a similar approach could be adopted Australia wide and in New Zealand. This would be consistent with Ministerial Policy guidelines which require assessment of alternative strategies prior to choosing mandatory fortification. • Suggested strategies to improve the iodine status of Tasmania include widening the range of foods under MoU to include cereals and biscuits and/or increasing the range of iodised salt included in the products.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Questions why industry was not consulted prior to selection of two FSANZ scenarios (cereal based foods and processed foods). • Questions the effectiveness of the proposal to improve the iodine status of women of child bearing age in South Eastern Australia because they will still require supplementation. • Acknowledges that the use of iodised salt in place of non-iodised salt can be an effective strategy to address iodine deficiency in affected populations. • Noted health concerns related to iodine intake e.g. individuals who may have a pre-existing thyroid condition or who are sensitive to iodine even within recommended range and potential product liability issues for manufacturers. • Questions the need to subject the whole Australian and New Zealand populations to mandatory fortification of staple food products (Queensland and WA had adequate iodine status). • Concerned that some elderly patients could experience iodine induced hyperthyroidism for up to 10 years when there are no health benefits for this age group. • Concerned that FSANZ is not able to accurately assess the outcomes of the mandatory fortification program in WA and Qld and thus are at an increased risk of iodine excess. • Questions inconsistent conflicting statements in the Draft Assessment Report in relation to the association between iodine intake and thyroid cancer. • Notes that some groups will exceed the UL. • Concerned about the availability of food vehicles for Indigenous Australians. • Recommends access to non-iodised products for those at risk of adverse health risks e.g. those with hyperthyroidism and young children. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Questions why milk and milk products have not been used as a possible food vehicle given they are major contributors to iodine intake. • Questions the use of 10 year old data for selecting the food vehicle. • Concerned that using cereal-based foods fails to reach those suffering from celiac disease (prevalence of one in 100 in Australia and 1 in 84 in New Zealand) <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Questions the reliability of the NNS as a data source for dietary modelling. • Believes FSANZ's dietary modelling has ignored the contribution of milk to dietary intakes and has potentially overestimated the contribution of salt from bread (compared with GWF data - average proportion of salt in GWF products is 0.7 - 1.25% compared with 1.36% used by FSANZ). • FSANZ should obtain up to date information on these products from manufacturers prior to undertaking dietary modelling. • Questions whether FSANZ used 2006 bread consumption data in the dietary modelling. • As one of the main target groups for mandatory fortification, it is not adequate to use theoretical diets to assess the dietary intakes of Australian and New Zealand children. • Questions assumptions used in dietary modelling about consumer behaviour.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Believes that there is a lack of consumer choice within the product categories proposed for fortification. • Those with pre-existing thyroid conditions advised to limit their iodine intake may need to avoid staple products if there are no non-iodised options available. • GWF undertook consumer research (n = 1310) to determine community attitudes towards food fortification in Australia. Results indicated that the Australian population is opposed to compulsory fortification of food and want to be given choice. Key findings include: <ul style="list-style-type: none"> – 84% of respondents preferred voluntary fortification to compulsory fortification; and – 62% of respondents were concerned that compulsory fortification shows a trend towards making staple foods, such as bread, act like medicine. • Believes the proposal does not meet FSANZ's primary objective to ensure 'provision of adequate information to enable consumers to make informed choices' as consumers are not made aware of the possibility of iodine-induced hyperthyroidism and the lack of availability of non-iodised versions of the selected food vehicles. • Does not consider salt-free bread or breakfast cereals to be a viable alternative for those wishing to avoid fortified versions. • Believes MoU with industry will provide more consumer choice. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Labelling requirements will not provide consumers with amounts of added iodine. • Questions FSANZ calculations used to determine whether bread would qualify for a 'source' claim. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Expressed concern that the proposal may create artificial barriers to imported products being able to compete fairly in the Australian market. • Recommend consulting the Dept. of Foreign Affairs and Trade to ensure that the mandatory fortification proposal is not in breach of Australia's obligations under the WTO. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> • Supported retaining the current permission for iodised salt for discretionary use, promoting substitution of iodised salt for non-iodised salt for such use. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Considers removal of voluntary permission of salt iodisation is for FSANZ to determine through dietary modelling, not for industry. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Supports a transition period of two years due to demand for advertising agencies and printers. • Two year implementation would also allow time to implement baseline monitoring and would minimise cost to industry for packaging changes. • Align labelling changes with other changes such as health claims, folic acid fortification and nutrient reference values.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Recommends FSANZ consult with industry prior to developing an implementation guide which should be finalised well before any changes to the Code come into effect. <p><i>Use of salt in non-mandated foods</i></p> <ul style="list-style-type: none"> • GWF will provide this information as part of the MoU proposal. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Believes the current mandatory proposal is NOT consistent with the Policy Guideline. The proposal is based on 11 years old nutrition data and there is no acceptable monitoring program in place. • Alternative public health strategies such as voluntary fortification and education strategies have not been properly assessed. • Believes voluntary fortification will meet policy guidelines more effectively than mandatory fortification. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Notes monitoring and evaluation is a fundamental component of any mandatory fortification system, especially for risk of IHH as well as effectiveness of iodine deficiency. • Notes that the monitoring system is still to be negotiated with other health and regulatory agencies in Australia and New Zealand, so there is no commitment in place and not a good track record with thiamine or voluntary folic acid fortification. • Cites reference for frequency and complications of iodine induced hyperthyroidism as a result of poor monitoring of salt iodine concentration which permits uneven rations of iodine, and inadequate medical attention which delays diagnosis and treatment. (Dunn et al 1998a) • Refers to WHO reference (WHO 2001) which raises questions to be addressed by a monitoring program including salt iodisation, whether the target population is being reached, impact on iodine status and IDD as a public health problem. • Notes negative outcomes observed in overseas countries with limited monitoring. (Delange et al 2001) • Considers monitoring is often neglected in favour of implementation. • Supports developing and maintaining a trans Tasman monitoring program for urinary iodine status in the target population to estimate prevalence of IDD. • Recommends also monitor use of discretionary salt. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports developing and maintaining an industry awareness campaign of the need to use iodised salt in food manufacture. • Supports developing and maintaining a consumer education campaign aimed at the target population about the importance of iodine in the diet. • Education needs to be targeted on individual needs, and depending on whether an area is iodine deficient or iodine replete. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • FSANZ's proposal cannot be justified as cost benefit analysis could not conclude there is a net benefit associated with mandatory fortification.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Notes the Cost Benefit Analysis prepared by Access Economics suggests exploring an alternative proposal which embraces all of the potential benefits or finding another vehicle which better targets those in need, including those in geographic areas of Australia where iodine was identified. • Concerned about a rise in bread prices as a result of iodine and folic acid fortification and GWF is willing to provide confidential information to support these statements. • Concerned that GWF research shows that consumers may choose to avoid fortified cereal based products due to opposition to fortification. • Suggests perhaps industry should be directly compensated for costs incurred. • Notes the short time given (one week) to provide estimates on cost to industry to Access Economics. • Notes no cost is quantified for reduced consumer choice of products or cost to coeliacs who will have limited access to cereal based products. • Should include costs to governments of anti-discrimination action taken by those adversely affected by the decision to mandate the addition of iodine to bread. • The cost of potential health risks to identified vulnerable groups have not been included which brings into question the integrity of the report. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Concerned regarding the short consultation period (1 month). • Notes that two major proposals affecting the bread industry were undertaken close together with shortened consultation times. • The objective to reduce the prevalence of iodine deficiency lacks specificity in stating the size and time period for the reduction. • Expresses concern that the issues raised in the Summary of Submissions for the Initial Assessment Report have not been adequately in the Draft Assessment, namely: <ul style="list-style-type: none"> – success of current fortification strategies to increase iodine intake; and – lack of consumer choice associated with mandatory fortification.
<p>Go Grains and Nutrition Ltd Australia Trish Griffiths</p>	<p>Supports Modified Option 1</p> <ul style="list-style-type: none"> • Supports extending voluntary permissions for iodine fortification for a wider range of foods together with target strategies for populations in areas of deficiency. • Accepts the use of iodised salt in place of non-iodised salt can be an effective strategy to address iodine deficiency but does not believe mandatory fortification of all bread, breakfast cereals and biscuits is consistent with the Policy Guideline. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • The food vehicle assumes bread is a staple food widely consumed by the target population. Questions whether the 1995 NNS data reflects the type of food eaten in 2006. • Limited data available suggests bread may not be the best vehicle to reach women. Notes a Newspoll survey in 2006 found women of childbearing age ate only 11 slices of bread a week with 21% eating no bread at all. Refers to several Go Grains surveys indicating negative attitudes to bread especially amongst women.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Long term safety: considers it essential attention is given to long-term risk of unintentional adverse effects on other population groups, especially those with hypothyroidism who may be sensitive to sudden increases in iodine intake. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Believes mandatory fortification compromises consumer choice and that salt free products are not acceptable choices. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Technical issues: notes there is some evidence iodising salt increases the oxidising potential, increasing the risk of rancidity. This risk needs to be clarified to the satisfaction of industry. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Considers data is lacking to demonstrate mandatory fortification will deliver a sufficient amount of iodine to the target population. • There is not a system in place to monitor effectiveness. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • An appropriate monitoring and surveillance system needs to be implemented prior to any change in fortification practice in Australia. There is no indication of a commitment to monitoring and enforcement and the track record is not encouraging e.g. thiamin and voluntary folate fortification. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Concerned the CBA does not include costs of establishing an ongoing monitoring system. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Considers the proposal is based on out dated consumption data and this is not an acceptable basis to make a decision about mandatory fortification for a whole population. • Notes iodine status of pregnant and breastfeeding women is lacking – baseline data is needed for a minimum of 12 months prior to implementation to assess the effectiveness. • Considers the monitoring strategy as proposed is unlikely to be achievable in terms of budget and timeframe, with reliance on the new NNS. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Requests clarification of the definition of biscuits and bread – e.g. it is not clear whether specialty bread such as organic and gluten free are included in the proposal. • If all bread are included the issues and costs will need to be addressed by other industries e.g. the rice industry is substantially different to the wheat industry.
<p>Heinz Australia and Heinz Wattie's Australia and New Zealand Lisa Warren</p>	<p>Supports Modified Option 1</p> <ul style="list-style-type: none"> • Continues to favour extension of permissions for voluntary iodine fortification as well as promotion of voluntary options to increase industry uptake. • Requests that mandatory fortification of iodine does not include Standard 2.9.2 - Foods for Infants, where an infant is determined as a person up to the age of 12 months.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Safety and efficacy/food vehicle</i></p> <ul style="list-style-type: none"> Notes commercially prepared infant foods are low in sodium. Questions the usefulness of mandatory iodine fortification of foods within Standard 2.9.2 due to the extremely low quantities of salt permitted. The exception is teething rusks where salt is added to obtain a hard texture. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> Notes that although the Draft Assessment refers to the need to increase iodine intakes of infants, the data only refers to young children over the age of one year.
<p>Kraft Foods Limited Australia Allan Poynton</p>	<p>Supports Option 1 – status quo</p> <ul style="list-style-type: none"> Acknowledge iodine deficiency disorders and accepts increasing iodine intake can alleviate these. Does not agree that the information provided constitutes sufficient grounds for mandatory fortification. Is prepared to discuss a MoU whereby the majority of biscuits sold in Australia could be manufactured with iodised salt. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Suggests identification of subsets of the population would help to identify appropriate vehicles for fortification other than discretionary salt and salt for bread making. Believes bread would appear to be the most suitable vehicle. Salt intake via bread would be higher than biscuits. Bread is more uniform product and can be tailored for regional / local markets. Notes processed foods are more likely to be imported and exported with trade issues. Does not consider biscuits to be a useful carrier for iodine for several reasons: <ul style="list-style-type: none"> – salt levels are variable, delivery would not be evenly distributed; – the salt level in biscuits is quite low; – the consumption of biscuits is far less uniform than bread across the population; and – peaks and troughs in iodine intake from biscuits would put people on iodine controlled diets most at risk. If FSANZ continues with fortification of biscuits, then a MoU rather than mandatory fortification would be a practical mechanism, combined with education. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerned about those in the population on iodine controlled diets - providing a varied diet will become even more challenging if staple foods are iodised. <p><i>Trade</i></p> <ul style="list-style-type: none"> Notes all biscuits Kraft Foods Ltd. sells in Australia are imported from Kraft locations overseas which raises practical issues with compliance to mandatory fortification, with the majority from China. China sources salt from the Chinese government only and this is iodised at a rate of 20-35 mg/kg. Salt iodised at any other level is not able to be obtained. The Australian market is quite small and other countries do not require iodised salt in biscuits. This would add complexity and costs to manage.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> As Australia is a small percentage of the total, there is likely to be non compliance with small volumes. Importers of these biscuits would consider mandating the use of iodised salt for Australian biscuits to be a barrier to trade. Japan will not allow iodised salt – Japan is a profitable market and important for Australia’s balance of trade. Estimates approximately 25% of all biscuits sold in Australia are imported from different countries with differing requirements. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> In line with providing choice, voluntary permissions should be allowed to stay unless there is shown to be an issue. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Considers it is the responsibility of Governments, not industry to inform people they need to increase their iodine intake. Considers the public respond more positively to information that an issue can be addressed through food consumption, rather than through authorities medicating through food. Believes food companies cannot and should not lead an awareness campaign. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> Notes the data indicates deficiencies in parts of Australia and NZ. However, little evidence has been provided of subsets of the population at most risk. Considers the data does not seem to support universal mandatory fortification so does not appear to comply with the FSANZ requirement for risk based analysis.
<p>NZ Association of Bakers Inc New Zealand Marcia Dunnett</p>	<p>Does not support Option 2 – provides an alternative proposal</p> <ul style="list-style-type: none"> Remains fundamentally opposed to mandatory fortification of all bread with any additives. Considers mandatory fortification of all bread is an excessive response. <p>Recommends an alternative proposal:</p> <ul style="list-style-type: none"> fortify a significant proportion of a range of bread (e.g. all but the heavy health segment) so that an element of consumer choice remains; and Actively promote through a government funded and industry supported education campaign (point of sale material and labelling) on the benefits of bread containing iodised salt. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Refers to consumer research which showed NZ consumers are strongly opposed to mandatory fortification with any additive, and considered mandatory fortification of bread would alter their view of bread as a wholesome health product. There are sufficient differences between NZ and Australia to warrant the implementation of the alternative approach submitted which maintains consumer choice while the vast majority of bread consumed, particularly by children, would be fortified. <p><i>Trade</i></p> <ul style="list-style-type: none"> Export risk: consider it is not clear in the proposal that iodised salt will not be required to be used in export products unless it was a requirement of the final destination. Requests this be clearly outlined in the final report.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Implementation/ cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Believes it will be extremely difficult to implement the changes for both folate and iodine in a 12 month period. • Considers costs outlined in the proposal are grossly underestimated and that the 12 month timeframe would require significant write-off of packaging. • Believes clarification of these costs and timeframe are essential before the final recommendation is put forward. • Notes the proposed alternative would require bakeries that produce heavy health bread to carry two salt lines but that this is not regarded as a major issue. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Stresses the need for independent validation from the health Authorities to ensure consumer buy-in. Questions the nature of the educational campaign – asks will it identify that changes have been instigated by FSANZ rather than the baking industry?
<p>New Zealand Food and Grocery Council New Zealand Brenda Cutress</p>	<p>Appears to support Option 1 – Maintaining the <i>status quo</i> plus MoUs with industry as per Tasmania, providing it is accompanied by effective education.</p> <p>Does NOT support Option 2 – Preferred approach for mandatory iodine fortification.</p> <ul style="list-style-type: none"> • The Draft Assessment should give similar consideration other alternatives to mandatory fortification. These other alternative strategies would be more effective in achieving the outcome. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Does not support mandatory approach which should only be used as a last resort if other approaches fail and even then there may be reasons why a mandatory approach may not be acceptable. • Believes that the proposal is not based on best evidence (from the information included in the Draft Assessment on experience from overseas countries which have used mandatory and voluntary fortification). • Argues that a voluntary approach is the most effective strategy and preferable, and cites Tasmania as a successful program. • In Denmark, mandatory fortification resulted in a tendency to increase hyperthyroidism, albeit of an acceptable magnitude. • Supports voluntary fortification with selection of a range of products which meet the objective of raising the iodine status to the desired level to overcome deficiencies while ensuring the risks of overexposure do not occur. • Recognises that iodised salt (beyond current permissions) will assist in alleviating the current concerns of a re-emergence of mild to moderate iodine deficiency resulting from inadequate iodine intake in New Zealand and parts of Australia <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Concerned that percentage of salt in final product is not accurate. • New Zealand Bakers Association notes that the percentage of salt in the majority of bread is 1.75 – 2% salt on cereal weight therefore the percentage of salt in the final product is closer to 1% rather than 1.36% as included in the Draft Report. • Notes that not all sodium on the label is from salt (some may be sodium bicarbonate) – resulting in an overestimation of the contribution of iodised salt in the dietary modelling.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Mandatory fortification will result in a lack of consumer choice. • Believes FSANZ downplays results of NZ studies which have shown that consumers do not approve of mandatory fortification even where there are health benefits. • There is an extremely limited range of salt-free breakfast cereals and unleavened bread available in NZ meaning there is no real choice for consumers who wish to avoid food containing iodised salt. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Considers FSANZ has not given sufficient regard to the impact of mandatory fortification of cereal based foods on trade, especially in New Zealand which is a larger importer of biscuits and exporter of cereal-based products. • Supports exemption for imports from mandatory fortification to avoid different ranges of iodine levels permitted in salt in overseas countries. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Notes that 12 month implementation is insufficient for some companies which build up stocks of labels for two – three years. • Believes cost of label changes has been underestimated (can cost between \$50,000 for a smaller company with approximately 50SKUs to over \$1.5million for a large company with many hundreds of SKUs). • Recommend coordinating label changes with other changes to the Food Standards Code to contain costs. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Considers monitoring the key sources of dietary iodine on iodine status in the target and non-target populations to be an essential and fundamental component of fortification whether mandatory or voluntary fortification is adopted. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports a campaign to encourage use of iodised discretionary salt (where used) and selection of processed products that contain iodised rather than non-iodised salt. The majority of New Zealand consumers would be unaware of NZ Health and Nutrition guidelines that emphasise the desirability of using iodised salt (when used). • Also supports the importance of raising awareness with the industry of using iodised salt. <p><i>Other issues –short time period</i></p> <ul style="list-style-type: none"> • Short time for public consultation has precluded more detailed import/export statistics or the iodine permissions in countries of import and export (FGC will submit this information at a later date). <p><i>Other issues – natural foods</i></p> <ul style="list-style-type: none"> • Considers natural foods are disadvantaged under the current mandatory fortification proposal as they would not be able to claim 'natural' in New Zealand under the Fair Trading Act. Seeks an exemption if this concern is confirmed by the NZ Commerce Commission.

SUBMITTER	SUBMISSION COMMENTS
<p>Salt Institute USA Richard Hanneman</p>	<p>Supports Option 2 – Mandatory iodine fortification</p> <ul style="list-style-type: none"> Highly supportive of FSANZ approach using iodised salt as the vehicle and extending its use in measured steps - consistent with overseas experiences. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Supports addition of iodised salt to bread, breakfast cereals and biscuits and extending use in measured steps if inadequate improvement in iodine status. Consumers preparing less food at home, using more processed foods and restaurant or takeaway foods. Notes the recent decline in packaged salt sales and consumers not choosing <i>iodised</i> table salt. <p><i>Trade</i></p> <ul style="list-style-type: none"> Dismisses the implications for trading with Japan of introducing mandatory fortification as domestic producers will continue to supply unfortified salt to most of the food processing industry. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Supports monitoring to determine need to extend use of iodised salt to other foods or to increase iodine added to salt if current intervention is inadequate. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Believes the proposal would be strengthened by including a statement that the government is committed to protecting mental development of next generation through iodisation of salt and this is first step to carry that proposal into effect. Supports public education campaign, especially in schools. Supports education program targeting pregnant women advising the importance of their iodine intake for the mental development of their developing child. <p><i>Technical issues</i></p> <ul style="list-style-type: none"> No technical issues for salt producers to adjust fortification level. <p><i>Other issues</i></p> <ul style="list-style-type: none"> The declining iodine nutrition status of Australians and New Zealanders parallels that of Americans and Canadians.
<p>Soil & Health Association of New Zealand New Zealand Steffan Browning</p>	<p>Appears to support Modified Option 1 – Maintaining the <i>status quo</i></p> <p>Does not support Option 2 – Preferred approach is mandatory iodine fortification and recommends an exemption for organic foods if mandatory iodine fortification is adopted. Represents companies producing organic food and organic farming in NZ. States their motto is '<i>Healthy soil, healthy food, healthy people</i>'</p> <p style="padding-left: 40px;">‘An exemption would allow the organic producers to continue exploring genetic material and growing methods that deliver ‘genuine’ organic whole foods and will also give consumers a choice.’</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Recommends an exemption for certified organic producers and processors in the event that mandatory fortification with iodine is adopted. Does not support mass medication.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Expressed concern that components such as soy products and fluoride in the contemporary diet may be factors in the rise in iodine deficiency. • Acknowledges the Draft Assessment finding that pregnant and breastfeeding women in Australia and New Zealand may require daily iodine supplements. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Supports informed and fair consumer choice. • States that organic consumers prefer a solution to the cause rather than a focus on the treatment of symptoms. • States that in the event of a need for supplementation, natural products as ingredients are preferred e.g. seaweeds and certified organic kelp are used by organic consumers as a natural source of iodine. • Acknowledges the high level of nutritional and health awareness of organic consumers. • Expresses concern that fortification with any synthetic additive is contrary to the ideals of the organic consumers and believes mandatory fortification will reduce choice for those wanting to avoid additives. • Considers that broader consumer choice than unleavened bread and a few cereals are appropriate as choices in the Draft Assessment are not really choices. • Notes that current voluntary fortification requirements allow consumer choice and fair trade as long as clear labelling is present. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Advises that organic production and processing is based on minimum alteration or addition to food composition. Organic processing standards restrict additives in bread. • Expressed concern that the standard for organic bread would have to be changed to something less than consumer expectations if mandatory fortification is introduced. • Noted the requirement for food labelling and promotional claims to be in accordance with the fair trading legislation of Australia and New Zealand and that FSANZ is clarifying the use of descriptors such as 'natural food' and 'organic foods' with the ACCC and the NZCC in relation to foods using iodised salt. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Expresses concern that mandatory fortification requirements disadvantages small commercial operations e.g. small domestic market focussed bakeries may have difficulty complying with mandatory fortification requirements. They consider that these bakeries and access to markets requiring no added iodine need to be permitted in the interest of fair trade. An exemption for organic foods would reduce the level of commercial disadvantage. • Believes an appropriate descriptor or definition of 'organic' produce or goods is likely to be 'that which has been produced according to either a 'National' organic standard, or is organically certified and that the proposed 12 month transition period is sufficient time for that mechanism to be established. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • If an exemption from fortification is granted for organic foods, monitoring will show any need for increased education or recommendations required for organic consumer groups.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports an education program through the health system, including information on iodine sources and inhibitors, with optional supplementation a possibility.
<p>Uncle Toby's Australia Kirsten Grinter</p>	<p>Supports Modified Option 1 – Maintaining the status quo plus MoUs with industry</p> <p>Supports development of a comprehensive voluntary program - including development of a MoU, an industry awareness program and consumer education program.</p> <p>Considers that extending the permissions for iodine fortification to a wider range of foods in conjunction with industry awareness and consumer education program will provide consumers with a greater product choice to achieve an appropriate amount of iodine in their diet to meet the health objective without compromising consumer choice.</p> <p>Does not support option 2 as it :</p> <ul style="list-style-type: none"> • fails to meet the objective of being effective; • fails to meet the policy requirements for mandatory fortification; • removes consumer choice; • fails to be an effective solution for those with coeliac disease who do not consume wheat based products; • creates unjustified trade restrictions for imported food causing potential WTO issues; and • has not been shown to be effective internationally. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Prevalence of iodine deficiency in Tasmanian children fell from 21% to 10.9% following introduction of voluntary iodine fortification in Tasmania. However, the level of iodine in salt was too low to eliminate the issue altogether and the food vehicles too limited to reach the target group or perhaps the consumer education program was not sufficiently sustained. • Acknowledges the medical evidence that indicates the adverse health effects collectively referred to as iodine deficiency disorders (IDD) and accepts that increasing population iodine intake can prevent adverse health effects. • Identifies need for assessment of the long term risk of high iodine intakes across the general population, particularly in the absence of adequate data on iodine status of the Australian population. • Expresses concern that the addition of iodised salt to non-mandated foods could increase exposure of consumers to iodine. • Expresses concern regarding the risk of unintentional adverse health effects, especially in individuals who have a long history of iodine deficiency and who may respond adversely to increased intake well below the provisional maximum tolerable daily intake of 17 ug per kg body weight. • Acknowledges that NZ data indicate that 28% of children in NZ could be classified as iodine deficient while Australian National Iodine Nutrition Survey results indicated a mild deficiency in children in NSW, Vic and SA but not in WA or Queensland.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> Expresses concerns that evaluation of potential food groups for iodine fortification has been based on 12 year old nutrition survey data, and significant changes to the food supply have occurred since then. The data no longer accurately reflects the types of food eaten nor provides relevant information about consumption of foods by population segments. There is a lack of data on current intakes of iodine in Australia and New Zealand. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Under voluntary fortification, increased permissions can achieve the objective of preventing IDD without removing consumer choice. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> Supports maintaining current permissions for iodised salt for discretionary use and promoting substitution of iodised salt for non-iodised salt. <p><i>Implementation</i></p> <ul style="list-style-type: none"> Notes the need for a considerable lead time for manufacturers if significant proportions of manufacturers moved to iodised salt. <p><i>Use of salt in non-mandated foods</i></p> <ul style="list-style-type: none"> Notes that small to medium-sized businesses could encounter difficulties in handling more than one supply of salt and may prefer to use one salt supply which could result in the addition of iodised salt to a wider than anticipated range of foods. Notes that the company has the capacity to manage alternative salt supplies within the manufacturing plant, but that this would add to the burden of complexity. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Supports developing and maintaining a trans-Tasman monitoring program for urinary iodine status in the target population to estimate prevalence of IDD. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Supports development and maintenance of a comprehensive consumer education program about the importance of iodine in the diet, aimed at the target population, predominantly in NSW, Vic, SA and NZ. Supports developing and maintaining an industry awareness campaign of the need for iodised salt in food manufacture. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> Notes increased cost of moving to iodised salt is \$20 per tonne. Notes increased cost of small impact labelling changes is approximately \$1500 per change. The cost significantly escalates depending on the number of SKUs. Notes ongoing costs for analytical testing of iodine content of the mix, pre-mix or final product to verify the addition of iodine and the level added. <p><i>Other</i></p> <ul style="list-style-type: none"> Expresses concern that the Scope of the Proposal does not seem to reflect the international evidence supporting mandatory fortification in Attachment 4 of the proposal. Suggests FSANZ investigate international voluntary programs to be able to implement a comprehensive successful program that will meet the public health objectives.

SUBMITTER	SUBMISSION COMMENTS
<p>School of Public Health University of Sydney Australia Mu Li</p>	<p>Prefers Option 2 – Mandatory fortification</p> <ul style="list-style-type: none"> But believe the fortification of salt with iodine in bread, biscuits and breakfast cereals <i>only</i> is inadequate and will not meet daily iodine requirements. Realises that FSANZ's decision will have a long lasting effect on the iodine status for the people and urge them to take a stand to ensure the mental and physical health of future generations are not compromised by giving into industry's pressure for a half hearted mandatory iodine fortification. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> The Proposal is based on data which is 10 years old. Demography and eating patterns have likely changed. The traditional cereal based diet may not be as pervasive through the population as it once was. Believe that cereal based products are not the best vehicle because vulnerable groups, like women of child bearing age and young children, may not consume enough of the fortified cereal foods. Salt has been chosen globally as the main vehicle for iodine fortification because it is widely consumed by the population. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> Disappointed that the Proposal suggests lowering the iodine level in table salt. Evidence points to a deficient intake of iodine. China only lowered iodine fortification level when the population median UIE reached 300 µg/L.
<p>Australian Medical Association (AMA) Australia Josie Hill</p>	<p>Supports Option 2 – Mandatory fortification</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> While the AMA supports mandatory fortification, it does not support FSANZ's preferred approach. <i>Universal salt iodisation</i> is the most appropriate and simplest public health approach. However, believes any progress in mandatory fortification has a potential for public benefit. The AMA supports the WHO, ICCIDD and UNICEF who advocate universal salt iodisation. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> Believes the likely costs of iodine fortification are moderate and a good investment to avoid the effects of iodine deficiency. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> On the available evidence, believes that mandatory fortification does not pose a health risk to the general public and only a low risk to those who are sensitive to iodine. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Monitoring issues should be resolved before the proposed iodine fortification. However, does not believe they should contribute to delay in advancing progress on iodine fortification. Ongoing monitoring is important to gauge effectiveness of fortification. Monitoring must include a National Nutrition Survey. Current data is 10 years old. Although applauding the intention of the commonwealth government to measure the nutritional habits of children, also need to collect data on other sections of the community, e.g. women of childbearing age, particularly important for iodine fortification.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • AMA calls for a National Nutrition Centre to monitor urine samples and to work collaboratively with FSANZ on issues relating to iodine fortification. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Believes that doctors and medical professionals are well placed to assist with the transition into a fortified food environment.
<p>Australian Division of World Action Group on Salt and Health Australia Caryl Nowson</p>	<p>Does not support current mandatory fortification proposal</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Believes salt iodisation conflicts with current Australian nutrition policies and dietary guidelines and world accepted nutrition policies (WHO and SACN, UK). • There is strong evidence that a reduction in dietary salt can reduce cardiovascular disease. Current nutrition guidelines aim to reduce the dietary intake of salt at a population level. • Over 75% of dietary sodium is derived from manufactured foods. • A gradual reduction, over a five year period, in the sodium content of manufactured foods, could reduce the average intake of salt from 9g/day to 6 g/day, in line with current government policy, and the stated upper limit. • This would necessitate the co-operation of the food industry. • Iodisation of salt will provide conflicting messages to the public. • To achieve adequate iodine an adult would have to consume 5 g of salt per day if all manufactured foods were fortified at 20 mg/kg, which is above the UL for sodium, and is 1 g higher than the Suggested Dietary Target. <p><i>Bread, breakfast cereals, biscuits</i></p> <ul style="list-style-type: none"> • Those choosing lower sodium/salt reduced bread and cereals are unlikely to achieve the recommended intake of iodine. • The salt content of these foods is extremely variable: <ul style="list-style-type: none"> – breakfast cereals vary from 3 to 820 mg/100 g (a 270-fold difference, making iodine fortification erratic – biscuits vary from 20 to 1390 mg/100g a 70 fold difference – breads vary from 400 – 725 mg/100g. • The high fat, sugar, and/or salt content of many breakfast cereals and biscuits is contrary to Australian Dietary Guidelines, and it is not appropriate to give people a health reason for buying them. • The health giving reputation of supplementary iodine would risk a boost in sales of many foods of questionable nutritional value. • Bread has some advantages as a vehicle for iodine: <ul style="list-style-type: none"> – bread is a staple food and is included in the Australian Guide to Healthy Eating; and – all bread would qualify for inclusion when recommending Australians to eat more bread. • Alternative approaches to achieving iodine sufficiency: <ul style="list-style-type: none"> – A specific amount of iodine should be mandated in specific core foods, rather than in three restricted food groups. – Exclude biscuits and crackers as a vehicle for iodisation.

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	<ul style="list-style-type: none"> - Manufacturers could choose their own method of iodisation. As iodisation of salt is not the only method available. - There needs to be continued investigation of alternative methods of iodine delivery (see Trevor Beard's submission). <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • FSANZ must take responsibility for ensuring adequate monitoring of dietary intake of iodine through regular surveys utilising urine collections. • There needs to be an ongoing government funded program of monitoring under the direction of FSANZ. • Responsibility for implementation of iodisation and monitoring must be administered by the same government body. • Dietary modelling must be assessed to ensure that all sections of the population can achieve an adequate intake of iodine, whilst achieving the Suggested Dietary Target for sodium.
<p>Crop and Food Research New Zealand food composition database NZFCD Jason McLaughlin</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Notes mandatory iodine fortification will improve the database's ability to provide complete data on the levels of iodine in foods. They are currently entering additional iodine values on 2700 foods into database. Of these values only 11% are New Zealand analytical values and the remainder are imputed or derived. Coverage of baked products is slightly better at 17%. NZFCD also uses the Manufactured Foods Database (MFD) but this is also incomplete as manufacturers do not always provide the required information.</p> <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Note that Nutrient Information Panels will now need to declare if iodised salt was used in the product. This information will assist NZFCD to determine which foods will need to have an updated iodine value in the database. • The MFD would be a better source of information on iodine fortified products after adoption of mandatory fortification. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Envisage the need to collaborate with FSANZ Food Composition program and /or the food industry to develop protocols for calculating appropriate iodine values for the NZFCD. • The resources required to update the national food composition database for New Zealand will require a formalised working partnership with external stakeholders such as FSANZ, NZ Ministry of Health and NZ Food Safety Authority. <p><i>Level of fortification</i></p> <ul style="list-style-type: none"> • Calculation of iodine content of fortified foods will be difficult given the wide range of fortification permitted (e.g. 20 – 45 mg iodine / kg salt)
<p>Dietitians Association of Australia (DAA) Kate Poyner</p>	<p>Supports Option 2 - Mandatory fortification</p> <p>DAA Represents 3000 dietitians, dietetic students and associate members. They believe mandatory fortification will reduce the mild to moderate iodine deficiency in Australia and New Zealand. Considers the Tasmanian experience has provided compelling evidence of improved iodine status of the population through fortifying bread with iodine.</p>

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Recognises that mandatory fortification of food with iodine will improve the iodine status for the population of Australia and New Zealand. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Many pregnant and breastfeeding women may still find it difficult to achieve NRVs for iodine intake. • Additional iodine supplementation may be necessary for many women of childbearing age, particularly those living in iodine depleted areas like SE Australia and New Zealand. • There may be a need for a low cost vitamin and mineral supplement for women to meet the increased nutritional needs of pregnancy and lactation. • People with existing thyroid conditions may need a change of management with increased iodine in food supply. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> • DAA supports current salt permissions. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • There is consensus among DAA members that a comprehensive monitoring and review program is essential to assess the effectiveness of, continuing need for, and any adverse effects from iodine fortification. • DAA asks for a firm commitment from Commonwealth, State and Territory governments in Australia and from the New Zealand Government that appropriate monitoring be undertaken. • DAA acknowledges that monitoring all age groups is desirable but costly and believes that a monitoring program would ideally consider: <ul style="list-style-type: none"> - health status, including but not limited to iodine deficiency disorders; - urinary iodine excretion (UIE), in school age children, women of childbearing age and children under three; - nutrient intake and food consumption patterns as assessed by food frequency questionnaires; - food composition data on iodine from major dietary sources; - compliance modelling for industry; and - monitoring should be across all States and territories of Australia and New Zealand due to variation of naturally occurring iodine. • Australia and New Zealand have relatively good baseline data on population iodine status. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • There is a need for public health programs to highlight the importance of nutrition both before conception and during pregnancy and lactation. Iodine, folic acid and many other nutrients are essential before and during pregnancy. • A broad based education program for women of childbearing age is essential because: <ul style="list-style-type: none"> - the level of mandatory supplementation will not enable many women to achieve NRVs for iodine during pregnancy and lactation; - women may incorrectly believe that they do not need any supplementation if foods are fortified with iodine; and

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> - - some women will consume little or none of the iodine fortified foods. This would include those women who are allergic or intolerant to wheat, those who consume little bread and /or those who limit processed food intake in order to limit sodium intake. • DAA believes that supplement programs and education programs are a government responsibility and will require ongoing support. • DAA considers that human development programs at secondary school are an ideal time to educate girls about iodine. • Education programs may need to be tailored for particular states to suit iodine availability in local food supplies.
<p>Manufactured Foods Database New Zealand Lyn Gillanders, Allannah Steeper</p>	<p>Supports Option 2 – Mandatory iodine fortification</p> <p>MFD compiles a database on food ingredients, and presence/absence of common allergens, from information supplied by New Zealand and Australian food manufacturers. This includes a list of foods that are voluntarily fortified. They currently have self reported sodium values for all 6.000 foods on the database.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports fortification of biscuits, bread and breakfast cereals but notes that reducing discretionary salt intake is a current health goal for New Zealanders. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Notes that salt begins to be listed as an ingredient when sodium is greater than 20 mg/100 gm. • Estimates that 25% of breakfast cereals do not have added salt. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports monitoring and review as a fundamental component of the proposal to assess the effectiveness of and continuing need for the mandating of fortification. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Iodine public health education has been ‘lost on a generation of younger people’. • Adequate funding will be needed for effective public education. • Lifestyle and cooking magazines advocate use of sea salt and this dilutes any health messages to use iodised salt. These publications could be used to increase public awareness of need to use iodised salt.
<p>Massey University New Zealand Janet Weber</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Emphatic support for Option 2. Prefers universal salt iodisation (scenario 2 in the Draft Assessment) but accepts it may not be warranted considering the extra cost to industry and the relatively small number of people not covered under scenario 1 (bread, breakfast cereals and biscuits). If scenario 1 is adopted recommend mandatory fortification of all table salt or, at a minimum support the continuing need for the voluntary permission to iodise table salt.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Need to consider alternative vehicles for those who don’t eat very much or any, wheat, gluten or other cereal products.

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	<p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • If iodised salt widely taken up by industry, (likely if health claims allowed), there is a possibility of excess intake for parts of population. • Voluntary permissions should be allowed only for other cereal foods e.g. pikelets, cakes etc • Voluntary fortification is dangerous because there is little control over how much iodine is consumed. • Prefers mandatory iodisation of table salt because this would result in a smaller number of people with intake under the EAR (from Draft assessment - Table 5). • Concerned that the proposed reduction in iodine level in table salt will affect some at risk groups (see below) <p><i>Level of fortification</i></p> <ul style="list-style-type: none"> • Notes that iodisation level of 20-45 mg iodine per kg salt is higher than in other countries and reflects the current high salt intake of Australians and New Zealanders especially through processed foods. • Suggests a government funded incentive to reduce sodium levels in food in association with the mandatory fortification process. • Current level of fortification will have to be reassessed and adjusted as necessary. • This would proactively address the contradictory messages of the need to ingest more salt for its iodine content and less salt for its sodium content. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considers nutrition related health claims should not be allowed for iodine except for naturally occurring iodine. As iodine is linked with salt, a high level of iodine will also signal a high sodium content. • Iodine content should be permitted on the NIP, to assist consumers to make a food choice. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Believes monitoring of the food supply and population is crucial to ensure that iodine intake does not become excessive. In South Africa following mandatory fortification of table salt manufacturers were unaware that they were using iodised salt. • Adequate funds must be assured for the comprehensive monitoring outlined in the proposal. • Without financial commitment to monitoring the voluntary permission to allow iodised salt in other processed foods should be revoked • Notes WHO provides useful guidelines for monitoring programs. • Recent monitoring program developed in Denmark may provide an exemplary monitoring model. • Important to collect baseline data. • Casual urine sampling in conjunction with the NNS, would be adequate to assess urinary iodine excretion. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Vulnerable groups like gluten intolerant people and ethnic groups who do not eat foods fortified with iodine, will need to be sampled separately. Asians are not currently included in NNS at a level for statistical inference to be made.

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	<ul style="list-style-type: none"> • Need to monitor for increased incidence of autoimmune thyroid disease and thyroid papillary cancers which may increase as iodine levels go up, particularly in areas with people with the highest iodine deficiency levels. • Need to monitor the use of iodine containing colouring agents in foods, pharmaceuticals and cosmetics. These have been linked to thyroid toxicity (IOM 2001) (Currently the monitoring of thyroid function of those taking the drug amiodarone is inadequate with respect to recommended guidelines, and is probably due to lack of knowledge of the guidelines). <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Considers it important to educate physicians prescribing drugs which contain iodine so they can monitor their patients and recommend iodine free salt, bread, breakfast cereals if necessary. • Nutrition education should target all at risk populations, including pregnant and lactating women, women of childbearing age, parents of young children, gluten sensitive people, ethnic groups who do not eat fortified foods and people suffering from thyroid conditions. • Physicians and health care professionals will need continuing education on iodine fortification and be included in the monitoring process/information. • Clear guidelines on how much iodine fortified foods to consume in order to get recommended levels of iodine • Education on lowering sodium levels in diet addressed alongside iodine education. • Supplements need to be readily available, and may be the best option for those who do not consume adequate quantity of fortified foods regularly.
<p>Menzies Research Institute Australia Trevor Beard</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>‘The problem with iodising bread with salt is to reconcile the conflict between providing iodine and progressively reducing salt.’</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Considers salt is an easy and quick vehicle for iodising food. However, using salt as the iodising vehicle would ‘block’ the voluntary reduction of salt in bread. The Heart Foundation has started reducing the salt allowed in bread for the ‘Tick’ and has announced further reductions. Further reductions in the salt content of bread would also reduce the iodine content. • Although salt strengthens gluten, slows the rise and adds flavour to bread, many successful No Salt and Low Salt bread are being produced. • AWASH, (Australian Division of World Action on Salt and Health) is campaigning for less salt, but if salt is iodised, reducing the salt content will also reduce the iodine content. • The Heart Foundation and individual bakeries must be free to promote healthier low salt bread and cater for people who want it. • Blocking the voluntary reduction of salt in bread will obstruct progress in controlling hypertension and its complications (heart disease, stroke and kidney failure). • Hypertension is as serious and prevalent as iodine deficiency disorders. Of those who reach middle age, 90% will develop hypertension.

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	<ul style="list-style-type: none"> • Hypertension/prehypertension can be treated very effectively with a healthier diet and exercise. A healthy target for salt/sodium intake is 65 mmol/day and Australia's NRVs set a target intake for salt/sodium at 75 mmol/day. The diet group that reversed prehypertension in the DASH diet used low salt bread (sodium \leq 120 mg/100 g). • Proposes three possible solutions: <ul style="list-style-type: none"> – Iodine fortification should be permitted by any other means at the discretion of the baker. This would be an outcome based standard which would be randomly monitored. – Make fortification levels high enough for low salt bread. Bread salt to be iodised at a rate, high enough to deliver the full dose of iodine when added at 0.4% of the flour weight. This low salt bread would comply with Australian Dietary Guidelines. In higher salt breads the extra salt would be uniodised. – A mandatory program of progressive reduction in salt content (e.g. 10% per annum) could continue until all Australian bread was low salt. <p>This might be acceptable to the bakery industry who would all be on an level playing ground, i.e. no one company would lose market share to another making bread with a higher salt content.</p> <p>Suggests a cap on salt content in bread of 1.8% of the dry ingredients.</p> <p>While salt content of bread was gradually reduced Option 1 could also be incorporated.</p> <p><i>Other possible vehicles for iodine</i></p> <ul style="list-style-type: none"> • Considers salt is a good vehicle because if an error occurred in production the strong taste of salt would alert consumers to a possible overdose of iodine. However, the two best vehicles for iodine are dough improvers and dough making flour. • Fortification of flour would take time to develop. • It would be cheap and easy to reintroduce the bread improver iodised with potassium iodate that was used in Tasmania in the 1960s. • Potassium iodate is an excellent dough improver, and can be added in varying proportions to a variety of bread improvers, to provide the correct dose of iodine. • Iodine content of bread using iodised bread improver is more reliable than in bread using iodised salt due to difficulties with quality control of salt iodisation techniques. • Homemade, no added salt bread can be fortified with iodine at the rate of 15 μgm per slice by using a reliable 0.4% potassium iodide solution delivered from a dropper.
National Heart Foundation (NHF) Australia Barbara Eden	<p>Does not Support Option 1 or 2</p> <ul style="list-style-type: none"> • The NHF does not support the fortification of any foods with iodine using iodised salt because this method of delivery: <ul style="list-style-type: none"> – conflicts with Australian and International public health recommendations; – conflicts with evidence-based nutrition; – conflicts with the Heart Foundation's Tick program; and – may risk encouraging the food industry to add more salt to their foods.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • The NHF believes that FSANZ has made a strong case for fortification of core foods with iodine and encourages FSANZ to consider alternative approaches for achieving iodine sufficiency in the Australian and New Zealand population. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Does not support Option 1 because they understand there is a re-emergence of iodine deficiency in Australia and New Zealand that needs to be addressed. <p><i>Food vehicle</i></p> <p><u>Salt</u></p> <ul style="list-style-type: none"> • Does not support option 2 because they believe that salt is an inappropriate food vehicle for iodine fortification. <p>i) Health recommendations</p> <ul style="list-style-type: none"> • Concerned that using salt as the vehicle for iodine fortification sends a conflicting message about salt intake to consumers because it conflicts with Australian and International health messages e.g. <ul style="list-style-type: none"> – NRVs for Australia and new Zealand recommends an upper limit (UL) of sodium for adults of 100 mmol/day and a suggested dietary target (SDT) of 70 mmol/day to reduce risk of chronic disease; – To achieve iodine sufficiency, and meet EAR of 100 µg/day an adult would need to consume at least 100 mmol of sodium/day. This is higher than the SDT of 70 mmol/day; – Dietary Guidelines for Australian Adults recommends that consumers choose foods low in salt and warns against consuming processed cereals with high salt levels; – To achieve NRVs the Dietary Guidelines recommend that adults should consume fresh food, foods normally processed without salt and low salt or no-added-salt groceries, and they should avoid adding salt to food; – WHO recommends that all adults consume less than 5 g salt /day and UK Food Standards Agency has set a target for average salt intake to be reduced to 6 g salt/day. <p>ii) Evidence</p> <ul style="list-style-type: none"> • Using salt as a vehicle for iodine fortification conflicts with the Heart Foundation’s evidence-based nutrition reviews. The Heart Foundation will continue to support further decrease in sodium intake through further gradual reductions in our food supply. Evidence on the effects of sodium on blood pressure, stroke and cardiovascular disease includes: <ul style="list-style-type: none"> – Reducing dietary sodium from 140 to 100 mmol/day is associated with a fall in systolic blood pressure of 2 mmHg in hypertensive and normotensive individuals – Reducing dietary sodium from 140 to 65 mmol/day is associated with a fall in systolic blood pressure of 7 mmHg in hypertensive and normotensive individuals – High dietary sodium intake is associated with increased stroke incidence, and mortality from coronary heart disease and cardiovascular disease – A general reduction in sodium intake could be better achieved by a general reduction in the sodium content of manufactured food products than by dietary advice alone

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	<p>iii) Heart Foundation, NHMRC and the food industry</p> <ul style="list-style-type: none"> • Much of the salt consumed by Australians is from manufactured foods. • Australian studies have shown that major food manufacturers have been lowering the salt content of foods in response to consumer demands and nutrition benchmarks, (including the Tick program). • The food industry needs incentives to decrease sodium levels in products which have added salt or other sodium compounds. • Sodium content can be lowered without loss of product acceptability. • NHF has been advocating for less salt for 40 years. The Tick program has been challenging manufacturers for 17 years and has driven reformulation and new formulations of food products, for example: <ul style="list-style-type: none"> – 235 tonnes of sodium were removed annually from the food supply by Kellogg reformulating 12 cereals; – A range of Tick approved luncheon meats developed with 50% less sodium than similar products; – Tick meat pies contain 50% less sodium than average pies; – The Tick program is incrementally reducing the sodium content of bread from 450 mg to 400 mg/100 g over 2 years in consultation with the bread industry; and – A recent review of the Tick criteria shows further sodium reduction in 10 categories. • In 1982 NHMRC recommended that food manufacturers be asked to lower the salt content of food. Manufacturers responded with a range of reduced and low salt alternatives now available. A survey found an overall decrease in sodium content of 10% compared to 15 years ago. <p>iv) Iodine related health claims</p> <ul style="list-style-type: none"> • Concerned that Proposal P230 states that ‘mandatory fortification presents the opportunity for food manufacturers to make nutrition and health claims’ and that fortification with iodine will encourage industry to use higher salt levels in manufactured foods so that they can make health claims related to iodine • Proposal P230 has the potential to set back the progress made by the food industry over the past 20 years which has seen a reduction in salt levels and new products with low salt levels. <p><u>Biscuits</u></p> <ul style="list-style-type: none"> • The Heart Foundation recommends that biscuits be consumed only once a week as they are not core foods and can increase saturated and trans fat intake. • The Australian Guide to healthy eating lists biscuits as extra foods together with meat pies and hot chips. <p><i>Alternative approaches</i></p> <ul style="list-style-type: none"> • Supports the alternative approaches suggested by AWASH (see Trevor Beard’s submission).
<p>The New Zealand Nutrition Foundation New Zealand Sue Pollard</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Agrees in principle with increasing the iodine status of the population through fortification but concerned with the use of salt as the vehicle. This may give inconsistent messages to the population with regard to reducing salt intake, making it difficult for the population to achieve adequate levels of iodine if salt intake is reduced.</p>

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	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Agrees that a long term fortification strategy is needed to target the population as a whole with an appropriate level of iodine. • Concerned with the effects of iodine deficiency, during pregnancy, on the unborn foetus and on mental development in early childhood. • Supports additional mechanisms to ensure that women receive sufficient iodine. • Concerned that children should not receive more than the upper limit for iodine (200 µg per day in 1-3 year olds and 300 µg per day in 4-8 year olds). • Concerned for people who avoid bread and cereals for various reasons, e.g. those with wheat allergy and coeliac disease. Believes it is important to establish how/if the iodine needs for these groups can be met. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Fortification of bread and breakfast cereals is appropriate because these foods form the basis of a healthy diet. • Fortification of salt with iodine will give a contradictory message not consistent with Australian and New Zealand nutritional guidelines. • Supports the replacement of non-iodised salt with iodised salt only where it is absolutely necessary to use salt in foods. • Has concerns about using iodised salt as the only (or major means of fortification). High salt intakes are linked to hypertension which increases the risk of heart disease. Heart disease was the leading cause of death in 2000. • Concerned that iodising salt will lead to an increase in salt intake in the NZ population. • 85% of salt intake is from manufactured foods. While some salt is necessary for functionality and taste, manufacturers should reduce the salt content of foods as far as practically possible. • Food manufacturers should be discouraged from adding salt to an extended range of their processed foods in order to promote iodine intakes. • Those food manufacturers who already have salt reduction policies in place should be commended. • Would not recommend maintaining current salt use in order to supply sufficient levels of iodine. • Suggests that part of the decreasing iodine intake may be due to decreased intake of salt in response to health messages. • Believes that other strategies for increasing iodine intake will be needed to ensure adequate iodine intakes 'in the absence of excess sodium intakes.' • Believes there is a need for a coordinated program of research to identify alternative ways of fortifying foods with iodine, e.g. direct addition of potassium iodide or iodate to food. This would involve ascertaining the levels of iodine that could be added to foods before bioavailability was affected and the possibility of altering/reducing the shelf life of the food vehicle(s). <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • As all staple/ cereal foods/major food group will be fortified with iodine, those consumers wishing to avoid iodine in their diet have limited food options. • Some consumers wish to avoid salted products while still consuming adequate iodine. This is not possible if salt is the vehicle for fortification.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Appropriate labelling of iodine in foods will allow consumers to avoid iodised products. • Labelling should guide and inform customers with the amount of iodine and percentage of RDI provided by a specified serving size. • Because food composition tables do not include iodine, this will necessitate analysis of foods. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • The iodine status of the population should be monitored as an integral part of the iodine fortification approach to ensure ongoing safety and effectiveness. • The iodine content of foods with both fortified and naturally occurring iodine should be monitored. • Monitoring is important to ensure that the safe upper limit for iodine is not exceeded, especially if iodine is added to a wide variety of foods. • Excess levels of iodine can lead to hyperthyroidism. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • A marketing and education strategy should go ‘hand in hand’ with fortification. • It is important to raise awareness of the issue amongst New Zealand consumers, in particular pregnant and breastfeeding women and parents or guardians of young children. • It is also important to raise awareness of iodine among health professionals so that pregnant and breastfeeding women are advised to regularly consume iodine containing foods and to take an oral iodine supplement if one becomes available as a registered medicine.
<p>NSW Centre for Public Health Nutrition Australia Vicki Flood</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Notes issues concerning the choice of food vehicle but ‘this should not detract from’ support for mandatory fortification of foods with iodine.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Although acknowledging that WHO has recommended adding iodine to salt and previous experience adding iodine to salt, query whether salt is the most appropriate food vehicle. • The Australian Dietary Guidelines recommend the use of foods low in salt and the NRVs recommend a lower sodium intake so there is potential for an inconsistent health message to the public about use of salt. • If the sodium content of future food products is decreased some increase in the dose of iodine will need to be considered. • Concerned about the use of energy dense, nutrient poor, ‘extra’ foods like biscuits to provide iodine in the diet. • Believes that bread is an appropriate food for fortification as it is a staple. There may be some population subgroups who consume little bread and other cereal products e.g. coeliacs and some ethnic communities. • Suggests considering other core foods as vehicles for iodine fortification e.g. milk and milk products.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believes there is good evidence to suggest a mild to moderate iodine deficiency in the Australian population. • As children in Queensland and Western Australia have adequate iodine status, concerned that mandatory fortification may cause more children to exceed the upper limit for iodine. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Supports the addition of iodine to the Nutrition Information Panel to inform consumers on the amount of iodine present in fortified foods which could vary within food types dependent on the amount of salt in the food. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Mandatory fortification requires adequate monitoring of the iodine content of foods, iodine status of the population and at-risk groups and thyroid disease surveillance. • The monitoring system should be in place before any fortification measures are instigated. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports an extensive education campaign to inform the public about iodine fortification and the need for pregnant and breastfeeding women to be supplemented in addition to consuming iodine fortified foods. • Need for education of consumers and medical practitioners to raise awareness about iodine induced hypothyroidism and hyperthyroidism. • Groups who eat little bread and/or cereal foods may need education to encourage consumption of iodine from other sources.
<p>NZ Dietetics Association New Zealand Jan Milne</p>	<p>Supports Option 2 - Mandatory fortification (only for bread and breakfast cereals, not for biscuits)</p> <p><i>Food vehicle</i></p> <p><u>Salt</u></p> <ul style="list-style-type: none"> • Have grave concerns if the use of salt as the fortification vehicle resulted in any increase in salt consumption. (The NZ Food and Nutrition Guidelines recommend that salt and sodium be kept to a minimum. New Zealanders consume 7.1-10.1 g of salt per day). <p><u>Bread and breakfast cereals</u></p> <ul style="list-style-type: none"> • Bread and breakfast cereals contribute 25.7% and 5.8% respectively of New Zealanders total salt intake. • The New Zealand Food and Nutrition Guidelines encourage new Zealanders to eat at least 4, (preschoolers) and 6, (adults) serves of bread and cereals daily, which makes them appropriate choices for fortification. • Endorse replacement of existing salt with iodised salt in these foods but advise caution, (even sodium restrictions or salt reductions) so that the salt content of these foods are not increased. <p><u>Biscuits</u></p> <ul style="list-style-type: none"> • NZDA members do not support the fortification of biscuits with iodised salt as NZ has an obesity epidemic and they feel a responsibility to promote foods that will enhance population health.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Biscuits were the main food contributor of energy, total fat and saturated fat in the 2002 Children’s Nutrition Survey. The NZ Food and Nutrition Guidelines do not encourage their regular consumption. • Iodine fortification may be interpreted as a ploy to increase their marketability, where we are encouraging decreased consumption of these items. • It may be necessary to increase the fortification of bread and breakfast cereals in order to achieve the desired levels of iodine in the food supply. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Reinforce the importance of a sound monitoring system if mandatory fortification is introduced. • Monitoring should be the responsibility of the Ministry of Health in New Zealand and should be incorporated into national health and nutrition surveys. • Urinary iodine and sodium secretion should be monitored. • There needs to be a commitment to regularly checking and enforcing the requirements of mandatory fortification in both local and imported foods. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Moderate iodine deficiency reported in pregnant women and 6-12 month infants. • Iodine status of New Zealand children was low and indicative of mild iodine deficiency (Children’s Nutrition Survey 2002). • Decreasing levels of iodine intake in adults (1997-98 NZ Total Diet Survey), below the Australian Recommended Dietary Intakes (RDIs). • Some population groups, e.g. Asian communities or people with coeliac disease, may not benefit from the fortification of bread and breakfast cereals. May need to consider their needs separately, with targeted campaigns for alternative sources of iodine. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Fish and seafood are expensive food items. If there was an effective campaign for the population to increase seafood intake market forces could cause further price rises, making seafood intake beyond the financial reach of many New Zealanders.
<p>Gesundheitsamt Public Health Board Germany Eugen Kriener</p>	<p>Preferred option not stated</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Extrapolating the Upper Level of Iodine Intake for children from adult data on a metabolic bodyweight basis is inappropriate. Recommends the use the Upper Limit for iodine set out in Chapter 12 of the joint FAO/WHO expert consultation on human vitamin and mineral requirements i.e. 50 ug per kg of bodyweight per day for children aged 1-6 years. • Notes that despite public health campaigns to promote the use of iodine supplements for pregnant a lactating women, only a small proportion of pregnant and lactating women in Germany take iodine supplements. • Suggests that fortification should seek to raise intake of the 90% of the population to or above the RDI as opposed to the EAR. • Questions if iodine losses during processing, storage and cooking have been estimated correctly suggesting such losses are in the range of 6-20%.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Notes that even moderate deficiency does not have ‘moderate’ consequences citing delayed mental function, learning capacities and motor functions. • Advocates the same level of iodisation in discretionary salt in line with mandatory fortification concentrations. • Advocates provision of iodine supplements to pregnant and breastfeeding women at a level appropriate to those at the lower end of iodine intake. • Notes that in Germany despite long-standing guidelines advocating iodine supplements the only thing many doctors know about iodine is that ‘it could be too much’. • Suggests iodine fortification of animal feeds to augment iodisation of the human food supply. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Notes that a statement made by the ICCIDD (www.iccidd.org) writes about the German government declaring that iodised salt is not required for bakeries, meat, sausages, or industrial foods is incorrect. Instead, in 1993, the Ministry of Nutrition, Agriculture and Costumer Protection declared that for non-packaged food, in contrast to packaged food, the use of iodised salt need not be declared.
<p>Royal New Zealand Plunket Society (Inc)</p> <p>New Zealand</p> <p>Angela Baldwin</p>	<p>Supports Option 2 – Mandatory iodine fortification Fully supports the proposal.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considers mandatory fortification to be clearly in line with well child health goals. • Supports plans to reduce concentration of iodine in salt. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Believes it is important for the population to feel confident in managing the levels of iodine they and their children take in. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports monitoring consumer behaviour and the effect of mandatory iodine fortification on the population. • Urges timely assessment of the effects, positive or negative on the health of infants and young children. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports need for supplemental iodine intake by pregnant and breastfeeding women and those of child bearing age.
<p>Taranaki District Health Board (TDHB)</p> <p>New Zealand</p> <p>Jill Nicholls (Representing dietitians and nutritionists)</p>	<p>Supports Option 2 – Mandatory fortification</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Believes that the mandatory use of iodised salt in all bread, biscuits and breakfast cereals is a good way to ensure adequate iodine intakes. <p><i>Removal of voluntary permission of salt iodisation/use of salt in non-mandated foods</i></p> <ul style="list-style-type: none"> • Believes that once iodine fortification is implemented other voluntary use of iodised salt by industry should not be permitted because it may result in excessive iodine intake.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Concerned at possibility of food manufacturers adding iodised salt to high salt, pre-packaged foods and marketing them as healthy due to their being a source of iodine. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believes that a considerable number of New Zealanders are no longer getting an adequate intake of iodine because they have taken up the public health message to use less salt. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Concerned that the potential for public misinformation is great, especially with reference to food manufacturers making health claims for iodine content of their foods. • Suggests that well funded wide reaching, and ongoing education campaigns targeted at entire population should be an important adjunct of this proposal. • Ongoing education programs for pregnant and breastfeeding women are important.
<p>Tasmanian Ministerial Thyroid Advisory Committee Tasmania Judy Seal</p>	<p>Supports Option 2 – Mandatory fortification</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Disappointed that mandatory universal salt iodisation has not been supported as the preferred option. Believes USI would: <ul style="list-style-type: none"> – be more effective; – simplify communication with manufacturers; – simplify enforcement; – simplify monitoring of food composition; – result in a more sustainable solution; and – be consistent with international recommendations. • Believes that voluntary fortification is an inadequate response to protecting public health and safety and commend the fact that voluntary fortification has not been considered. While Tasmania has had some success with voluntary fortification concerned about the reach of the program to subpopulation groups, sustainability and ongoing costs of maintaining industry commitment. • Understand that reluctance to increase the level of iodine fortification, relates to minimising the proportion of individuals who exceed the upper limit. • Draft Assessment highlights the upper limits do not represent absolute thresholds for toxicity and there is a wide margin for safety and intakes in young children are unlikely to be a safety risk. • There is a risk that cautious language about exceeding the UL implies toxicity and may lead to a misunderstanding with the general public.
<p>JC Stewart Private Australia</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Studied iodine nutrition and thyroid disorders for 40 years. Member of Thyroid Clinic at Launceston General Hospital and of the State Thyroid Advisory Committee from 1968-2003. Co-authored a number of papers concerning the occurrence of IHH.</p> <p>Would prefer universal salt iodisation, (USI) but is happy to support the current proposals subject to a higher level of fortification.</p>

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believes that only a mandatory approach to iodine fortification would work. • Is aware of no voluntary scheme of iodine supplementation that has been of lasting benefit. • The proposed level of iodisation is insufficient to meet the needs of pregnant and lactating women. With a minimal increase in real risk the iodisation level could, and should be raised. • Thanks to iodophors in milk, the Australian population was iodine replete for about 30 years starting in the mid sixties, and there is unlikely to be a pool of people at risk of IHH. • Young children can tolerate a much higher daily intake than the proposed upper limit. • Unjustified fear of adverse effects risks making the proposal more of a gesture than a serious attempt to eradicate iodine deficiency. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • No explanation given in Draft Assessment for not recommending USI as advocated by the ICCIDD. • Believes that USI would be simpler to effect and more dependably successful. • By confining iodine to a few foods some consumers will not receive iodine. • Manufacturers of these foods may feel they are being victimised and oppose the measure. • Here are so many bakeries in the country that policing compliance would be practically impossible. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Milk still contains appreciable quantities of iodine, from teat dips (about 150 µg). But this level may fall if another teat dip were used. The population would then have a significantly lower iodine intake. • Monitoring of urinary iodine levels is essential in perpetuity because of the possibility of unforeseeable changes in dietary iodine. • There should be provision for rapid adjustment to the level of fortification should such a change occur.
<p>Endocrine Society of Australia (ESA)</p> <p>Australia</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Strongly supports the proposed mandatory iodine fortification of salt but does not believe this proposal will address iodine deficiency in crucial groups e.g. pregnant and breastfeeding women.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believe a mandatory program is justified because voluntary programs have not been successful elsewhere. • Because of the importance of iodine for brain development in newborn babies, ESA recommends that all pregnant and breastfeeding women and all women planning pregnant should be iodine replete. • They recommend an intake of 250 µg/day, in line with the WHO guidelines. • Even with iodine fortification, to reach this intake, supplementation of these women, would be necessary.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Prefers universal salt iodisation (USI), (consistent with the WHO position on iodine fortification). <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • A system of monitoring of iodine status, especially of vulnerable groups, should be set up in conjunction with the introduction of iodine fortification. • Monitoring should be ongoing, to prevent re-emergence of iodine deficiency. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Recognise that there are issues of personal choice and commercial costs, but believe that the balance of public good markedly favours mandatory iodine fortification. • The small risk of iodine-induced hyperthyroidism is manageable and outweighed by the public good.
<p>National Heart Foundation of New Zealand</p> <p>New Zealand</p> <p>David Munro</p>	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <p>Agrees there is an emerging problem with iodine deficiency in New Zealand but does not believe FSANZ has presented enough evidence to support Option 2.</p> <p>Is concerned that using salt as a vehicle for iodine is inconsistent with national dietary guidelines and could stifle efforts to reduce the sodium content of food.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • High blood pressure is an important risk factor for cardiovascular disease and stroke with a continuous association and no lower threshold. Many cardiovascular events occur at below predefined cut-offs for hypertension. High blood pressure has been estimated to cause 3699 deaths in 1997. • Dietary sodium is an important determinant of blood pressure. New Zealanders dietary intake of sodium is generally excessive, averaging 113-150 mmol/L. This is seven times the adequate intake and 113-150% of the upper limit. • Reducing New Zealanders' exposure to salt is one of the key population health messages underpinning the New Zealand Ministry of Health's Healthy Eating – Healthy Action implementation plan 2004-2010. • Analysis of New Zealanders dietary intake show that breads continue to contribute the majority of dietary sodium and are therefore an important vector for reducing the population's exposure to sodium. Stepwise reduction of sodium in bread has the potential to reduce population intakes of dietary sodium thereby reducing hypertension. • This seems feasible as research has shown there is a wide range of sodium levels in New Zealand breads 350 – 600 mg/100g. • Lower priced bread and breakfast cereals typically contain higher sodium levels. There is a need for sodium reduction across the board but especially in low cost food categories. Lower socio-economic groups have a higher rate of cardiovascular disease. • A multifaceted approach including regulatory and industry led initiatives to reduce sodium content of commercially prepared foods is recommended. • A decrease in dietary sodium of 100 mmol/day could lower systolic pressure by 6 mmHg and could prevent 282 deaths a year in New Zealand from 2011.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Dietary modelling or further risk assessment is needed to ensure that the fortification of iodine into high salt foods such as bread and breakfast cereals will not adversely affect public health and stifle current and future attempts to remove sodium from the food supply.
<p>School of Public Health The University of Sydney Australia Soja John Thaikattil</p>	<p>Supports Option 2 – Mandatory fortification</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believes that mandatory programs are more effective for population wide public issues. • Industry is driven and motivated by profit, and it is almost futile to ask them to act against their own self interest. But there is room to encourage them to be part of this public health initiative. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • The diverse dietary habits of different groups who might not benefit from the current choice of food vehicle should be identified. • Mandatory fortification could then be extended to include iodised salt to appropriate diets of such ethnic groups. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Believes there should be a National Nutrition Survey (NNS) within the next 12 months to collect baseline data, another 2 years after fortification comes into effect, for assessment of immediate benefit and risk, and thereafter in conjunction with the National Census. • The advantages of baseline data include: <ul style="list-style-type: none"> – a better basis for monitoring the efficacy of the fortification program; – the current data available to FSANZ for their policy decision is too old; – dietary habits change with time and new products are introduced constantly. FSANZ needs to understand the current trends in consumption to make well informed policy decisions; and – FSANZ would have the opportunity to detect negative trends and outcomes early and take steps to resolve them if possible. • The NNS questionnaire should be designed so it can detect dietary habits of all ethnic groups, some of whom may not benefit from the current proposed food vehicles. • It would be useful to determine which ethnic groups may not require the use of additional iodised salt because their diet already contains adequate iodine e.g. those who eat large quantities of seafood. • Unidentified food frequency questionnaire (FFQ) could be made available on the FSANZ website. • School teachers could give guidance about filling in FFQ. • Unidentified FFQ could be distributed to households with census papers. • A randomly selected sample of the population could be invited to give blood samples. • The cost of regular NNS could be passed on to the public in some way, after raising public awareness of the importance of folic acid and iodine.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Communication and education</i></p> <ul style="list-style-type: none"> • There should be general public awareness campaigns. • The role of iodine for mother and child could be included in school sex education programs along with the importance of folic acid in prevention of NTDs. Education in school paves the way for making information public knowledge with time. • Health professionals should continue to be involved in educating the would-be mother and recommend or prescribe supplements as required. • The public needs to be informed that the benefits of iodine fortification are subtle and can only be fully appreciated in the next generation.
<p>University of Otago New Zealand Sheila Skeaff</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Commends ‘FSANZ on a thorough and balanced report on this topic’. Believes that ‘mandatory fortification is an excellent first step in addressing iodine deficiency in school aged children and adults but concerned that the proposal will not provide enough iodine to children under 3 (particularly those living in New Zealand) and to pregnant and lactating women.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Because the adverse effects of iodine deficiency are most pronounced during early life, pregnant and lactating women should be the ‘specific objective of the regulatory measures outlined in this Proposal’. • This proposal is unlikely to increase the iodine content of the diets of pregnant and lactating women to adequate much less optimal levels. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Believe that despite widespread education programmes and a recommendation for pregnant and lactating women to take iodine supplements many will continue to have inadequate iodine status. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • There is an obvious need for ongoing surveillance of the population particularly at risk groups such as very young children, and pregnant and lactating women. • The effect of the proposal on iodine status will need to be re-evaluated at regular intervals.
<p>Private Australia Max Watson</p>	<p>Strong argument for supporting Option 2 - Mandatory iodine fortification</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports fortification of cereal flour as suitable vehicle. However, suggests little thought given to mandating use of iodised salt across the food industry generally (with due consideration to fortification level) which would benefit consumers with poorer diets and at higher risk of iodine insufficiency. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Monitoring and enforcement of compliance is an essential component and high priority for successful implementation. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • As with fortification with folic acid, concern expressed that compliance with addition of iodine is rated as ‘low-medium’. • Notes importance of adequate monitoring and surveillance, particularly for unanticipated outcomes.

SUBMITTER	SUBMISSION COMMENTS
Private Australia Beverley Wood (Consultant dietitian)	<p>Supports Option 2 – Mandatory iodine fortification</p> <p>Commends FSANZ for a well written and researched report.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Use of iodised salt in manufacture of bread, breakfast cereals and biscuits is well supported by arguments in the report. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Believes that most bread, breakfast cereals and biscuits are manufactured in Australia and NZ. • Proposal may limit small manufacturers importing some ethnic /unusual products into Australia. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Does not support removal of voluntary permission for iodisation of table salt. • Believes that only smaller manufacturers would choose to add iodised salt to other foods they manufacture because iodised salt is more expensive. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Advises continuous monitoring should be a feature of the implementation strategy.
Department of Agriculture, Fisheries and Forestry (DAFF) Australia Richard Souness and Mark Schipp	<p>Does not support the preferred approach</p> <ul style="list-style-type: none"> • Supports strategies to address iodine deficiency, however believes that initiatives should impose minimal regulatory and financial burden on industry. • DAFF have a number of concerns with the preferred approach and considers that further work is required to address these concerns to ensure the most effective approach for achieving adequate iodine intake. • Concerned that following Ministerial advice the regulatory options of extended voluntary permissions and promotion of voluntary options to increase industry uptake were removed, both of which DAFF supported. • Considers the expansion of voluntary fortification with iodine should not be eliminated as it would increase consumer access to a wider range of iodine sources, and its potential has been demonstrated by the improvement in iodine status following the introduction of a voluntary program in Tasmania. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned that the proposed approach has the potential for some individuals to exceed the upper limit, especially young children and those with a thyroid condition. • Considers that mandatory fortification may create the perception that mandatory fortification alone will meet the requirements of the target group. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Considers that mandatory fortification eliminates consumer choice, and some people may wish to consume non-fortified products. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Concern about the trade-related costs of mandatory fortification on manufacturers exporting to countries that prohibit the importation of foods fortified with iodine. Estimates the additional costs to these manufacturers of maintaining separate production lines and associated costs to be more that \$2.3 million in ongoing outlays per year.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Considers a voluntary approach to iodine fortification allows manufacturers the flexibility to cater to the needs of export markets. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Notes that Australia imports biscuits – worth \$177 million in 2004/05. (Listed 19 countries that exported biscuits to Australia.) <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Considers existing permissions for voluntary iodine fortification should not be removed and the range of voluntarily fortified foods extended, rather than implementation of mandatory fortification. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Concerned that the first Specific Order Policy Principle for mandatory fortification has not been met, as they consider the results of the National Iodine Nutrition Study do not establish that the extent of iodine deficiency in Australia is of a severity or prevalence as to require the introduction of mandatory fortification. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Concerned that the prioritisation of enforcement activity will be difficult, as checking labels of specific imported food for the presence of iodised salt does not provide a direct link to public health and safety. Therefore, considers voluntary fortification options and surveillance activities by FSANZ such as through the Total Diet Survey would be more appropriate. • Considers the geographic diversity in iodine status has the potential to produce inconsistent implementation and compliance with, and enforcement of, mandatory fortification, resulting in an uneven playing field for industry, particularly for manufacturers in areas identified as iodine deficient. • Due to the potential health risks, advocates that any decision to implement mandatory fortification needs to be accompanied by a robust monitoring framework with a definite timeframe. • Considers there needs to be a coordinated commitment from states and territory governments to allocate funding for monitoring activities. • Advocates monitoring as considers it is unfair on industry to impose a long-term strategy which may not achieve the desired outcome. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports the implementation of appropriate health promotion and education strategies to promote awareness of iodine, particularly for those groups such as pregnant and lactating women whose needs will unlikely be met by fortification alone. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Considers the difficulty in quantifying any potential benefits in monetary terms, particularly in regard to improved productivity, highlights the inequitable burden that would be imposed on industry if this Proposal is approved. • Notes that according to the cost benefit analysis, industry would bear the majority of the upfront and ongoing costs.

SUBMITTER	SUBMISSION COMMENTS
Department of Human Services Victoria Australia Victor Di Paola	<p>Does not support either option</p> <ul style="list-style-type: none"> Does not support either of the options as currently drafted, and instead provides an alternative option. Their major concerns are the inconsistency of the proposed food vehicles with national nutrition policies, fundamental flaws with the dietary modelling and lack of adherence to Ministerial Policy Guidelines. However, considers addressing the mildly iodine deficient status of the Victorian and NSW populations is a matter of urgency in order to prevent a further deterioration in iodine status. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Notes that some products within these food vehicle categories have a high fat and/or sugar and/or salt content, and that this is inconsistent with the Ministerial Policy Guideline. Concerned that these products will be able to carry a nutrient content claim for iodine, and that inappropriate or misleading information could reach the consumer, including messages that these are appropriate food choices regardless of their fat/sugar/salt content. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerned that any supplementation may increase the percentage of children with urinary iodine excretion levels above 300 µg/L. Cites a paper by Mu <i>et al</i> that showed more than 10% of children in Western Australia and 5% in Queensland have urinary iodine excretion levels of greater than 300 µg/L. Considers that if a national program is to proceed that it needs to ensure that in replete States a normal distribution of iodine intake occurs, and not a distribution skewed toward higher iodine intakes. Notes that iodine fortification will not reach minority groups such as those with coeliac disease, wheat sensitivity, and some ethnic groups and the Australian Indigenous population who have a lower consumption of processed foods or who prepare bread alternatives in the home. Recommends a targeted communication and education strategy to address these minority groups. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Considers consumer choice is potentially less vital when fortifying a food supply to restore a nutrient to adequate levels and correct a deficiency in a population. However, concerned that the proposed approach is a nationwide measure despite only mild deficiency being demonstrated in certain populations and only in two states in Australia (considers Tasmania is now replete). Instead considers iodine deficiency to be a localised issue that should be addressed through campaigns targeting those affected. <p><i>Trade</i></p> <ul style="list-style-type: none"> Considers the Proposal has considerable implications for the import and export of organic products, as current organic standards generally don't permit iodised salt in certified products. Considers organic imports would be most greatly affected as the majority of products imported are processed foods including cereal products. Notes that the financial cost of this potential loss of trade to Victoria has not been estimated.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • Acknowledges that iodised discretionary salt will provide a source of iodine for those people who are low consumers of the selected food vehicles and is consistent with the New Zealand dietary guidelines. • Comments that it is not possible to predict the degree that iodised salt that will be used in other food products, and therefore a potential risk to public health may arise due to over consumption of iodine, particularly in young children. Notes that FSANZ has not proposed a strategy to manage this risk. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Principle 1: Considers the health need has only been demonstrated in two States, not for the whole Australian population. • Principle 2: Considers that FSANZ has not demonstrated that mandatory fortification with iodine is the most effective public health strategy, and that there is insufficient data to make such a determination. • Principle 3: Considers the use of all biscuits and all cereals as suitable food vehicles is contrary to the national nutrition guidelines, as some of these products are high in fat, sugar or salt. • Principle 4: Considers that the preferred approach will be likely to result in excess or imbalance for some population groups, though accepts that these excesses or imbalances are unlikely to be detrimental. • Principle 5: Considers that with available data it is impossible to assess whether the proposed mandatory fortification will deliver effective amounts of iodine with specific effect to the target population. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Comments that international experience shows that a monitoring system is vital to ensure the sustainability and effectiveness of the program. • Notes that the WHO/IDD recommend that a monitoring program should involve both process and impact evaluation to ensure a robust and sustainable monitoring framework. • Considers the cost advocated in the Cost-Benefit Analysis will not allow for more than a meagre monitoring program. • Considers that the proposed framework needs to be further detailed in order to transfer it into a workable initiative, and will be more costly than identified. • Additional aspects to be included in the framework include: <ul style="list-style-type: none"> – committed Federal and State funding for these initiatives; – a nationally coordinated body responsible for managing the monitoring and evaluation program; – a commitment to review the legislation and its effectiveness on the basis of monitoring and evaluation results; – baseline and post fortification data on iodine status in different geographical locations and for pregnant women; – coordination and cooperation with the salt industry to ensure the mandated levels are adhered to; and – the contribution of supplements to overall iodine intake in all groups, particularly young children. • Considers a descriptive timeline must be in place to guide the monitoring process.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Proposes that monitoring commence within two years of mandatory fortification with ongoing review every five years, and needs to continue for a minimum of two generations. • Requests that a benchmark for safety be established, which would stipulate the acceptable proportion of the population exceeding the upper limit based on current recommendations. If monitoring determines that this benchmark has been exceeded, the food vehicles and level of fortification would then need to be reconsidered. • Considers it unlikely that mandatory fortification with iodine would be proactively enforced without substantial Government funding, due to the multitude of food products being fortified and the lack of direct and immediate risk to public health. • Considers ‘reactive enforcement’ would also be unlikely as consumers would be unable to determine if a product contained less or more iodine than that mandated. • Comments that within Victoria it is expected that monitoring of iodine levels in food would be a low priority for Local Government surveillance programs, and hence would rely on good manufacturing practice within industry. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Suggests that the communication and education strategy be clear for each State, including consideration of the potential geographical differences in iodine levels/intakes within each state. This would require further studies to be completed in States thought to be replete to discount geographical anomalies. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Considers the dietary modelling undertaken by FSANZ to determine the appropriate fortification level is ‘fundamentally flawed’, and does not enable an accurate and valid determination of population based risk assessments: <ul style="list-style-type: none"> – Incomplete or data not available on current intakes of iodine in the Australian population from food, supplements, water or via commercial cleaning processes; – No accurate data on the intake of salt; – The proposed food vehicles are based on the last 1995 NNS; – Assessments of fortification on replete states were based on water even though it is unclear what sources/factors are contributing to the iodine status in those states, and that the small number of water samples used were not representative of available water; and – The proposed level of fortification is different to the level modelled, and therefore the proportion of people exceeding the UL is underestimated. • Requests the collection of a range of ‘useful’ baseline data, to assist in the selection of the most appropriate food vehicles and level of fortification. <p><i>Alternative option</i></p> <ul style="list-style-type: none"> • Victoria proposes the following alternative for mandatory fortification with iodine: <ul style="list-style-type: none"> – mandatory fortification using iodised salt only in those bread, breakfast cereals and biscuits that are consistent with the national dietary guidelines; – voluntary permissions for the use of iodine in salt and reduced sodium mixtures to be allowed for discretionary purposes only; and – the level of fortification to be in the range of 15-35 mg iodine per kg salt for both mandatory and voluntary fortification permissions.

SUBMITTER	SUBMISSION COMMENTS
<p>NSW Health & NSW Food Authority Australia Bill Porter & Stephen Corbett</p>	<p>Generally supports Option 2 – Mandatory fortification with iodine</p> <p>Generally supports the preferred approach, and agrees with recommendations that any change must be accompanied by appropriate education programs and a monitoring framework.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Provides a summary of the forecasted impact of mandatory iodine fortification, and concludes that the proposed addition of iodine to salt in NSW is likely to reduce the risk of sub-clinical hypothyroidism, and in the longer term the risk of overt hypothyroidism in their community. • Considers the possible adverse health affects were adequately addressed in the report, and agrees these can be addressed through community education and monitoring. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Notes that the level of fortification for the voluntary permission of salt iodisation will need to be revisited if biscuits are removed from the list of food vehicles. • Considers the option of removing biscuits from the foods to be fortified has some merit in view of the problems associated with imports, clarifying the interface between biscuits, cakes, pastries and confectionery, and the limited ability to make iodine claims on biscuits. • Notes the argument raised by Tasmania that removing biscuits would result in only a marginal improvement in iodine intake in that State. • Suggests that if it is not feasible to substitute biscuits with another food, such as potato chips, then the shortfall could be addressed by increasing the iodine level in salt for the remaining food vehicles. • Notes there are some indications from industry normal salt will be replaced with iodised salt in all products, and the potential for this to increase the iodine intake in some individuals more than intended. • Notes that preliminary advice from the bread industry confirms use of iodised salt does not pose any technical difficulties, however industry has not generally conducted storage trials to determine the stability of the iodine over the storage life of the product. • Appreciates that the mandatory fortification of iodine to table salt alone, as adopted by other countries, may miss significant sections of the population. • Considers the experience in Tasmania supports a mandated rather than a voluntary approach to iodine fortification. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considers it inequitable to require all biscuits to use iodised salt in lieu of normal salt, but only allow some biscuits to make a claim (i.e. as allowed under Standard 1.3.2 for biscuits containing not more than 20% fat and not more than 5% sugars). • Notes that an entry in the Nutrition Information Panel for iodine would be regarded as a claim and would be subject to the limitations of Standard 1.3.2. • Considers on balance that the inclusion of iodine in the Nutrition Information Panel is warranted and requests that FSANZ reconsiders its position on this matter. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Considers the report may understate the significance for imported products such as biscuits into Australia, and assume that this issue will be addressed in the WTO notification.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> Notes that manufacturers could use the current voluntary permissions and add iodised salt to bread, biscuits and breakfast cereals at a higher level up until the end of the transition period, which could impact on the assessment of health risk from increased iodine intake. Considers that it may be worthwhile to consider limiting the addition of iodised salt only to foods with specific permissions, i.e. bread, breakfast cereal and biscuits. This would simplify the monitoring framework and decrease the risks of excessive intake. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Considers the categorisation of biscuits will be difficult, and may have significant implications for enforcement by the jurisdictions and the monitoring framework. Anticipates there will be difficulties in measuring outcomes in relation to iodine contents of fortified foods as there will be no specified range of iodine in the end product. Instead the iodine level will correspond to the level of added salt and be subject to losses during processing and storage. Notes that to determine iodine levels, where they are not declared, it will be necessary to rely on analysis of formulations on a case by case basis. Notes that end product levels are not readily enforceable without determining the level of added salt as opposed to total salt, providing allowance for iodine degradation over the life of the product, and differentiating between added salt and salt present by carry-over from another ingredient. Notes that both monitoring and enforcement will require significant resources, which they consider have not been allowed for in this process. Considers a combined monitoring approach for a variety of additives should be considered, rather than iodine alone, and in particular efficiencies be sought in relation to biological and nutritional monitoring. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Considers communication and education initiatives an essential component of the Proposal, however there needs to be a commitment for funding. To be undertaken for both the public and for the food industry, including importers and small businesses. Strategies should take into account the sectors of the population that do not eat bread or breakfast cereals, such as coeliacs and some ethnic groups.
<p>New Zealand Food Safety Authority (NZFSA) New Zealand Carole Inkster</p>	<p>Partial support for the preferred approach</p> <ul style="list-style-type: none"> Partial support for the preferred option, but does not support the inclusion of biscuits or breadcrumbs in the Standard. Committed to mandatory fortification as the most effective option for addressing iodine deficiency across the population at this time. Submission sets out the views of the NZFSA, the Ministry of Health, the Ministry of Foreign Affairs and Trade, the Ministry of Economic Development and the Ministry of Consumer Affairs. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> The proposed level of iodine fortification is limited by concerns about the number of 1-3 year olds expected to exceed the UL. Fortification may be safe for children at higher levels than currently proposed, and higher levels would achieve higher iodine intakes for pregnant and breastfeeding women.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Highlights uncertainties around the intake of iodine in children aged 1-3 years, and subsequently the importance of monitoring. • The Ministry of Health is generally supportive of the Proposal, noting the beneficial health outcomes. However, expresses concern regarding potential adverse health outcomes, particularly in relation to young children exceeding the UL. • The Ministry of Health considers pregnant and breastfeeding women are at higher risk of inadequate intakes compared to the total population, and notes that the proposed approach does not meet the RDI for iodine for these women. Agrees that a single nutrient supplement of 100-150 mg of iodine should be made available as a registered medicine, and the iodine level in the supplement needs to be consistent between Australia and New Zealand. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports the iodisation of salt as the preferred vehicle for addition of iodine to food, as this is in line with international recommendations, and international experience has shown this to be technically feasible. • Supports the option of requiring salt in cereal-based foods to be iodised rather than all processed foods, as it achieves an acceptable outcome in terms of increasing iodine intakes of the general New Zealand population, and it places fewer burdens on industry. • Considers that by not requiring salt to be iodised in all processed foods, this allows choice for those who wish to avoid iodine fortified foods. • Considers it important that it is made clear at Final Assessment that all cereal-based products included in the Standard, including unpacked bread, made with salt as an ingredient must use iodised salt. • Notes that there are likely to be further reductions in the salt content of processed foods, as promoted by Government and public health initiatives, and therefore the level of fortification may need to be reconsidered in the future if reductions in the salt content of processed foods mean that the population does not reach expected intakes of iodine. • Recommends that biscuits, both sweet and savoury, be excluded from the Standard for the following reasons: <ul style="list-style-type: none"> – many biscuits are high in fat, salt and sugar and the promotion of regular consumption of such foods is not consistent with the food and nutrition guidelines; – the dietary modelling indicates that biscuits contribute only a minimal amount of iodine; and – significant volumes of biscuits are imported into New Zealand from outside Australia and requiring iodised salt in these would pose significant problems. • Considers the range 20-45 mg of iodine per kg of salt reasonable. However, suggests the Standard should specify that the target should be 30 mg iodine per kg of salt so that this is used as the mid-range figure and becomes the average level of addition across the food supply. • Requests that FSANZ considers prescribing the term 'iodised salt' when used in the ingredient list. Does not support the use of other phrases such as 'salt with added iodine'. • Recommends that consideration be given to removing breadcrumbs from mandatory requirements, for trade purposes.

SUBMITTER	SUBMISSION COMMENTS
	<p data-bbox="392 226 549 248"><i>Labelling/claims</i></p> <ul data-bbox="392 264 1203 367" style="list-style-type: none"> • Recommends that iodine content claims be prohibited for all foods, as the purpose of the Proposal is to add iodine to the food supply and as a consequence of this they do not want claims about iodine on foods that are not consistent with the food and nutrition guidelines. <p data-bbox="392 383 448 405"><i>Trade</i></p> <ul data-bbox="392 421 1203 1055" style="list-style-type: none"> • Notes trade implications for food produced in New Zealand for export as currently these foods must comply with the Food Standards Code. Therefore, all foods covered by this Proposal would contain iodised salt, which could be trade positive or trade negative depending on the receiving country's position on foods with added iodine. • Understands that unbaked doughs and bread mixes for export are not required to comply with the Food Standards Code, as they do not meet the definition of bread as they are not baked. • Notes the export of crumbed meat and fish products is an issue, and recommends removing breadcrumbs from the mandatory requirements. • The Ministry of Foreign Affairs and Trade requests that every effort is made to minimise the number of products requiring fortification to minimise trade implications. • Notes that New Zealand imports approximately \$150 million per annum of bread, breakfast cereals and biscuits, with over 75% of these imports coming from Australia. • Notes the trade impacts on those products imported from outside Australia, particularly for biscuits. • Notes that if the regulation is challenged by trading partners, New Zealand will need to demonstrate that it is the least trade restrictive measure to address iodine deficiency. <p data-bbox="392 1070 624 1093"><i>Current salt permissions</i></p> <ul data-bbox="392 1108 1203 1189" style="list-style-type: none"> • Supports the retention of iodised salt for discretionary use as it is a source of iodine for consumers with low consumption of cereal-based foods, and also if removed, consumers may find this a confusing and contradictory health message. <p data-bbox="392 1205 863 1227"><i>Removal of voluntary permission of salt iodisation</i></p> <ul data-bbox="392 1243 1190 1301" style="list-style-type: none"> • Supports retaining current voluntary permissions, but the potential increase in the range of foods containing iodine must be monitored by FSANZ. <p data-bbox="392 1317 539 1339"><i>Implementation</i></p> <ul data-bbox="392 1355 1203 1458" style="list-style-type: none"> • Recommends that consideration be given to the inclusion of separate but mirror standards in the Food Standards Code for Australia and New Zealand, to ensure that should Australian jurisdictions require further work on the proposed Standard that implementation in New Zealand can proceed. <p data-bbox="392 1473 655 1496"><i>Monitoring and compliance</i></p> <ul data-bbox="392 1512 1203 1749" style="list-style-type: none"> • Considers it imperative that monitoring, especially of at risk groups, is in place prior to implementation, and that the level of fortification is reviewed in relation to the outcomes of monitoring, to ensure that the program is effective and safe. • Acknowledges that monitoring is outside FSANZ's mandate and is the responsibility of the New Zealand Government, however believes that FSANZ plays a vital role in determining the overall monitoring framework. • Notes that the Ministry of Health will monitor the health and nutritional status of the population and NZFSA will monitor the food supply.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Considers it is important that a monitoring system is in place prior to fortification with iodine. • Notes monitoring activities likely to be conducted in New Zealand are: <ul style="list-style-type: none"> – National Nutrition Surveys; – Additional surveys on iodine status of specific groups e.g. pregnant and breastfeeding women, and children; – Involvement of the primary care sector, particularly for the early detection of iodine-induced hyperthyroidism; – The New Zealand Total Diet Survey; – Continuation of the Manufactured Food Database; and – Enforcement activities e.g. though proposed Food Control Plans. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Will consider the communication strategy when it becomes available, and will work with FSANZ to implement the necessary communication to New Zealanders. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Agrees with the conclusion that there is a large degree of uncertainty surrounding the calculation of net benefits for the Proposal. • Disagrees with the suggestion that it may be worth considering an alternative proposal to deliver the health outcome, and is committed to mandatory fortification as the most effective option for addressing iodine deficiency across the population at this time. <p><i>Assessment of iodine status</i></p> <ul style="list-style-type: none"> • Believes that the assessment of the iodine status of New Zealanders in the Draft Assessment Report accurately reflects the mild iodine deficiency of the general population. • Notes the thyroid hormone results from the 2002 National Children’s Nutrition Survey reported by Skeaff in 2005 confirms FSANZ’s assessment. • Cites results from the recent Thyromobile and Iodine in Pregnancy study, which indicates that pregnant women as a group are moderately iodine deficient. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • The Ministry of Health has concerns about information on the iodine intakes for 1-3 year olds derived from the simulated diets, which suggests that a portion of 1-3 year olds is exceeding the UL. Notes that these results are not consistent with iodine status results for 230 South Island children aged 6-24 months which indicate mild iodine deficiency. • Requests FSANZ review the upper limit of iodine in Formulated Supplementary Foods for Young Children (FSFYC), as recently approved under Application A528. Does not agree with the data used in the dietary exposure assessment for children aged 1-3 years, noting that one serving per day is used. Also considers that the risk assessment should be conducted on the worst case scenario i.e. toddlers consuming two or three servings per day of FSFYC. • Considers that the number of young New Zealand children exceeding the UL for iodine would be greater than stated in the Draft Assessment Report. • Provides results of dietary modelling for New Zealand children as conducted by the University of Otago. The results indicate that a proportion of children aged 5-14 years are unlikely to meet the EAR for iodine following mandatory fortification.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> Notes that the discretionary salt intake of children used in the Proposal is likely to be an overestimate, and that discretionary salt will still be subject to voluntary fortification, thus reducing the potential exposure to iodine.
<p>Environmental Health Unit of Queensland Health Australia Gary Bielby</p>	<p>Supports a Modified Option 2 – Mandatory iodine fortification</p> <p>Supports a modified Option 2. Does not support the addition of iodised salt to biscuits.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concern about the lack of detail on how iodine will be made available to those who do not eat bread, bread products, breakfast cereals and salt. For example, those consuming a low carbohydrate diet, those consuming a low iodine diet for medical reasons, those ethnic groups who mainly consume other sources of carbohydrate. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Recommends labelling of iodine be mandated in the nutrition information panel. Notes that the proposed mandatory fortification will not ensure adequate intakes for pregnant and breastfeeding women, and this would allow these consumers to calculate their iodine intake from fortified foods to inform their decision regarding the necessity for and strength of iodine supplements. Recommends that highly sugared breakfast cereals not be able to make nutrient content claims about iodine. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> Recommends retaining voluntary permission for iodised salt as mandating the fortification of all salt would mean all processed foods would be fortified. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Supports mandatory fortification on the understanding that: <ul style="list-style-type: none"> jurisdictions commit to the financial and other obligations of ensuring adequate monitoring and surveillance of dietary intake, nutritional status and health outcomes; adequate lead in time is allowed for the collection of baseline data, particularly up-to-date dietary intake data; and commitment to regular monitoring needs to be agreed upon by jurisdictions before implementation. Seeks clarification on the costs of monitoring and surveillance activities, noting that information given in the Draft Assessment Report appears to differ substantially. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Seeks clarification on the proposed communication and education strategy, including what it entails, who are the target groups, what is the role of jurisdictions, what is the approximate cost, how will GPs and other health professionals be informed, and is it more than a brochure and web page? <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> Concern that the impact analysis does not include the costs to government of health promotion, education, monitoring and surveillance, and notes that it cannot be assumed that these activities are already happening in all jurisdictions.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Concern about the lack of baseline nutrient intake data with which to compare future monitoring and surveillance activities. • Concern about the lack of data on dietary supplement and discretionary salt intake. • Concern whether the National Iodine Nutrition Study had adequate representation of Indigenous groups and whether it is representative of the number of regional variations in iodine intake that may exist in a large decentralised state like Queensland.
<p>South Australia Department of Health Australia Joanne Cammans</p>	<p>Supports Option 2 – Mandatory fortification with iodine</p> <p>Supports the preferred approach for mandatory fortification with iodine, however raises some issues for consideration at Final Assessment.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned that the level of iodine proposed will deliver insufficient iodine to those populations who are deficient, as discussed at the Jurisdictional Forum Teleconference in September 2006. It was considered that there exists more of a health risk by not delivering sufficient iodine than if iodine levels surpassed upper limits. • Supports consideration of increased iodine fortificant levels and/or ongoing monitoring, to establish good data on the outcomes of the program. • Notes the need for young children with limited intake of processed foods and women who consume little of the proposed food vehicles to be specifically targeted with education campaigns. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • It appears likely that manufacturers will use iodised salt in <i>all</i> products, not only those selected food vehicles. Therefore, there is potential for oversupply of iodine in the food system. Notes that this should be considered further at Final Assessment. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Notes that the proposed Standard would regulate the level of iodine in iodised salt and not in food. There is potential for manufacturers to add excess salt/iodine to make a health claim. They recommend an upper limit be imposed for iodisation. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Asks if manufacturers can consistently fortify salt with iodine within a prescribed range. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Considers ongoing monitoring of iodine levels in salt and processed foods, and via blood and urine testing, is imperative to the success and evaluation of the fortification program. • Supports the need for a coordinated monitoring program post fortification. • Considers the role of monitoring should be referred to the Ministerial Council/Food Regulation Standing Committee for consideration of a coordinated approach.

SUBMITTER	SUBMISSION COMMENTS
Department of Health and Human Services, Tasmania Australia Judy Seal	<p>Supports Option 2 – Mandatory fortification with iodine</p> <p>Supports the proposed approach for mandatory fortification with iodine, however expresses strong preference for mandatory USI.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Comments that voluntary fortification has not been considered a realistic regulatory response to this important public health issue. • Notes that while some short term modest improvement in iodine status was achieved in Tasmania with an interim voluntary fortification program at a population level, they have concern about the reach of the program to sub-population groups, the sustainability of the program, and the ongoing costs of maintaining industry commitment. • Concerned that the proposed option, which involves a reduced level of salt iodisation, may result in a reduction in iodine intake in Tasmania compared with current intake under their interim voluntary program. • Dietary modelling conducted by Tasmania shows that the proposed approach will only achieve marginally more (i.e. 6 µg iodine per day) than the current Tasmanian interim program. • Considers the proposed approach will be inadequate to meet population iodine needs and the range of foods will need to be extended in the future. • Notes that the intention is to achieve a marginal increase in iodine, and that the needs of pregnant and lactating women are unlikely to be met without additional supplementation. • Comments on the apparent reluctance to increase the level of iodine fortification in Australia beyond what has been proposed so as to minimise the proportion of individuals who exceed the UL, particularly young children. • However, notes that the ULs do not <i>represent absolute thresholds for toxicity</i> and there is a <i>wide margin of safety associated with the ULs</i> and that intakes in young children above the UL are <i>unlikely to represent a health and safety risk</i>. • Notes advice from their Thyroid Advisory Committee that there is a risk that cautious language about exceeding the UL implies toxicity (without good justification) and this may lead to misunderstanding by the general public, and may compromise the fortification program. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Disappointed that mandatory USI has not been supported as the preferred option. Believes USI would be more effective, simplify communication with manufacturers, simplify enforcement, simplify the monitoring of food composition, result in a more sustainable solution and be consistent with international recommendations. <p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • Concerned that voluntary permissions lead to uncertainty about the level of iodine in food in Australia and New Zealand, noting public health expert advice to AHMC. • Notes that until the proposed Standard is fully implemented it will be hard to predict how many additional foods will contain iodised salt using the voluntary permissions. • Notes the German experience combining voluntary and mandatory iodine fortification has been criticised, with the conclusion that without appropriate legislative measures to enforce USI the insufficient iodine status in Germany could become a never-ending story.

SUBMITTER	SUBMISSION COMMENTS
	<p data-bbox="392 235 654 264"><i>Monitoring and compliance</i></p> <ul data-bbox="392 280 1200 564" style="list-style-type: none"> <li data-bbox="392 280 1200 353">• Notes that appropriate monitoring needs to be implemented to complement the program, including health outcomes, nutritional status, nutrient intake, food composition and industry compliance. <li data-bbox="392 369 1200 450">• Considers a urinary iodine survey of school children should be conducted during 2008, to compare baseline data and determine if the proposed mandatory requirements need to be extended to a greater range of processed foods. <li data-bbox="392 465 1200 564">• Considers the monitoring of iodine status and iodine intake should be integrated into a broader nutrition monitoring and surveillance system so that monitoring is ongoing and sustainable, and the information could be used to refine the mandatory fortification program in the future.

Summary of Submitter Comments to Proposal P230 Issues Paper

In May 2007, FSANZ, received **48** responses to the Issues Paper for Proposal P230 – Consideration of Mandatory Fortification with Iodine, outlining the proposed changes under consideration for Final Assessment. The paper addressed the major themes that arose from submissions to the Draft Assessment and additional work undertaken. Six responses were received from government, 17 from industry, 19 from public health and academia and six from interested individuals and consumer groups. A summary of submitter comments is provided in the table below.

The Issues Paper outlined that at Draft Assessment, FSANZ proposed the mandatory replacement of salt with iodised salt in bread, breakfast cereals and biscuits. However, at Final Assessment, FSANZ proposed removing biscuits and breakfast cereals as food vehicles. The Issues Paper outlined the following proposed approach:

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| <ul style="list-style-type: none">• the mandatory replacement of salt with iodised salt in bread as the preferred approach to address the re-emergence of iodine deficiency in Australia and New Zealand, with a salt iodisation range from 35-55 mg of iodine per kg of salt.• retaining the <i>voluntary</i> permission for iodine in iodised salt and reduced sodium salt but adjusting it from the current range of 25-65 mg per kg to 35-55 mg per kg, to make it consistent with the mandatory requirement. |
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Key Issues Identified from Submitter Comments

1. Regulatory options

The majority of government stakeholders, public health professionals and consumer groups indicated qualified support for the Proposal. There was general acknowledgement among stakeholders on the inability of the Proposal to fully meet the substantially increased iodine requirements of pregnant and lactating women, and breast-fed 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 addressing the current iodine deficiency. They noted that mandatory fortification is preferable to voluntary fortification as it provides greater certainty, sustainability, equity, and reach. However, a number of public health stakeholders believed that Universal Salt Iodisation (USI) would provide higher iodine intakes for pregnant and lactating 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 opposed mandatory fortification, citing the increased regulatory burden, removal of consumer choice, and trade impacts as reasons for their opposition. They considered *mandatory fortification is not the most effective public health strategy, preferring voluntary fortification, in conjunction with the promotion of iodine as a processing aid.*

A Memorandum of Understanding (MoU) and an education campaign are also an integral part of this alternate approach. Industry considered international studies and the voluntary Tasmanian experience demonstrate the success of voluntary fortification in decreasing iodine deficiency.

Industry and some government stakeholder also argued that the current proposal is 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.

2. Food vehicles

Most stakeholders supported the decision not to include breakfast cereals or biscuits in the current mandatory fortification proposal. Some, however, expressed concern regarding the medicalisation of the food supply if bread is fortified with thiamin, folic acid and iodised salt.

Many considered that the addition of iodine should not legitimise the consumption of unhealthy foods and supported the addition of iodine to foods consistent with nutritional guidelines. Public health stakeholders expressed concern about the wide variation in salt and therefore iodine content of different bread, in particular, in low salt bread. Some expressed concern with salt as the food vehicle.

Industry stakeholders raised concern that many women in the target group are low bread eaters. Stakeholders identified the need to explore direct addition of iodine or additional food vehicles such as breakfast cereals, milk and water. However, others did not support direct addition of iodine to bread in Australia due to inadequate equipment and resources of small, in-store bakeries.

3. Safety and efficacy

Many stakeholders commented that the substantially increased iodine needs of pregnant and breastfeeding women, and therefore breast fed infants, were not fully met by the Proposal. They also noted that those who do not eat bread with iodised salt will not benefit from iodine fortification and considered that FSANZ should consider how iodine intake could be increased in these groups.

A small number of consumers, with a history of thyroid disorders, expressed concern about potential adverse effects from increased amounts of iodine in the food supply. These individuals viewed mandatory fortification as an infringement of their rights. They considered that there was limited data available on the adverse effects of mandatory fortification or on the number of people affected by hyperthyroidism. Government stakeholders requested age-related information on the extent of iodine deficiency in Australia.

Some health professional stakeholders questioned the relevance of the currently established Upper Level of Intake (UL) for iodine in young children. They noted that the UL was extrapolated from adult data on a metabolic body weight basis, with no regard to the relatively greater iodine requirement in early childhood. FSANZ was urged to ask the National Health and Medical Research Council (NHMRC) to consider reviewing the UL for iodine in children.

Public health and government stakeholders also recommended FSANZ review the availability of appropriate supplements, including pregnancy supplements containing iodine.

4. Consumer choice

Consumer choice was a major reason given by many stakeholders who did not support mandatory fortification. Organic, unleavened or gluten-free bread was not considered to provide 'real' choice. Some expressed the view that excluding organic bread from mandatory fortification created inequity, as these products are more expensive than non-organic bread.

5. Trade

Some industry stakeholders expressed concern about the potential impact of mandatory fortification on imports and exports, especially on crumbed products exported to Japan.

6. Labelling and Claims

Some consumers and groups expressed concern that using iodised salt could encourage manufacturers to increase salt levels to make health claims. Mandatory requirements should not discourage the food industry from reducing the amount of salt in bread.

A number of public health and consumer groups supported including iodine in the nutrition information panel (NIP). In contrast, industry did not support the inclusion of iodine in the NIP. There was general agreement for the inclusion of 'iodised salt' in the ingredient list to inform those wishing to avoid iodine fortified foods.

Some public health professionals did not support the use of nutrition and related claims on fortified foods. However, industry stakeholders requested a review of the current restrictions on iodine content claims and supported the development of a general level health claim. Industry considered that the proposed wording of the current health claim statement was not meaningful for consumers and put forward alternate wording.

7. Implementation and Transition Period

The majority of stakeholders supported the proposed two-year implementation period. Industry sought clarification of the definition of bread and the requirement for fortification of breadcrumbs, seasonings and toppings and associated labelling provisions. Government stakeholders raised concern regarding the lack of resources for Local Government Agencies who will have responsibility for enforcement activities.

Industry questioned the feasibility of iodised salt use by a very small number of bakeries that use a brining system to add salt to bread. It was recommended that FSANZ investigate this matter further. One major salt manufacturer reported that their quality control data indicated that the salt iodisation range of 35-55 mg of iodine per kg of salt could not be achieved 100% of the time. They requested the current range of 25-65 mg/kg be maintained.

There was general support among stakeholders for the exemption of 'organic' bread, although some questioned the lack of a FSANZ definition of 'organic' or 'heavy health bread'. New Zealand recommended a more specific provision to exempt bread made under or aligned with an organic certification agency to assist with compliance and enforcement.

New Zealand industry requested clarification of the definition of ‘natural’ to ensure the addition of iodised salt to these products would still allow this claim.

Industry stakeholders requested sufficient time to align packaging changes to minimise the write off of existing stock. Some government stakeholders recommended a stock-in-trade provision to allow industry to manage content and label changeover within the phase-in period. Development of a Users’ Guide was also supported.

8. Costs

A number of stakeholders considered the lack of quantitative estimates for ascertaining the health benefit of the Proposal makes it difficult for FSANZ to rationalise the costs imposed by the proposed fortification. One public health stakeholder considered that the economic cost of a decrease in IQ caused by iodine deficiency had been underestimated in the report. Industry recommended FSANZ commission a cost effectiveness analysis which addresses restriction of consumer choice, potential adverse effects, costs of monitoring intake and health outcome, and complementary policies necessary, but outside the purview of FSANZ. Some stakeholders questioned the industry costs included in the report. The risk of litigation and possible compensation for losses by manufacturers as a result of mandatory fortification were raised by a small number of stakeholders.

Some individuals with thyroid related medical conditions noted that mandatory fortification would increase the cost of monitoring their condition through extra medical consultations, pathology tests and time spent attending appointments. They also considered that these costs and purchasing more expensive non-iodised alternatives had not been taken into account in the cost benefit analysis. Those with low socio-economic status or who live in rural areas would be disadvantaged by the proposed mandatory fortification approach.

Government stakeholders suggested FSANZ include the costs of introducing further regulatory changes if the current proposal proves unsuccessful e.g. increasing iodine concentration in salt, or trade impacts arising from using iodised salt in breakfast cereals.

9. Monitoring and Compliance

There was general agreement on the need for an effective and integrated Trans-Tasman monitoring program to assess iodine in the food supply and the impact of iodine fortification on the population. While acknowledging that monitoring is not wholly within FSANZ’s remit, many comments noted the lack of a national framework and a firm commitment to fund and coordinate such a program by the Commonwealth, state and territory governments. The collection of baseline data on food and water was identified as a priority, along with the need to monitor the impact of salt reduction programs.

Stakeholders supported monitoring at-risk individuals to determine any increase in the incidence of iodine-related conditions. They also supported monitoring groups who do not eat fortified bread. Some industry stakeholders recommended a sunset provision to enable a review of compliance, safety and efficacy data for mandatory fortification.

10. Communication and Education

Most stakeholders acknowledged the need for an effective communication and education strategy, including at-risk groups. Several stakeholders expressed concern regarding inconsistent messages, as consumers are encouraged to moderate salt intake.

Public health professionals recommended integrating advice to pregnant women, for example, including information on iodine, folic acid and mercury, supplements, and advice for non-bread eaters. Messages should be developed in collaboration with target groups. Many stakeholders supported collaboration between industry, government, medical, health and consumer organisations to develop and implement the strategy.

11. Dietary Intake Assessment

Some industry stakeholders expressed concern regarding the lack of data on bread consumption (total consumption and by population group), estimates of total salt consumption and the iodine content of Australian and New Zealand foods. Government stakeholders requested additional dietary modelling scenarios to compare outcomes with those presented at Draft Assessment. They also requested information on the iodine content of infant formulas. Industry stakeholders questioned the dietary modelling undertaken by FSANZ on the alternate voluntary approach proposed by industry and supported reconsideration of this approach promoting iodine as a processing aid.

12. Consistency with Policy Guidelines

A number of stakeholders who did not support the preferred option, stated that they believed it was inconsistent with the FSANZ Act and the Policy Guidelines on fortification. They specifically questioned whether mandatory fortification is the most effective public health strategy and requested FSANZ include a comprehensive assessment of all options for improving iodine status in the Final Assessment.

13. Voluntary Permission for Iodine in Iodised Salt

The majority of stakeholders supported retaining the voluntary permission for iodised salt as it allows industry to add iodised salt to a broader range of foods. It also provides a source of iodine for those who do not eat bread for medical or cultural reasons. Removal of this permission would restrict consumer choice and create confusion, especially in New Zealand where currently 74.5% of discretionary salt is iodised.

SUBMITTER	SUBMITTER COMMENTS
<p>Australian Consumers' Association (ACA)</p> <p>Australia</p> <p>Clare Hughes</p>	<p>Supports mandatory fortification with iodine, if commitment made to monitoring and evaluation</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Iodine should be added to foods consistent with the nutritional guidelines. • The addition of iodine should not legitimise the consumption of unhealthy foods. • The use of iodised salt should not encourage manufacturers to increase the salt level in order to make a health claim. • The mandatory requirements should not discourage the food industry from reducing the amount of salt in bread. • Supports the decision not to fortify breakfast cereals or biscuits. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerns that those who do not eat bread will not benefit from iodine fortification. • Concerns that many pregnant and lactating women will not eat enough bread to get adequate iodine. • FSANZ should consider how iodine intake could be increased in these groups. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Monitoring should assess iodine in the food supply and the impact of iodine fortification on the population. • Appreciates that a monitoring and evaluation program is not wholly within the scope of FSANZ responsibilities. • Not aware of any firm commitment from the Commonwealth, state and territory governments of funding or other resources for monitoring or evaluation. • Monitoring of individuals is essential to assess the impact of the intervention and determine if there has been an increase in the number of individuals with excessive iodine consumption. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Any intervention to fortify the food supply should be accompanied by a public awareness campaign outlining the health benefits of iodine and food sources of iodine. • It should also explain why foods are fortified and how consumers can increase consumption of iodine through fortified foods.
<p>Ellen McEwen</p> <p>Private</p> <p>Australia</p>	<p>Does not support mandatory fortification with iodine</p> <p>Considers the justification for mandatory fortification is expediency. Believes that mandatory fortification tramples on the rights of minorities for the benefit of the majority.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Monitoring those people with existing thyroid conditions will not help those who have not yet been diagnosed with an overactive thyroid. • Hyperthyroidism may be difficult to diagnose and is similar to general fatigue. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Does not include tracking the impact of iodine fortification on those at risk of hyperthyroidism.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Need to educate those in retail and hospitality sector about the needs of those with hyperthyroidism. Difficult to select foods without iodine fortification, especially if uptake of voluntary permissions is widespread. <p><i>Costs</i></p> <ul style="list-style-type: none"> • There would be increased costs for those with hyperthyroidism: <ul style="list-style-type: none"> – extra doctors consultations; – more pathology tests; – time lost from work and family sitting in doctors’ waiting rooms; – extra cost of organic or yeast free bread; and – those with Graves disease will be forced to choose from a limited range of bread. • The above will disadvantage those with low socio-economic status and /or living in rural areas.
<p>Alison Joy Mace Private New Zealand</p>	<p>Supports mandatory fortification with iodine</p> <p>Concerns about the reliance on iodised table salt when many health conscious people are using less table salt.</p> <p>Believes that mandatory iodisation may assist in correcting inadequate iodine status in the South Island of New Zealand.</p>
<p>Peter Chamberlain Private Australia</p>	<p>Preference not specified</p> <p>Believes the alternatives to mandatory fortification are:</p> <ul style="list-style-type: none"> – a major public education campaign, which has worked in the past; and – voluntary fortification of bread or other staple foods. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Many people are concerned with the level of sodium in their diet. They may choose organic bread and therefore miss out on iodisation. • States there are many people who will be eating bread that is not iodised i.e. bread without yeast or organic bread. • No attempt has been made to quantify the numbers of people who will miss out on iodine fortification. Many more people are eating organic bread now. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • FSANZ should monitor those people who do not eat bread that is fortified with iodine.
<p>Patricia St John Private New Zealand</p>	<p>Does not support mandatory fortification with iodine</p> <p>Mandatory fortification should only be undertaken when the deficiency is severe and other alternatives have been tried and failed.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • A ‘significant proportion’ of the population has autoimmune thyroid disease and would be adversely affected by fortification of bread with iodine. • Iodine fortification may create (new) thyroid problems in the population. • Adequate alternatives must be provided for those who will be adversely affected by iodine fortification.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> • Access Economics said data presented in draft proposal was based on unconvincing and uncertain evidence. • Clinical effects of mild iodine deficiency are uncertain but cannot result in iodine deficiency diseases which are only a result of severe iodine deficiency, starvation and lack of variety of food choices. Even as population iodine status decreases to marginal ‘there is no clear evidence of impaired intellectual function or growth retardation’ (referenced in comments). • FSANZ’s claims that increased motor skills, cognition skills and concentration would ensue from iodine fortification are misleading, as the benefits are unquantifiable (Access Economics). • High iodine intakes are undesirable especially for children under eight whose safe maximum intake is half that of adults. • Approach to improve iodine status should be cautious to avoid iodine induced hyperthyroidism (IIH). • Data is lacking on the effects of IIH. • Many health problems identified in the Access Economics report are ignored in the Issues Paper. • There is no Australian or New Zealand data on adverse effects of Proposal. • The majority of children are not iodine deficient and eat more bread than adults. • No data on the number of people affected by hyperthyroidism. Community surveys show an incidence from 7-22%. A larger proportion can have latent or subclinical disease, and up to 36% of adult women are estimated to have thyroid antibodies. The Proposal used data from the Wickham Survey showing 9% could have hypothyroidism or hyperthyroidism. • Thyroid medications are increased with caution, as increasing thyroid hormones can cause sudden death from heart failure in those with thyroid and heart conditions. • The problem of insufficient iodine intake for pregnant and lactating women is outside the scope of this Proposal and it should be for health professionals to assess the need for supplementation. • Many thyroid problems of pregnancy are not simple thyroid deficiency but are the result of latent thyroid disease. • Believes the recent problem with insufficient dietary iodine stems from increased cost of fish and milk, decreased consumption of table salt, decreased awareness of the importance of adequate dietary iodine and an increase in the consumption of soy products which are goitrogenic. • Does not know whether current iodine status reflects a steady state or is decreasing over time. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Considers clarification is needed on definitions for organic bread and bread. • Questions if aerated frozen dough will be exempt. • A New Zealand bakery does not use a yeast leavened process. If their product is not defined as bread they will maintain their markets and have a cost advantage over competitors, however if defined as bread this will impact on trade especially to USA and Japan. • Suggests bread from small niche bakeries should not be iodised to give more consumer choice, as this would only affect 5% of the market.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> • Concerns that producers may increase the level of iodine in bread to make a good source claim, which would lead to an increased level of salt in bread. • Considers health warnings on the label will be necessary. <p><i>Costs</i></p> <ul style="list-style-type: none"> • Access Economics report refers to a lack of data on health costs of the Proposal. • Cost estimates for monitoring population health were not covered. • FSANZ need to include the increased costs for those with autoimmune disease for alternative organic bread. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Concerns that FSANZ does not propose to monitor iodine in bread, only in salt and the use of iodised salt. • Concerns that FSANZ considers monitoring the effects of iodisation on population health as a government responsibility. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Data used is poor and old (Australia 1995 and New Zealand 1997 National Nutrition Surveys). No urine excretion tests were carried out.
<p>Susan McGahan Private Australia</p>	<p>Does not support mandatory fortification with iodine</p> <p>Requests that FSANZ reconsider adding iodine to bread as it is already difficult for those sensitive to iodine to avoid iodine in other foods, medications and supplements.</p>
<p>Australian Food and Grocery Council (AFGC) Australia David Roberts</p>	<p>Does not support mandatory fortification with iodine</p> <p><i>Preferred approach</i></p> <ul style="list-style-type: none"> • Recommends a voluntary approach, led by industry, to promote iodine as a processing aid, together with the AFGC proposed Memorandum of Understanding (MoU) – attached to response. The MoU with industry for voluntary use of iodised salt in food manufacture could be applied regionally, as only some parts of Australia are iodine replete. • States that new evidence of the effect of voluntary fortification in pregnant women from Tasmania supports the AFGC proposal to utilise a wide variety of voluntary permissions under a MoU, and suggests that a mandatory focus on a single food vehicle will not deliver an effective outcome (referenced). • Recommends FSANZ reconsider the likely uptake of a voluntary scheme based on the outcome from Tasmania and the likely incentive of a general level health claim. • States that most countries where iodised salt is recommended do so under a voluntary scheme. • Considers FSANZ has failed, on the evidence before them and contained within the expert report commissioned by Australian Health Ministers Advisory Council (AHMAC), to develop a regulatory measure that satisfies the requirements for effectiveness. Considers FSANZ has also failed to meet the requirements of the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) for mandatory fortification. Therefore, suggests that FSANZ withdraw the Proposal.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Recommends amending Standard 2.10.2 to allow iodised salt to make an iodine content claim indicating the amount of iodine per 100g without this triggering the need for a full Nutrition Information Panel (NIP). • Recommends that products containing iodised salt be allowed to make iodine content claims. • Considers the proposed pre-approved general level claim will not be understood by consumers. • Recommends the following general level health claims be permitted: <ul style="list-style-type: none"> – 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. • Considers that current restrictions on vitamin and mineral claims in Standard 1.3.2 restricts the role the food industry can play in communicating iodine content to consumers. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Does not consider that exempting organic bread retains consumer choice as: <ul style="list-style-type: none"> – not all consumers value organic bread; – organic bread are limited in offering and availability; and – organic bread is more expensive and therefore the consumer will incur a price penalty. <p><i>Costs</i></p> <ul style="list-style-type: none"> • Recommends that FSANZ commission a cost effectiveness analysis that includes restriction of consumer choice; potential adverse effects; costs of monitoring intake and health outcome; and complementary policies necessary but outside the purview of FSANZ, to complement the analysis that has been undertaken to date. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Questions the dietary modelling undertaken by FSANZ on the proposed AFGC voluntary approach, and supports reconsideration of this approach promoting iodine as a processing aid. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Recommends the draft Standard be reviewed to clarify the intent that all salt added to bread dough must be fortified, and therefore salt added as a topping is excluded. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • If mandatory approach is adopted, recommends that the Standard should lapse after 4 years if: <ul style="list-style-type: none"> – 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. • Rejects the use of food intake measurement as a surrogate for the health outcome.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Additional comments</i></p> <ul style="list-style-type: none"> Does not believe that FSANZ will consider issues raised by submitters in response to the Issues Paper in the same manner as if a Preliminary Final Assessment Report (PFAR) was released.
<p>Campbell Arnott's Asia Pacific Australia Michael Depalo</p>	<p>Does not support mandatory fortification with iodine</p> <p>Supports voluntary fortification with iodised salt or other iodine source.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerns regarding mandatory fortification across a broad range of foods and impact on individuals with hyperthyroidism. <p><i>Costs</i></p> <ul style="list-style-type: none"> Concerns regarding underestimation of education, monitoring and enforcement costs. <p><i>Trade</i></p> <ul style="list-style-type: none"> Concerns regarding potential impact of mandatory fortification on imports and exports (especially to Japan). <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Concerns regarding impact of mandatory fortification on consumer choice. Supports removal of biscuits as a vehicle for mandatory fortification. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Supports education campaigns promoting benefits of iodine and natural sources which are consistent with nutrition guidelines. Concerns about inconsistent messages, as consumers are being encouraged to moderate salt intake.
<p>Cerebos Foods Australia Patricia Verhoeven</p>	<p>Does not support mandatory fortification with iodine</p> <p>Supports the AFGC comments and a voluntary approach with a MoU.</p> <ul style="list-style-type: none"> Reasons for not supporting mandatory fortification include: <ul style="list-style-type: none"> not the most effective public health strategy; removes consumer choice; exemption of organic bread does not address consumer choice (limited availability and increased cost); impact on select population groups e.g. coeliacs, those with Grave's disease; and international studies indicate voluntary fortification is successful (further supported by results of Tasmanian MoU – decrease in iodine deficiency from 21% to 10.5% in four years). <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> Supports retention of voluntary permission for iodised salt as: <ul style="list-style-type: none"> demonstrated as an effective strategy internationally; retains consumer choice; allows industry to select most suitable food vehicles for target group; retail salt scan data indicates consumers are choosing more iodised salt, but this is not resulting in growth of overall discretionary salt sales;

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> - readily available and economical source of iodine for at risk groups; - removal of permission would restrict consumer choice and create consumer confusion, especially in New Zealand where currently 74.5% of discretionary salt is iodised; - source of iodine for those with coeliac disease; and - allows manufacturers to legally add iodised salt to manufactured foods. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Recommends redrafting the proposed variation to Standard 2.1.1 to clearly indicate FSANZ intent that salt added to bread dough must be iodised while salt used as a seasoning on top of focaccia-style bread is exempt. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Food labels are an important communication medium, providing consumers with information on the iodine content of foods. • Supports development and introduction of a general level health claim to use on a variety of foods containing iodised salt. • Considers FSANZ proposed wording for a health claim statement is not meaningful for consumers and proposes preferred alternate wording or modification of the FSANZ wording. • Seeks a review of current restrictions on iodine content claims to enable food manufacturers to use food labels to communicate education messages to consumers on a wider range of manufactured foods. • No incentive for manufacturers to voluntarily add iodised salt to products unless they can promote awareness of the importance of iodine on labels. (includes products such as gravies and gravy mixes, sauce and sauce mixes, meal bases, salad dressings and cooking aids). • Recommends amendment of Standard 2.10.2 to permit iodised salt to make a content claim per 100g salt without triggering a NIP to encourage use of iodised discretionary salt. • Recommends amendment of Standard 1.3.2 to allow products containing iodised salt to make iodine content claims when a serve of the food has 10% RDI. • No evidence to suggest that allowing health claims would impede attempts to lower the salt content of foods. • Seeks assurance that comments regarding health claims will be considered despite being after the closing date for submissions on Proposal P293.

SUBMITTER	SUBMITTER COMMENTS
Cheetham Salt Australia John Murray	<p>Supports mandatory fortification with iodine</p> <p><i>Costs</i></p> <ul style="list-style-type: none"> • Costs spread over a smaller volume with removal of breakfast cereals and biscuits. <p><i>Level of fortification</i></p> <ul style="list-style-type: none"> • States that the reduced fortification range of 35-55 mg/kg is unachievable and recommends retaining current level of 25-65 mg/kg (2 standard deviations). • Advised that testing showed that calculated mean of 44 mg/kg, but standard deviation was 9.9. • Three standard deviations is the normal measure of process capability. • Iodine is added as milled potassium iodate (solid), but not sure of practice of other manufacturers.
Food Technology Association of Australia Australia Tony Zipper	<p>Preference not specified</p> <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Considers mandatory fortification does not give consumers a choice. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Why only fortify bread which will also be fortified with thiamin and folic acid - bread will have 'medical connotations' rather than be a staple food. • Should other methods of addition of iodine be permitted in other foods e.g. add directly to breakfast cereals or to water, milk? • Concerns with exempting organic and 'heavy health' (New Zealand) bread as FSANZ has not defined organic/heavy health bread. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • People who can't tolerate salt or iodine will have choice of a staple food restricted. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Allowing claims would be some compensation to manufacturers. • Would crumbed foods require labelling with 'iodine' if less than 5% crumbs? <p><i>Level of fortification</i></p> <ul style="list-style-type: none"> • Will salt reduced bread have a higher level of iodine fortification? <p><i>Implementation</i></p> <ul style="list-style-type: none"> • A two year introduction will mean more people will suffer from iodine deficiency. • Will gluten free bread be exempt? <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Enforcement to start upon gazettal to better track fortification effects. • Bread manufacturers will be legally liable for any associated litigation. • Who will pay for follow-up surveys? <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Will an education program on iodine lead to increased iodised salt in foods which would lead to consumption of more salt and a negative health outcome? • Who will pay for education?

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Costs</i></p> <ul style="list-style-type: none"> • It will be difficult for manufacturers to justify the recovery of extra costs of iodisation. • Questions if Government compensation is available for industry for this enforced action? • Industry will have to increase analytical work to ensure uniformity etc.
<p>Coles Myer Limited Australia Kim Tikellis</p>	<p>Does not support mandatory fortification with iodine</p> <p><i>Preferred approach</i></p> <p>Supports:</p> <ul style="list-style-type: none"> • Extending voluntary provisions. • Education campaign to promote: <ul style="list-style-type: none"> – increased supplement use by target group; – voluntary fortification of table salt and naturally occurring sources of iodine. • Retaining voluntary permission for iodised table salt, but adjusting range to 35-55µg iodine per kg, consistent with mandatory requirement. • If mandatory fortification is the preferred option, supports fortification of salt in bread, subject to an active salt reduction policy across the food supply. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports voluntary fortification of bread and milk with iodine. • Opposes the direct addition of iodine to bread in Australia due to inadequate equipment and resources of small in-store bakeries. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Suggests documentation of minimum tolerance level of 20% in the user guide to the Standard for enforcement purposes. • Include position in relation to ‘natural’, ‘organic’ and ‘no added salt’ claims in the explanatory notes and user guide. • Recommends availability of a User Guide at gazetta. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Willing to assist in the development of a national enforcement approach. • Recommends a sunset provision for review to examine compliance, safety, dietary intake and efficacy data for mandatory fortification. <p><i>Labelling</i></p> <ul style="list-style-type: none"> • Does not support iodine in the NIP for mandatory iodine fortification, but supports mandatory iodine NIP declaration for voluntary iodine fortification or foods making nutrition or health claims about naturally occurring iodine. <p><i>Costs</i></p> <ul style="list-style-type: none"> • Requests consideration of cost effects of adding ‘iodised salt’ to the digi-labels in in-store bakeries where space is limited. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Welcomes opportunities to support health promotion initiatives via range of methods e.g. in store signage, check-out screens, newsletters, catalogues, sponsored magazine articles etc.

SUBMITTER	SUBMITTER COMMENTS
Food and Beverage Importers Australia Australia A J Beaver	<p>Does not support mandatory fortification with iodine</p> <p>Believes a MoU for voluntary use of iodised salt in food manufacture should be tried before mandatory iodisation is implemented.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports removal of biscuits as a food vehicle because of the impact on trade. <p><i>Cost</i></p> <ul style="list-style-type: none"> • Concerns that the proposal will still have trade implications as some products defined as bread may be imported into Australia.
Flour Millers Council of Australia Australia Graeme Lukey	<p>Does not support mandatory fortification with iodine</p> <p>Does not support mandatory fortification with iodine as a public health strategy to address a health problem that is not shared by the whole population.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • With more research we will know whether the iodine deficiency would be better addressed with fortifying food or by modifying agricultural practices. • Consumers should be able to choose whether or not their food is iodised. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Reasons for the current deficiency are not fully understood. The necessary data should be available to government for research so that best decisions can be made. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Ongoing monitoring and surveillance of dietary intake should be a key element of mandatory fortification.
Dairy Australia Australia Jacinta Orr	<p>Does not support mandatory fortification with iodine</p> <ul style="list-style-type: none"> • Is unconvinced that mandatory fortification is the best solution based on available information. • Strongest contemporary evidence of successful population intervention in Australia is voluntary iodine fortification program in Tasmania. • Unaware of information suggesting voluntary fortification is less effective than mandatory. • Considers statement on the re-emergence of iodine deficiency correlating with changes in dairy industry practices distracts attention from the current determinants of poor iodine status. • Interested in developing innovative iodine enriched food products providing technical and safety issues are adequately addressed. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • No basis for prediction in Issues Paper regarding ‘current levels of iodine deficiency will become more serious’. • Concerns regarding the lack of understanding and speculative explanations of regional differences in iodine status. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports appropriately resourced research via the iodine monitoring strategy to identify nutrition issues which may be masked by mandatory fortification. • Supports assessment based on health improvement not dietary intake.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> Supports a 'sunset clause' to rescind the Standard if the intervention is not shown to be effective on direct health parameters. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Supports a general level health claim to encourage 'on pack' information about the nutritional need for iodine.
Dominion Salt New Zealand Brett Hobson	<p>Supports mandatory fortification with iodine</p> <p><i>Level of fortification</i></p> <ul style="list-style-type: none"> Supports an iodine range in bread salt equivalent to voluntary permissions. Iodine range of 35-55 mg/kg is achievable. <p><i>Technical issues</i></p> <ul style="list-style-type: none"> Iodine delivered in a brine solution – variation could be due to difference in solubility between salt and potassium iodate. Iodide is more soluble, but less stable - may release free iodine gas under certain circumstances. Technical solution may be batch mixing of iodised salt containing iodate or iodide in a brine, ensuring all solids are dissolved before use. <p><i>Implementation</i></p> <ul style="list-style-type: none"> One or two year implementation is achievable.
George Weston Foods Australia and New Zealand Fiona Fleming	<p>Does not support mandatory fortification with iodine</p> <ul style="list-style-type: none"> 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. Believes that this is an opportunity for industry, Government and FSANZ to work together to achieve a successful outcome in Australia and New Zealand. Does not support the Mandatory Fortification Proposal as it: <ul style="list-style-type: none"> fails to meet the policy requirements which support an assessment of alternative strategies prior to choosing mandatory fortification; 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. Also: <ul style="list-style-type: none"> iodine deficiency appears regionally rather than nation-wide; and it is not mandatory in most countries where the salt has been adopted as the delivery vehicle for iodine. <p><i>Preferred approach</i></p> <ul style="list-style-type: none"> Strongly supports the recommendations of the AFGC to: <ul style="list-style-type: none"> develop a MoU with industry for voluntary use of iodised salt in food manufacture; promote the use of iodine as a processing aid;

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> - develop and maintain an industry awareness campaign of the need to use iodised salt in food manufacture; - retain the current permission for iodised salt for discretionary use, and promote substitution of iodised salt for non-iodised salt for such use; - develop and maintain a consumer education campaign aimed at the target population about the importance of iodine in the diet; and - develop and maintain a trans-Tasman monitoring program for urinary iodine status in the target population to estimate prevalence of iodine deficiency disorders (IDD). <ul style="list-style-type: none"> • Also supports a clause in the legislation, if mandatory fortification is implemented, such that the Standard should lapse after 4 years if: <ul style="list-style-type: none"> - no measurement of the health effect has been undertaken; or - if measurement has occurred, such measurement fails to demonstrate a significant improvement in the health effect. • Supports the AFGC's recommendation of an agreed MoU with industry to voluntarily use iodised salt in food manufacture because it: <ul style="list-style-type: none"> - has evidence of effectiveness in the Australian market; - retains consumer choice; - it allows for those with coeliac disease to be reached through use in non wheat based products; and - has been shown to be effective internationally. • Also supports the AFGC recommendation to promote iodine as a processing aid (permitted for use for fruits, vegetables and eggs under Standard 1.3.3) as: <ul style="list-style-type: none"> - it is in line with national nutrition guidelines to increase consumption of fruits and vegetables; and - it has the potential to improve the reach of iodine to those who do not consume bread. <p><i>Consistency with policy principles</i></p> <ul style="list-style-type: none"> • Requests that FSANZ adequately assess other options for increasing iodine intakes in line with the policy principles for mandatory fortification. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Requests that FSANZ discuss the issue of fortification of the water supply as a possible way of alleviating iodine deficiency with the appropriate authorities. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Questions whether the use of dietary supplements including iodine was included in the modelling. • Questions whether the average salt content of bread was updated in FSANZ's latest dietary modelling since at draft assessment this was over estimated (1.36%) and therefore over estimated the effectiveness of the proposal. <p><i>Costs</i></p> <ul style="list-style-type: none"> • Questions costs not included in the Access Economics CA dated April 2007: <ul style="list-style-type: none"> - potential adverse health effects from excess iodine intake; - costs of monitoring; - restriction of consumer choice; and

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> – complementary policies required alongside fortification but outside the purview of FSANZ. <ul style="list-style-type: none"> • Also questions the discrepancy in industry costs in the report. • Questions how the ongoing costs for the voluntary program in Tasmania differ from costs associated with mandatory fortification. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Recommends outcome-based standards to allow industry flexibility in meeting the Standards. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Questions whether the inability of most bread to make a ‘good source’ claim will confuse consumers who will be advised to consume bread for iodine. • Requests FSANZ decides on a specific iodine health claim prior to Final Assessment. Suggests wording for claims. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Notes that in the editorial note to Standard 1.3.3 of the Food Standards Code, FSANZ states they will review the extent of the use of iodine as processing aid three years from inclusion in the Standard. It is imperative that this be reviewed as part of Proposal P230. • Questions if FSANZ will monitor the number of yeast-free bread using iodised salt? <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • 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. • Suggests that non-written material such as radio advertisements could play an important role in an education campaign.
<p>Go Grains Australia Trish Griffiths</p>	<p>Does not support mandatory fortification with iodine</p> <p>Considers the proposed approach is inconsistent with policy guidelines as:</p> <ul style="list-style-type: none"> • it will not deliver sufficient amount to the target group; and • no monitoring system is in place to monitor and review mandatory iodine fortification. <p>If mandatory fortification proceeds Go Grains seeks commitment from FSANZ and other agencies regarding:</p> <ul style="list-style-type: none"> – actively promoting the consumption of grain-based foods; and – monitoring consumption of grain based foods. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Recommends a consistent approach to food vehicle selection. • Concerns that issues raised by other food groups take priority over bread e.g. breakfast cereals. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Questions the safety of mandatory fortification, and raises concerns regarding the unacceptably high rates of thyrotoxicosis following the introduction of iodine fortification in Tasmania in the late 1960s which lead to its discontinuation in 1976.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports implementation of monitoring prior to mandatory fortification. • Identifies general lack information on iodine status of pregnant and breast-feeding women. <p><i>Dietary modelling</i></p> <p>Considers data missing in relation to:</p> <ul style="list-style-type: none"> – bread consumed – total consumed and segmented by population group; – quantitative estimates of total salt consumption; and – the iodine content of Australian and New Zealand foods. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Considers mandatory fortification compromises consumer choice and organic and salt-free bread are not adequate alternatives. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Considers mandatory fortification will not reach specific population groups e.g. those who avoid or limit bread consumption due to coeliac disease, wheat intolerance or allergy, personal preferences and cultural influences. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports an education campaign targeting at risk groups.
<p>Goodman Fielder Baking Australia Gordon Hardie</p>	<p>Does not support mandatory fortification with iodine</p> <ul style="list-style-type: none"> • Considers mandatory fortification is medication of the food supply. • Considers mandatory fortification is inconsistent with policy principles regarding demonstrated health need with respect to prevalence and severity. • Prevalence of iodine deficiency is uncertain and would be better addressed using a targeted approach with MoUs between State governments of South Australia, New South Wales and Victoria. • Results of Newspoll survey showed that 72% of Australian adults surveyed do not want Government mandating additives in the food supply. • Supports a MoU as considers that the Tasmanian approach has demonstrated a significant improvement in iodine status in Tasmania (reference in comments). <p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • Supports retaining current permission for iodised salt for discretionary use. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Notes that pregnant and breastfeeding women most likely won't get enough iodine through mandatory fortification of bread. • Considers a significant proportion of women in target group consume less than 1.4 slices of bread per day (43% of 18-24 yr olds and 38% of 35-44 year olds). <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Concerns for those with Grave's disease and thyroid cancer who may need to avoid bread.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Cost</i></p> <ul style="list-style-type: none"> • Recommends FSANZ commission a cost analysis on the cost of restriction to consumer choice, potential adverse health effects from excess iodine intake; monitoring nutrient intake and urinary iodine concentration and complementary policies required alongside fortification but outside the purview of FSANZ. • A regulatory impact statement which complies with the Office of Best Practice Regulation should include a cost effectiveness analysis. • Encourages FSANZ to include cost of labelling changes required for products containing more than 5% of breadcrumbs in cost benefit analysis. • Estimates a cost of changing packaging at \$1.4 million in Australia and New Zealand. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Majority of breadcrumbs are made from bread (6,000 tonnes per year by Goodman Fielder). • Considers mandatory fortification of breadcrumbs will have a significant impact on imports and exports especially of crumbed products to Japan. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Requests any changes to packaging to incorporate new mandated ingredients be transitioned at the same time, to allow for minimal write off of existing stock. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considers wording of the proposed general level health claim is not suitable for consumers e.g. thyroid hormones. Provides alternate wording. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Considers FSANZ has not used best available evidence and should seek from stakeholders information on current consumption patterns relevant to the application or proposal. If none is forthcoming, then FSANZ can justifiably state that they have used the best available evidence in their dietary modelling, albeit with severe limitations. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports national education campaign of promotion of fortified foods. • Supports industry awareness campaign re the use of iodised salt and iodine as a processing aid. • Supports promotion of naturally occurring sources of iodine such as seafood, milk and eggs. These foods also contribute omega 3 oils and calcium. • Recommends modifying and expanding the New South Wales Food Authority's education campaign on safe mercury levels in fish to develop a communication campaign for women planning pregnancy and pregnant women, promoting seafood as a source of iodine. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports trans-Tasman monitoring program for urinary iodine status in target population to estimate prevalence of IDD.

SUBMITTER	SUBMITTER COMMENTS
<p>New Zealand Association of Bakers (NZAB)</p> <p>New Zealand</p> <p>Annette Campbell</p>	<p>Does not support mandatory fortification with iodine</p> <p>Considers the proposed approach is excessive and impacts on consumer choice.</p> <p>Supports alternative proposal with MoU - to be overseen by joint committee of Government, industry and health representatives. Benefits include:</p> <ul style="list-style-type: none"> - addresses this public health issue; - preserves consumer choice; - industry and government working together; - allows targeted and focused campaign for at risk groups; and - government funded and industry supported education campaign. <p><i>Organic/natural</i></p> <ul style="list-style-type: none"> • Considers organic bread do not provide consumer choice. • Requests clarification of the status of natural products so that any addition of iodised salt would still allow this claim. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Industry would need permission to highlight claims on packaging and at point of sale within current health claims legislation. • Suggests alternate wording as proposed wording is not helpful for consumers. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Suggests that FSANZ consider Prof. Segal's report to understand the importance and economic value of consumer choice. <p><i>Technical issues</i></p> <ul style="list-style-type: none"> • Suggests that a member of New Zealand Association of Bakers (NZAB) uses brine system technology and that system is used widely internationally. • NZAB has not had time to research this issue and suggests that FSANZ 'investigate this further'. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports independent validation from health authorities to ensure consumer buy-in. • Supports a government funded and industry supported education campaign.
<p>New Zealand Food and Grocery Council</p> <p>New Zealand</p> <p>Brenda Cutress</p>	<p>Does not support mandatory fortification with iodine</p> <p>Supports voluntary fortification with MoU.</p> <ul style="list-style-type: none"> • Proposal is unreasonable, inequitable and excessive. • Considers extending use of iodine as a processing aid as can produce similar outcome to mandatory fortification in conjunction with a MoU. • Mandatory fortification is a last resort. <p>Benefits of voluntary fortification approach:</p> <ul style="list-style-type: none"> • Same objective can be achieved as mandatory fortification approach. • Maintains consumer choice (80% of New Zealand population oppose mandatory fortification. • Those who need to avoid high intakes of iodine would have choice. • The 12-13% who do not eat bread would have access to other food choices.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> • Women of child bearing age are not high consumers of bread, so a wider variety of products than just bread would increase the chance of raising the iodine level of women of child bearing age, pregnant and breast-feeding women. • Fulfil same criteria as mandatory fortification i.e. effectiveness, equity, efficiency, certainty, feasibility and sustainability that are required for an effective public health strategy. <p>Other comments:</p> <ul style="list-style-type: none"> • It would have been helpful if the dietary intake assessments for the industry MoU were included in the Issues Paper for review and comment. The range of foods could be amended to ensure the required levels of iodine are obtained. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Raises the option of fortification of water with iodine, especially in Australia where iodine deficiency is not a problem in some states. • Unleavened bread and organic bread do not provide 'real' choice. <p><i>Costs</i></p> <ul style="list-style-type: none"> • Suggests undertaking a cost benefit analysis of the removal of consumer choice. <p><i>Labelling and claims</i></p> <ul style="list-style-type: none"> • Suggests that the wording of proposed health claim would not be understood by the majority of consumers. Proposes alternate wording. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports a communication strategy. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Considers monitoring is essential.
<p>Salt Institute USA Richard Hanneman</p>	<p>Supports mandatory fortification with iodine</p> <ul style="list-style-type: none"> • Advises that providing iodised salt is relatively simple and inexpensive. • 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. • 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.
<p>Unilever Australasia Australia Julie Newlands</p>	<p>Does not support mandatory fortification with iodine</p> <ul style="list-style-type: none"> • Supports AFGC approach with MoU. • Considers mandatory fortification to be an impost on industry and restricts consumer choice. • Questions reasons for the release of an Issues Paper rather than a PFAR. • Considers evidence from Tasmanian MoU approach does not support mandatory fortification of a single food vehicle. <p><i>Technical issues</i></p> <ul style="list-style-type: none"> • Supports use of iodine as a processing aid.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports a communication program.
<p>New Zealand College of Midwives New Zealand Lesley Dixon</p>	<p>Provisional support for mandatory fortification with iodine</p> <p>Support dependent on wider consultation with public and with their members. Proposal is well researched and provides a comprehensive risk benefit analysis.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Accepts evidence and is concerned with the re-emergence of iodine deficiency. • Understands that dietary iodine intake is especially limited in pregnant women because they are advised not to eat large predatory fish. • Health risk from increased salt in diet. • Reassured that FSANZ has considered health risk from hypertension and to those with existing thyroid conditions. • States that fortification of bread with iodine is unlikely to fully meet needs of pregnant and lactating women. • Could alleviate existing conditions and provide improved iodine stores at the beginning of pregnancy. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Suggests consultation with public before decision on mandatory fortification. • Information on the health benefits and RDI of iodine should be provided for the public and health professionals.
<p>National Heart Foundation of Australia Australia Barbara Eden</p>	<p>Supports mandatory fortification with iodine</p> <p>Supports mandatory fortification in core foods including bread but has reservations with the use of iodised salt.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • If iodisation of bread alone does not improve iodine status adequately then believes that other core foods should be fortified, e.g. breakfast cereals and milk, not biscuits. • Believes that using salt as food vehicle conflicts with public health messages, evidence based nutrition and their ‘Tick Program’. • Adding a nutrient (iodine) with positive health benefits to a food via a nutrient (salt) with negative health effects may confuse consumers. • This may be a disincentive for the food industry to reduce salt levels and 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 salt iodised at 35µg iodine/100g will not meet the conditions to make a ‘good source’ claim. • The Heart Foundation encourages FSANZ to explore other methods of iodine fortification e.g. direct addition of iodine in bread, iodised feed for cows (Finland) and in animal feed and other foods in Finland, Norway and Sweden and Germany. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Urges FSANZ funded by government to ensure adequate monitoring of dietary intake of iodine.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> 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. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Believes that an education program on achieving adequate iodine intake and possibility of supplements is FSANZ's responsibility.
<p>National Council of Women of New Zealand New Zealand Christine Low and Jan Brown</p>	<p>Supports mandatory fortification with iodine</p> <p>Most members agree that mandatory preferable to voluntary and would be concerned if universal salt iodisation (USI) were adopted.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Some members have concerns with the increased level of fortification: that people who use iodised salt and consume iodised salt in bread may exceed the upper limit for safety. Most members were reassured that studies have shown addition of iodine is safe. Need to ensure that those with thyroid conditions or intolerances are monitored regularly. Agrees that iodisation of salt in bread would contribute to alleviating existing iodine deficiency. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Supports exemption of organic bread to provide consumer choice. Fortifying bread with iodised salt was preferable to iodising milk. Most members did not support iodisation of other processed foods (USI). <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Labelling must be changed to reflect any changes and needs to be easily read by consumers. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Monitoring to ensure ongoing effectiveness and safety of the mandatory fortification program. Formal reviews are essential. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Education initiatives to raise awareness and understanding of the Proposal. Collaboration with other organisations that educate consumers. Ensure that target groups in the population e.g. those with thyroid conditions should receive advice to avoid iodine rich foods or additional use of iodised salt. Ensure that pregnant and breastfeeding women are advised that they will need additional iodine supplements. This group will need specific messages.
<p>New Zealand Dietetic Association New Zealand Ms Jan Milne</p>	<p>Supports mandatory fortification with iodine</p> <p>The New Zealand Dietetic Association supports:</p> <ul style="list-style-type: none"> - the removal of biscuits; - use of salt in bread as the best vehicle; - that the most cost effective fortification is to use iodised salt only in bread rather than require all salt to be iodised; and - the exemption of organic bread.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Accepts the reasons for removing cereals from proposal but requests that if fortification is inadequate, direct addition of iodine to cereals be considered. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Aware that some groups, especially pregnant and lactating women, will still be at risk of iodine deficiency. Is concerned that supplementation will not reach all women. • Multivitamin supplements (Elevit and Pregnacare) available for pregnant and lactating women do not contain iodine. The Ministry of Health and Pharmac should make iodine supplements available for pregnant and lactating women as is done in Europe. • Supports use of general practitioner or specialist for those people at risk of high iodine intakes, suggest that registered dietitians be added to list of health professionals that can provide individuals with dietary advice. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Pregnant and lactating women are poorly informed about the need for iodine and extensive education will be required. The New Zealand Dietetic Association is willing to be involved in this. • Publicity and education will be required for those people who do not eat bread. Education on other sources of iodine for non-bread eaters should be consistent with the advice regarding mercury in fish. • Dietitians and midwives should be included as key professional groups that can target population groups at risk e.g. pregnant and lactating women. Children should also be added to the list of target groups that need advice regarding iodine. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Supports labelling bread to list iodised salt. • Accepts health claims regarding source and good source provide a method of consumer education. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Would like FSANZ to have a detailed plan regarding review of the level of iodine fortification and foods to be fortified if the current proposal proves inadequate for pregnant and lactating women. • Would like New Zealand national food composition tables to be updated.
<p>New Zealand Nutrition Foundation</p> <p>New Zealand Ms Kelsey Woodcock</p>	<p>Supports mandatory fortification with iodine</p> <p>Supports mandatory fortification as a starting point but believes it does not meet the needs of pregnant and lactating women and consumers who don't eat bread.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Food vehicles need to be broadened beyond bread, especially important to have wheat or gluten free food vehicles. • Recommends FSANZ reconsider USI. • Some consumers may choose to reduce salt in their diet while still consuming adequate iodine. This reinforces the need for further research into food vehicles other than salt. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Education campaign should raise awareness of iodine rich foods, iodised salt and multivitamins containing iodine for those with wheat/gluten intolerance.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> • Essential that health professionals and women of child bearing age are targeted to increase awareness of the requirement for iodine rich foods, iodised salt and multi vitamins containing iodine. • The general public should be advised to avoid using extra salt during cooking or at the table but to use iodised salt when they do. Increased use of salt is not consistent with current health messages re sodium and hypertension. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Iodine supplements are not currently available in New Zealand. • Elevit, a commonly recommended supplement in pregnancy contains no iodine. • FSANZ should investigate methods to make oral supplements available in New Zealand. • Suggests liaison with manufacturers of vitamins used during pregnancy and lactation to include iodine in appropriate amounts to their multivitamins. • Suggests that FSANZ explores the use of iodised oil for pregnant and lactating women as suggested by Trevor Beard. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Allowing health claims may encourage food manufacturers to maintain or increase the amount of salt in their products. • Policies need to ensure that this does not happen and also to prevent manufacturers being disadvantaged if they reduce sodium in their products. • Iodised products need to be appropriately labelled, as some consumers need to avoid iodine. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Ongoing monitoring and evaluation of the iodine status of the population is essential. • The iodine content of foods should be monitored.
<p>Asia-Pacific Region ICCIDD and Australian National Iodine Steering Committee Australia Creswell Eastman, Phillip Harding, Basil Hetzel, Mu Li</p>	<p>Supports mandatory fortification with iodine</p> <p>Supports mandatory fortification as effective for the majority of population but considers level of fortification inadequate for pregnant and lactating women and small infants.</p> <p>Considers this unfortunate because ‘the worst expression of iodine deficiency is seen in these groups’.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Believes that USI would provide higher iodine intake, for those with higher requirements i.e. pregnant and lactating women. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Developing foetus, (mother) and infant will need iodine supplements to avoid iodine deficiency. • Adverse effects of undesirable salt and/or iodine intake were adequately addressed by proposal. <p><i>Costs/benefit analysis</i></p> <ul style="list-style-type: none"> • Notes industry opposed to mandatory fortification because of cost of implementation and to regulation on principle. • Negative reactions to mandatory fortification might be based on a poor understanding of the issues involved, including the potential health benefit.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Believes that a consultative approach to industry explaining the benefits of mandatory fortification to community health. • Manufacturers should be encouraged to view mandatory fortification positively, as portraying their products to the public as conducive to good health. • Scientists and clinicians should be in dialogue with industry representatives and regulators working towards a collaborative rather than adversarial process. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Concerns that only process and some aspects of impact monitoring have been outlined. • Believes that the most important monitoring should be outcome based. • Need baseline data for pregnant and lactating women in both Australia and New Zealand.
<p>Meniere's Support Group of NSW Australia David Brigden</p>	<p>Supports mandatory fortification with iodine, but in foods other than salt</p> <p>Salt exacerbates their condition. They cannot eat commercial produced bread as it is too high in salt and therefore would not receive the benefits of iodisation.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Salt is not an appropriate vehicle for iodine fortification. • Prefer direct fortification of all flour (for home use and in processed foods) with iodine and folic acid. • Notes current salt intake in Australia is too high and would exacerbate several medical conditions including hypertension. • Fortifying salt would encourage the perception of salt as healthy and people may choose more highly salted bread. This may lead to an incorrect belief that all highly salted foods are healthy.
<p>Australian Division of World Action on Salt and Health (AWASH) Australia Jacqui Webster</p>	<p>Supports mandatory fortification with iodine, as an interim measure</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • 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). • Wide variation in the amount of salt in bread will produce different doses of iodine from different bread products. • Increasing the level of iodine in salt as the sodium level in bread decreases is not a good response as the bread with the lowest salt content will still have the lowest iodine content. • The absolute difference between 2 breads with different iodine contents will be even greater as the iodine level increases. • Plan with clear timelines to replace iodised salt with a better alternative such as iodised flour in bread perhaps in conjunction with folic acid. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Iodised bread is unlikely to provide sufficient iodine for the most vulnerable groups i.e. young children 9 months to 3 years who do not eat much bread. • Considers whether an alternative approach to iodisation is required to target high risk groups.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Use iodised bread initially but make sure that the importance of reducing salt intake is communicated clearly as a priority. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • A monitoring program should assess the impact on iodine status of the population.
<p>The Australian Thyroid Foundation Australia Beverly Garside</p>	<p>Offers qualified support for current mandatory fortification proposal</p> <p>Believes that <i>all</i> processed foods should be iodised.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Pregnant women are at particular risk for inadequate iodine as they often watch their weight and may not eat bread regularly and because they are advised not to eat large fish. • Iodine should be mandatory in all food sources to ensure that every mother and baby has enough iodine in their diet. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Research from the MJA shows that iodisation of bread in Tasmania does not provide adequate iodine for pregnant women. • Many doctors and obstetricians do not advise pregnant women to take iodine despite the paper by Creswell Eastman informing them of the importance of iodine supplements and the results of the NINS. • ADD and autism are steadily increasing. This may be due to iodine deficiency. • Those who suffer from coeliac disease or do not eat bread will be not benefit from the iodisation of salt in bread and will be discriminated against. • Those who do not eat bread should not have to pay for supplements. Some people cannot afford to buy supplements. • FSANZ should ensure that supplements contain adequate amounts of iodine. • The supplement 'Elevit' is often recommended by obstetricians as a multivitamin for pregnant women but it does not contain any iodine and is twice as expensive as other multivitamins. FSANZ should review 'Elevit'. <p><i>Cost</i></p> <ul style="list-style-type: none"> • Cost to society of autism and ADD if proved that they are caused by iodine deficiency. • It is discriminatory that some people who do not eat bread will need to pay for supplements. Many of these people may not be able to afford supplements. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Educate the medical profession about the importance of iodine for the mother and her developing foetus and the need for iodine supplements in pregnancy. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • A monitoring system needs to be in place before implementation of mandatory iodisation and follow up research is necessary after implementation.

SUBMITTER	SUBMITTER COMMENTS
<p>Australian Medical Association Australia Margaret Chirgwin</p>	<p>Supports mandatory fortification with iodine, but would prefer USI</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports USI the preferred approach of WHO, ICCIDD and UNICEF. • Mandatory will only have an impact on those people who eat bread. • In Tasmania 10% of children surveyed continued to have low iodine levels. Suggested this is due to their families' not consuming bread. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • The current level of fortification is unlikely to meet the needs of pregnant and breastfeeding women as well as children. They will still need supplementation, which is not the preferred public health approach. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Monitoring should be included as part of an updated NNS and should include collection of blood and urine samples. This will support ongoing monitoring of micronutrient levels in population. • Prefer urinary iodine concentration (UIC) across a representative sample of the population. Used by WHO and ICCIDD. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Doctors and other medical professionals are well placed to provide information on iodine fortification to their patients. • Doctors will be the first point of inquiry for those with thyroid disorders who are concerned with iodine fortification. • FSANZ will need to work closely with the medical profession in development of the communication strategy. Should include take home resources which doctors can provide to their patients. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Believes that one year is an adequate implementation time.
<p>Dietitians Association of Australia Australia Kate Poyner</p>	<p>Supports mandatory fortification with iodine</p> <p>The benefits of mandatory fortification will be compromised if not supported by a public health program included targeted monitoring and education of groups most at risk of iodine deficiency</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Concerns with salt as the vehicle. Bread is the major contributor of salt to the Australian diet. Communication should focus on iodine in bread not salt. • Concerned that reduced salt bread will have reduced iodine levels. • Seeks clarification whether good source claims would be available for bread fortified with iodine. • Would prefer consideration of an alternative method of fortification such as 'iodised kilojoules.' <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Many pregnant and lactating women will have difficulty reaching sufficient iodine intakes consistent with NRVs and may need iodine supplementation.

SUBMITTER	SUBMITTER COMMENTS
	<p><i>Implementation</i></p> <ul style="list-style-type: none"> • Changing the fortification level needs to be technologically easy so that as sodium is reduced in bread, iodine levels can be raised. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Details of the monitoring framework have not been announced. Concern that safety and efficacy of the proposed mandatory fortification cannot be evaluated without appropriate monitoring in place. • Monitoring and review is desirable for all age groups. WHO recommends schoolchildren be used as an indicator of the population iodine status. But this would not give an accurate indication of the iodine status of pregnant and lactating women. The Dietitians Association of Australia asks that women of childbearing age, and children under 3 years, particularly those in iodine depleted areas, be monitored. • A monitoring program should consider; i) Health status, ii) Urinary iodine excretion in school aged children, women of child bearing age and children under 3. iii) Nutrient intake and food consumption patterns as assessed by food frequency questionnaires. iv) Food composition data on iodine from major dietary sources v) Compliance monitoring for industry • Monitoring is a core government responsibility. • Labelling should be monitored, especially for those with thyroid conditions. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • There is a need for a public health program to highlight the importance of adequate iodine during pregnancy, lactation and childhood as present levels of fortification will not provide adequate iodine for many women. • Women may incorrectly believe that the fortification of bread will provide them with adequate iodine. • Some women will not consume bread due to allergies or food intolerance. • Suggest human development programs at secondary schools provide an opportunity for targeting adolescent girls. • The number of people exceeding the UL will be greater in Queensland and Western Australia. They might need a specific education program.
<p>Centre for Public Health Nutrition University of Sydney Australia Vicki Flood and Jimmy Louie</p>	<p>Supports mandatory fortification (with a few concerns)</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Pleased that biscuits have been removed • Acknowledges FSANZ's intention to reconsider breakfast cereals as a fortification vehicle if current approach is inadequate. • Acknowledge that FSANZ has considered the question of reducing salt in the diet and reassured by i) modelling that even with a 30% reduction in salt bread can still make a nutrition content claim ii) that manufacturers reduce the level of salt in bread iodine levels can be raised in salt. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerns that a substantial minority of people do not eat bread (14% from a New South Wales survey in 2002).

SUBMITTER	SUBMITTER COMMENTS
<p>Salt Matters of Australia and New Zealand</p> <p>Australia and New Zealand</p> <p>Trevor Beard</p>	<p>Supports mandatory fortification with iodine, as a short-term solution</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • It was true in the past and it is still true for 3rd world countries that using salt as a vehicle for iodine is the best way to ‘combat IDD’. • Using salt as the vehicle for iodine will create an epidemic of hypertension. • Australia should only use salt as an interim measure and should plan now for a change to a safe vehicle such as iodised dough improver or iodised bread flour. • Public confusion and administrative nightmare result from a marriage of two food additives with opposite health messages. • Salt Matters of Australia and New Zealand recommends adding iodine directly to bread flour. This could be managed with the same equipment as folic acid additions. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • The whole population approach is no longer adequate: those most in need of iodine, pregnant and lactating women, will not receive adequate iodine from mandatory fortification. • This special subgroup requires special prescriptive measures e.g. supplements, iodised oil etc. • Iodised oil could be used in clinics as part of primary health care. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • It will be difficult to increase the iodine content of salt if salt content of bread decreases because different bread manufacturers will not reduce salt content uniformly unless salt reduction in bread is mandatory. • Salt Matters of Australia and New Zealand recommends that when iodine fortification is implemented there should be a mandatory reduction of salt in all bread to 400 mg/100 g. • Health conscious consumers will choose bread with the highest iodine content if they listen to International Council for the Control of Iodine Deficiency Disorders and bread with the lowest salt if they listen to Salt Matters of Australia and New Zealand. This is a conflict for those trying to control their salt intake and provides an excuse for those who do not want to reduce salt intake. • Bread with the ‘Tick’ for low sodium will also contain the lowest iodine.
<p>Taranaki District Health Board, New Zealand</p> <p>New Zealand</p> <p>Amanda Brien</p>	<p>Supports mandatory fortification with iodine</p> <p>Believes a voluntary approach would not work but there are too many exemptions e.g. flat, organic, homemade and gluten free bread for it to be truly effective.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports removal of biscuits but believes cereals would be a good vehicle for mandatory iodised salt as they are a major food group that the population is encouraged to eat. In the New Zealand nutritional guidelines cereals are the same category as bread and can be considered a substitute for bread. • Support FSANZ exploring direct addition of iodine to cereals. • Believe that it is better to add salt to a staple than to advise people to add iodised salt to food. • Disappointed that the decision on the food vehicle was based on non nutritional considerations (trade, cost to industry).

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> • Is it possible to add iodine to the water supply? This would eliminate health inequalities and regional variation. • For this strategy to be effective nearly all bread would have to be iodised. Yeast free bread are becoming more common in the food supply and this would decrease the effectiveness of the proposal. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • The proposal is still inadequate to address needs of pregnant and lactating women and their children. Less than one quarter of pregnant and lactating women will obtain enough iodine. • Elevit a supplement currently recommended during pregnancy does not contain iodine. • Most pregnancies are undetected in the early stages when critical growth and neurological development occurs so would not be taking supplementation at the most crucial time. • The UL is not an issue and more study needs to be done in this area. • Toxicity is not a problem for Asian countries, in fact seems to contribute to this population's higher average intelligence quotient. • If bread becomes considered an iodine rich food will people with existing thyroid conditions be advised to reduce bread intake? This will have other nutritional implications: folic acid, fibre and carbohydrate intake. • Females tend to eat less food than males, especially if on 'low carbohydrate' diet. Will be difficult for women to obtain enough iodine from other dietary sources particularly as pregnant women are advised to avoid seafood. • Those of Middle-Eastern and Asian descent and those with coeliac disease will be disadvantaged because they do not eat bread as a staple food. • Supports the use of potassium iodate rather than sodium iodate due to the consequences of hypertension that result from increased dietary sodium. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Most bread manufacturers would be able to make a source claim for iodine but the less expensive brands may choose not to. This would lead consumers to believe that the cheaper breads had less iodine. • Manufacturers may see this as an opportunity to increase the cost of bread. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports monitoring iodine in the food supply so that the need for additional food vehicles can be reconsidered. • Questions data that indicates that 88% of Australians 2 years and over are consuming bread. Is this at a level to meet nutritional recommendations? A recent study in New Zealand Medical Journal by Theodore et al, found that only 7% of pre-school aged children in Auckland are meeting daily bread and cereal requirements. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Those of low socioeconomic status will be disadvantaged, as lack of education/ knowledge and or income means this group is less likely to obtain iodine supplements. • Health education alone does not result in complete compliance. A study in Germany found that only 59% of pregnant women and 21% of lactating women are taking the recommended supplementation following 13 years of public health efforts. • Health education of naturally rich sources of iodine will not ensure that minority groups not eating bread will get sufficient iodine. This increases disparities as there are few alternatives of iodine rich foods that are readily available or affordable.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> • Maori and other at risk ethnic and socioeconomic groups have been overlooked in the communication policy. Key messages need to be tailored for these groups and stakeholders need to be consulted to ensure that the messages are appropriate and effective. • Any education campaign would have to be sustained to ensure future mothers are aware of the matter.
<p>Massey University New Zealand</p> <p>Louise Brough, Jane Coad, Gary Mendoza and Janet Weber</p>	<p>Supports mandatory fortification with iodine</p> <p>Supports mandatory fortification with iodine, but the level is not sufficient for pregnant and lactating women.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • The level of fortification is based on an UL that is calculated on extrapolation of adult data based on body weight that is not appropriate. • There is no documentation of iodine toxicity from supplemented food in children. • In the UK median iodine intakes for children aged 11/2 - 41/2 were 100 µg/day with the 97.5 percentile being 322 µg/day with no adverse effects seen or concern regarding children being above the UL for iodine. • The Expert Group on Vitamins and Minerals in the UK state there is insufficient data to establish a safe upper level and state that children may consume high levels of iodine but there are compensatory mechanisms that alleviate concerns. • Acknowledges the difficulty of ignoring the UL but other countries have done so, and urge FSANZ to ask NHMRC to reconsider the UL. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Agrees with the decision to exempt organic bread. • Disappointed that iodisation of table salt is not mandatory. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Iodine content should be displayed on the NIP. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Should highlight importance of actively choosing iodised salt whenever salt is purchased. • Nutrition and related claims should not be allowed as a claim of high iodine will also signal high sodium level. This may confuse consumers. If level of iodine in salt is such that all breads can make a claims it should be mandatory to on all breads. • All bread manufacturers could be involved with a public sector education campaign to promote generic bread which would help to offset the costs of implementation. • A communication strategy should make it clear that iodine content is linked to salt. • The outline of the communications is appropriate but no indication of level of resources available. • The main message needs to come from the health food/standards sector not just the food industry to ensure credibility. • Special attention must be given to health professionals who might be sceptical about the use of fortified foods. • Important to address the needs of pregnant women and the health professionals who work with them. • Appropriate, low cost/free supplements must be available for this group.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> The difficulty of promoting a supplement for pregnancy has been illustrated by the lack of success with folate supplementation.
<p>Aidan McElduff Private Australia (Royal North Shore Hospital, Sydney)</p>	<p>Supports mandatory fortification with iodine</p> <p>Supports mandatory fortification but considers the proposed level of fortification inadequate for the most vulnerable group pregnant women and their infants.</p> <p>This strategy is least effective in targeting the most vulnerable group and iodine supplements will still be necessary.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Pregnant women and infants are a major subgroup vulnerable to serious consequences of iodine deficiency. Pregnant women present to medical care late in 1st trimester when developing foetus may have suffered damage due to iodine deficiency. Women should commence a supplement prior to pregnancy for effective prophylaxis against iodine deficiency. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Pre-pregnancy counselling is not particularly effective. Unlikely to improve iodine intake through supplement use without specific targeted education programs. Difficult to reach the most vulnerable. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Should ensure adequate intake and guard against excess. Dietary modelling would be a useful adjunct to monitoring the use of voluntary permissions. Understands FSANZ role in monitoring but there must be a financial commitment to monitoring.
<p>Sheila Skeaff Private New Zealand (Otago University, New Zealand)</p>	<p>Supports mandatory fortification with iodine</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Disappointed biscuits and cereals removed because 10% of the population who do not eat bread will not receive additional iodine. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> The additional iodine from fortification will not meet the requirements of the most important group; pregnant women. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Iodine status of the New Zealand population will need to be monitored. Assume iodine monitoring will occur through National Nutrition Surveys. <p><i>Implementation</i></p> <ul style="list-style-type: none"> Two-year implementation period seems more than generous. Hope iodine fortification will not be delayed if there are problems with folic acid. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Would like to see the communication and education strategy.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> • Strategy to inform pregnant women about iodine deficiency should already have been implemented.
<p>Eugen Kriener</p> <p>Private</p> <p>Germany</p> <p>(Wurzburg Board of Health, Germany)</p>	<p>Supports mandatory fortification with iodine</p> <p>Supports mandatory fortification but believes that it is inadequate and would support direct addition of iodine to breakfast cereals.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Suggest including direct iodination of breakfast cereals as the percentage of people not eating bread is too high. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believes that the UL for iodine is false. • There is hypothyroidism that is normally not detected in the foetus during pregnancy in areas with moderate iodine deficiency. This has been shown to impact on the babies IQ. • Authors of Spanish study (referenced in comments) claim 1.42 times the risk for an IQ below the 25th percentile when urinary levels are below 100 µg/L. • An Italian study (referenced in comments) showed moderate iodine deficiency caused a cognitive deficiency in 9.5% of children. • There is a dose-effect relationship between iodine supply and the risk of an IQ below the 25 percentile. With iodine intakes (for mothers?) increased to 150 µg/d (aligning with the EAR for pregnancy) the risk for an IQ below the 25th percentile can be reduced by 20%. It can be further reduced by another 20% when intakes increase to 225 µg/day. • Increasing the daily iodine intake of a population with an MUIC of 42 µg/L to 92 µg/L doesn't alter the intelligence distribution very much. • Mild iodine deficiency can lead to a high incidence of autonomous thyroid nodules with hyperthyroidism in the older population. This can lead to severe osteoporosis, and heart damage with heart failure and atrial fibrillation atrial thrombosis and atrial embolism causing apoplectic stroke. Switzerland solved this problem by raising the MUI excretion from 90 µg/L to 150 µg/L. • Austria had a mandatory salt iodation at 7.4 ppm iodine which resulted in an estimated average increase of 65 µg iodine per day. This increment only prevented visible goitre and the total goitre rate of children remained at 11.8%. Fortification was increased to 15 ppm and iodine was also added to animal feed to give an extra 60 µg iodine per day. • Infants and children have a markedly higher T4 turnover relative to adults. In infants T4 production is estimated to be 5-6 µg/kg per day. This decreases over the first few years of life to about 2-3 µg/kg per day at ages 3-9 years. Adult production rate is only 1.5 µg/kg per day. This suggests that infants and young children would have a higher EAR for iodine relative to bodyweight. Supported by epidemiological evidence in Japan where intakes for children are 600-700 µg iodine per day at age 1-3 years without visible deleterious effects. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • There should be a tax on non-iodised salt. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • It is urgent to monitor iodine in milk regularly and to make a legislation for iodine content in livestock feed. A change in iodine content of animal feed can have major effects on dietary iodine e.g. from milk, dairy food, meat etc. • Iodine content of nutritional supplements needs to be monitored.

SUBMITTER	SUBMITTER COMMENTS
Ben Balzar Private Australia	<p>Supports mandatory fortification with iodine but would prefer USI</p> <p>Believes that the current proposal is inadequate and prefers USI.</p> <p>Believes that FSANZ's inadequate recommendations are based on an invalid NHMRC upper level.</p> <p>Considers the Proposal is a sham program that will inevitably fail and require further modification and will damage the reputations of FSANZ, and nutritional and medical communities.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • The proposal will not address the emerging health problem adequately. • Fails to account for cultural diversity in Australia where some sub-groups may be more or less at risk of iodine deficiency due to different diets. The proposal may be in breach of general principles of multiculturalism and equality. • Defies the advice of the WHO experts, the ICCIDD and ACCIDD and leaves Australia open to ridicule. • The assumed UL for young children of 200-300 mmol/day is based totally on conjecture and is extrapolated from adult recommendations on a metabolic bodyweight basis. • Over reliance on the UL has lead FSANZ to propose ridiculously low levels of iodine fortification and will definitely result in brain damaged children. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • The modelling of children's intake iodine may have overlooked that children get a very large proportion of their food as dairy products and thus fortification of bread may have a smaller impact on them than on adults. <p><i>Cost</i></p> <ul style="list-style-type: none"> • The economic modelling seriously underestimates the economic costs of the definite injuries to IQ of Australian and New Zealand children from iodine deficiency. • The proposal and the economic modelling fails to acknowledge that a nation's greatest resource is the national IQ, and this is under direct threat by the current levels of iodine deficiency. Even small changes in IQ can cause a profound increase in the number of children with mild and severe developmental delay and decrease in the occurrence of genius and giftedness. A 1 point drop in IQ can result in a 2.3% drop in earnings. This 1 point drop in IQ in 250,000 children would add up to a loss of \$12 billion per annum. • The proposal opens the door to medico-legal proceedings against GPs, obstetricians, midwives and nutritionists that could total millions of dollars for brain injury claims. • The modelling used by Access Economics places an undue emphasis on EAR a level that is by definition inadequate as it will only make 50% of the population replete. • Modelling severely underestimates the benefits of iodine supplementation.

SUBMITTER	SUBMITTER COMMENTS
<p>New Zealand Food Safety Authority, Ministry of Health, Ministry of Foreign Affairs and Trade, Ministry of Economic Development and Ministry of Consumer Affairs</p> <p>New Zealand Carole Inkster</p>	<p>Supports mandatory fortification with iodine</p> <p>Key comments:</p> <ul style="list-style-type: none"> • Supports the mandatory replacement of salt with iodised salt in bread, with a salt iodisation range from 35-55 mg of iodine per kg of salt. • Supports retaining the voluntary permission for iodine in iodised salt and reduced sodium salt at the new range of 35-55 mg per kg to make it consistent with the mandatory requirement. • Acknowledges that the voluntary use of iodised salt in manufactured foods may also be an important contributor of iodine to the diet of New Zealanders. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Acknowledges that the proposed new approach to iodine fortification will not deliver enough iodine to fully meet the needs of pregnant and breast-feeding women, and some children. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Seeks a direct comparison of projected increase in average daily iodine intake of adults in the Issues Paper with the modelling done for the Draft Assessment Report. This should be presented in the Final Assessment Report. • Requests the % of adults at the lower end of the range of increase in average daily iodine intake (i.e. 30 µg/day) that will meet the RDI for iodine at 150 µg per day, especially in New Zealand. • Recommend that FSANZ reflect the impact of such salt reduction programs in their dietary modelling because the review process is unlikely to detect the impact of such strategies on iodine status quickly enough. <p><i>Costs</i></p> <ul style="list-style-type: none"> • Would like to see costs to Government of monitoring and communication included in the Final Assessment Report. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Supports the exemption of bread represented as organic from mandatory iodine fortification to provide consumers with a greater level of choice if they do not wish to consume iodine fortified bread. However, would like FSANZ to be more specific in the provision to exempt bread made under or aligned with an organic certification agency or a recognised agency (recognised by the relevant competent authority). This would accommodate the range of certified standards available for organic produce in New Zealand and assist with compliance and enforcement issues. • Supports the proposal to implement iodine fortification over the same timeframe as folic acid fortification. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Recognises that iodised table salt will continue to play a role in meeting the iodine needs of some individuals and that careful consideration will need to be given to how best to communicate health messages associated with the consumption of salt. • Seeks clarification from FSANZ as to whether the strategy to guide communication and education initiatives to raise awareness and understanding of the proposed Standard is a trans-Tasman strategy. If so, we recommend that New Zealand be involved in the development of the strategy to ensure that the New Zealand situation is adequately addressed and sufficient time and resource are available to implement the communication strategy.

SUBMITTER	SUBMITTER COMMENTS
	<ul style="list-style-type: none"> In the absence of a suitable iodine supplement for pregnant and breastfeeding women in New Zealand, thought will need to be given to how best to assist these women to achieve their RDI for iodine. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Acknowledges the potential role of iodine content claims in the promotion of iodine containing foods through voluntary fortification, but would be disappointed to see iodine content claims on foods inconsistent with Food and Nutrition Guidelines. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Recognises the need for on-going monitoring and the need for a review of the effectiveness of the Standard. Acknowledges that industry may undertake programs to reduce the salt content of their bread. New Zealand Food Safety Authority and Ministry of Health are interested in the impact that salt reduction strategies may have on the iodine intake and status of the population. Acknowledges a FSANZ role for some components of an overall monitoring system, including the contribution to updating Australian national food composition databases. Suggests that work be undertaken to share food composition data between the two countries, particularly for foods that are the same, to avoid duplication. Suggests need for a timeframe for review of the effectiveness of the Standard which will need to draw on health status data. Changes in fortification level, additional food vehicles or direct addition should be considered as part of any review process. It will be important for industry to keep the Ministry of Health and New Zealand Food Safety Authority informed as to the timing of the change to iodised salt in bread making because any overlap with the 2008 New Zealand Adult Nutrition Survey will have implications for estimating iodine intake and interpreting urinary iodine results.
<p>Department of Agriculture, Fisheries and Forestry</p> <p>Australia</p> <p>Richard Souness</p>	<p>Does not support mandatory fortification with iodine</p> <p>Supports strategies to reduce iodine deficiency, providing initiatives impose minimal regulatory and financial burden on industry.</p> <p><i>Costs</i></p> <ul style="list-style-type: none"> Acknowledges that FSANZ's revised approach to add iodised salt to bread as the food vehicle addresses previous technical and trade issues and reduces costs imposed by using breakfast cereals and biscuits. Acknowledges lack of empirical evidence in Australia to link an increase in iodine status with quantifiable health benefits. <p><i>Review of alternate approaches to increasing iodine intake</i></p> <ul style="list-style-type: none"> Considers that FSANZ needs to address the principles for good regulatory process that were recommended by the Report of the Taskforce on Reducing Regulatory Burdens on Business. Supports undertaking an evaluation of alternative approaches for increasing iodine intakes in Australia (consistent with Proposal P295 First Review Request). <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Supports further consideration of the need for baseline data and implementation of an effective monitoring and evaluation framework to monitor health benefits over time and to prevent an unjustifiable regulatory burden being imposed on industry.

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	<p><i>Implementation</i></p> <ul style="list-style-type: none"> • Supports a stock-in-trade provision in the Standard that legally allows industry to manage the content and label changeover within the phase in period. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports a communication strategy to advise consumers of the possible inclusion of iodine without accompanying labelling during the changeover period.
<p>New South Wales Food Authority/ New South Wales Health Australia David Cusack, Bill Porter and Kerry Chant</p>	<p>Preference not specified</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Suggests that quantitative data on the extent of iodine deficiency in the Australian community be provided in the Final Assessment Report. • Recommends including percentage of each specific age group in the population below the RDI. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports use of salt for bread-making as the vehicle for mandatory fortification with iodine. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Recommends including results in the Final Assessment Report of modified dietary intake assessment data using iodised salt at the proposed fortification level to determine the impact and appropriateness of this new approach. • Concerns regarding the level of iodine in infant formula and the impact on exclusively formula fed infants and recommends this issue be addressed in the Final Assessment Report. <p><i>Costs</i></p> <ul style="list-style-type: none"> • Requests FSANZ include the estimated cost of the current iodine deficiency to the Australian community and advise on the quantitative benefit delivered by iodine fortification in the final assessment report. • Should the initial proposal prove unsuccessful in achieving the health outcome, suggests FSANZ carefully investigate the costs of raising the level of iodine in salt used for bread making or substituting salt used for making breakfast cereals with iodised salt before moving forward. • Assumes that costs of non-compliance and subsequent investigations associated with non-compliance have been appropriately factored into cost estimates of this proposal on jurisdictions. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Suggests FSANZ thoroughly investigate trade implications arising from substituting salt used for making breakfast cereals with iodised salt. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • 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. 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.

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	<p><i>Implementation</i></p> <ul style="list-style-type: none"> • Suggests the removal of the proposed exemption for ‘organic’ bread until a standard definition of ‘organic’ has been determined. • Requests FSANZ to provide an exhaustive list of breads that will be exempt under this proposal, by virtue of the definition proposed by FSANZ for bread. • Suggests FSANZ provide guidance on the flexibility for a bread manufacturer to prepare their bread with iodised salt from the date of gazettal, or some other time in the transition period, but use up their old packaging stocks before changing to ones labelled with ‘iodised salt’ in the Final Assessment Report. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Monitoring programs for mandatory fortification will be addressed by AHMAC in mid-June. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Suggests FSANZ consult with health portfolios to ensure this Proposal is properly integrated into the health promotion framework and implemented in conjunction with other health initiatives. • 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. • Considers it important that educational material be prepared identifying foods that will be fortified with iodine under this proposal and how much iodine will be in a standard serve of these foods (i.e.: two slices of bread). Also suggests education material be prepared for those sectors of the community not consuming these foods, identifying alternate dietary sources of iodine and promoting the use and availability of iodine supplements. • Supports educational material targeted at those sensitive to iodine. • Suggests the preparation of educational material informing the public on the re-emergence of iodine deficiency in Australia and the importance of consuming sufficient dietary iodine to meet daily requirements.
<p>Department of Health and Human Services, Tasmania Australia Jen Savenake</p>	<p>Supports mandatory fortification with iodine</p> <p>Supports mandatory fortification, but considers USI more likely to achieve adequacy for pregnant and lactating women.</p> <p><i>Consistency with policy principles</i></p> <ul style="list-style-type: none"> • Considers there is no conflict with iodised salt as the food vehicle and the need for Australians to lower their salt intake. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considers voluntary fortification is inadequate as it does not provide certainty around the level of iodine in the food supply, reach across the population or sustainability of the program over time. • Tasmanian experience shows a small increase in iodine status with iodised salt in bread. • Proposed level of fortification is inadequate to meet the requirements of pregnant and lactating women. (data to be published in June MJA). • USI is more likely to achieve an adequate intake in this target group. • Recommend ongoing investigation of alternate sources of increasing iodine in the food supply e.g. fortification of breakfast cereals.

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	<p><i>Other comments</i></p> <ul style="list-style-type: none"> • Avoid further delays.
<p>Queensland Health Australia Gary Bielby</p>	<p>Supports mandatory fortification with iodine</p> <p>Whole of Queensland Government Response.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports voluntary permission to be consistent with mandatory range. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Supports exemption for organic bread and yeast-free bread. <p><i>Implementation and transition</i></p> <ul style="list-style-type: none"> • Supports two year implementation period. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Expressed continuing concerns regarding vulnerable groups who are non-bread eaters e.g. people trying to lose weight through low carbohydrate diets, those on low salt diets and some ethnic groups. <p><i>Costs</i></p> <ul style="list-style-type: none"> • Concerns that cost of monitoring and surveillance as well as education and health promotion activities are not included in the cost assessment. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Concerns regarding lack of data on supplements. • Collection of baseline data should include drinking water. • Lack of data of iodine status in rural and remote areas in Queensland. • Lack of data on iodine status of pregnant and breastfeeding women which has generally been shown to be lower than that of children. • Lack of data on discretionary salt intake. • Expressed concern about the Food Regulation Standing Committee’s proposal for monitoring framework for mandatory fortification and supports referral of the framework and draft monitoring systems for folic acid and iodine being referred to AHMAC for advice in relation to: <ul style="list-style-type: none"> - the integration of the proposed monitoring data collection with existing health collections for nutrition and health outcomes; - the appropriate bodies to oversee reporting and evaluation of data; and - the funding of these two monitoring systems.
<p>Department of Human Services Victoria Australia Victor Di Paola</p>	<p>Supports mandatory fortification with iodine</p> <p>Support for mandatory fortification is contingent on development of comprehensive monitoring program.</p> <p><i>Consistency with policy principles</i></p> <ul style="list-style-type: none"> • Concerns the proposal is inconsistent with the FSANZ Act and the fortification Policy Guideline. • The Specific Order Policy Principles 1, 2 and 4 for mandatory fortification have not been clearly demonstrated. • Policy Principle 2 has not been demonstrated in the following:

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	<ul style="list-style-type: none"> - FSANZ hasn't reviewed the relevant research thoroughly, especially in relation to analysing the costs and benefits of the proposal. - Wishes to ensure the most cost effective strategy is introduced. - Strategies other than fortifying the food supply have not been adequately assessed e.g. water fortification, soil enrichment, iodine added to animal feed or fertiliser. <ul style="list-style-type: none"> • Policy Principle 1: justification for mandatory fortification has not been clearly demonstrated given the differing levels of severity and prevalence in the Australian population. • Policy Principle 4 is contradicted for the Western Australia and Queensland populations who are iodine sufficient and would not benefit from iodine fortification. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • A robust monitoring system is integral and should be developed in conjunction with mandatory fortification not as a separate adjunct. • Support is contingent on establishment of a comprehensive national monitoring program. • Monitoring is essential to ascertain the success of the strategy in reaching all population groups and the need for any adjustment in iodine levels or food vehicles used. • Assumes that analysis of bread to determine final iodine levels will be done by Local Government Agencies. They have not been consulted and have not accepted the responsibilities. They may not have the resources to do this and must enforce issues with a public health priority. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports the change from cereals, biscuits and bread to bread only. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned that people with coeliac disease and those from cultures who do not regularly eat bread will not obtain any benefit from fortification of bread. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Needs to address those who do not eat bread and who will remain at risk of iodine deficiency. <p><i>Costs</i></p> <ul style="list-style-type: none"> • The Access Economics Report is incomplete and does not include many key costs. These include costs associated with: <ul style="list-style-type: none"> - monitoring - the restriction of consumer choice, and with - complementary policies required alongside fortification but outside the purview of FSANZ. • A comprehensive cost benefit analysis is imperative to inform decision making on the proposal. The cost benefit analysis needs to be consistent with the COAG Principles and Guidelines for National Standard Setting by Ministerial Councils and Standard Setting Bodies. • The cost of monitoring has to be considered as a necessary and fundamental part of the proposal. • Who will bear the cost has yet to be established.

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	<ul style="list-style-type: none"><li data-bbox="331 226 1181 331">• In Victoria, monitoring iodine will be competing with other immediate health resources such as heart disease and diabetes. Costs to the government in the report include awareness raising amongst GPs which is based on an extrapolation from one jurisdiction.<li data-bbox="331 344 1181 421">• Average costs to industry based on two samples is not robust. The average costs should be based on a larger sample size or there should be a range based on upper and lower costs.