FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

6-06
18 August 2006

DRAFT ASSESSMENT REPORT

PROPOSAL P230

CONSIDERATION OF MANDATORY FORTIFICATION WITH IODINE

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 18 September 2006
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

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

Executive Summary

Recent studies show a re-emergence of mild-to-moderate iodine deficiency resulting from inadequate iodine intake in New Zealand and in parts of Australia. A diet deficient in iodine is associated with a wide range of adverse impacts on health. In children iodine deficiency can impair the development of brain and nervous system, with the most crucial period being from foetal development to the third year of life. In adults iodine deficiency increases the risk of thyroid dysfunction in later life. Both adults and children are at risk of developing goitre.

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 response, FSANZ raised this Proposal (Proposal P230) and released an Initial Assessment presenting four options for public consultation in December 2004. The four options included 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.

On the basis of Ministerial advice received in 2005 that mandatory fortification with iodine is an effective strategy, FSANZ reduced the number of regulatory options considered in this Draft Assessment Report to maintenance of the *status quo* and mandatory fortification with iodine.

FSANZ has drawn on international experience in identifying appropriate food vehicles for considering mandatory iodine fortification. The World Health Organization (WHO) recommends iodisation of all salt as the main strategy for the control of global iodine deficiency. Iodisation of some or all food salt is common in many countries as the main or sole measure to address iodine deficiency. Iodised salt has been found to be a suitable substitute for non-iodised salt in the majority of foods tested.

The report focuses on consideration of mandatory fortification with iodine as a means of reducing iodine deficiency in Australia and New Zealand, it includes:

- an assessment of the health benefits and risks of increased dietary intakes of iodine by the Australian and New Zealand populations;
- identification of a preferred food vehicle and level of iodine concentration to achieve the desired health outcome;
- management of any identified risks;
- cost-benefit analysis;
- associated communication and education;
- monitoring and implementation issues; and
- presentation of a preferred regulatory approach.

This report also addresses issues arising from public submissions and targeted stakeholder consultations.

Preferred Approach

The mandatory replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits is the preferred approach to address the re-emergence of iodine deficiency in Australia and New Zealand. The salt iodisation level is to be in the range of 20-45 mg of iodine per kg of salt.

The voluntary permission for iodine in iodised salt and reduced salt will be retained, but will be adjusted from the current range of 25-65 mg per kg to 20-45 mg per kg, to be consistent with the mandatory requirement.

Reasons for the Preferred Approach

- the replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits would contribute considerably to alleviating the consequences of existing deficiency, and prevent it from becoming even more widespread and serious in the future;

- the use of iodised salt to reduce the prevalence of iodine deficiency is consistent with international guidance and experience;

- in Tasmania, the recent use of iodised salt in bread was a successful initiative to increase the iodine status of a mildly deficient population;

- on the available evidence, including overseas experience with mandatory fortification, the proposed level of fortification does not pose a risk to general public health and safety. The level has been set to minimise any potential health risks. In groups that are generally more sensitive to increases in iodine intake, e.g. individuals with existing, thyroid conditions, the risk of a negative impact on health is still considered to be very low.

- the replacement of salt with iodised salt in key cereal-based food is effective and technologically feasible;

- FSANZ considers that the proposal would deliver net-benefits to Australia and New Zealand:

  - while quantifying the dollar values of the benefits proved extremely difficult, the identified benefits are considered to be valuable, especially in relation to the small cost likely to be incurred by the community;
  - the cost to industry and government in the first year would be $A15.8 million and $NZ0.7 million in Australia and New Zealand respectively, but would be lower in each subsequent year at $A3.3 million and $NZ0.4 million respectively;
  - these costs may be passed on to consumers and in the first year would amount to A$0.79 per person in Australia and NZ$0.16 per person in New Zealand, but in each subsequent year would fall to A$0.17 per person in Australia and NZ$0.11 per person in New Zealand;

- consumers will be provided with information through ingredient labelling to identify the presence of iodised salt in the key cereal-based food; and

- 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 and parts of Australia.

Consultation

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.

Issues identified from public submissions formed the basis of further targeted consultation with key stakeholder groups. Information received has informed FSANZ's consideration of the appropriateness of the food vehicle, identification and investigation of risk management issues, the cost-benefit analysis, the recommendations for the implementation phase, and the monitoring requirements for mandatory fortification.

An Iodine Scientific Advisory Group (ISAG) was established by FSANZ to provide expert advice on scientific and medical matters relating to this Proposal. FSANZ also involved the fortification Standards Development Advisory Committee (SDAC) to help identify views and issues whilst progressing work on this Proposal.

In addition, FSANZ commissioned an independent economic consultancy organisation, Access Economics, to investigate the benefits and costs of replacing salt with iodised salt in key cereal-based products in Australia and New Zealand. Access Economics held further consultations with key stakeholders, particularly industry groups, in regard to the financial implications of mandatory fortification.

Implementation

If the FSANZ Board approve the proposed draft variations to *Australia New Zealand Food Standards Code* (the Code) following the completion of a Final Assessment for this Proposal, the Ministerial Council will be notified of that decision. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code are expected to come into effect 12 months from gazettal.

It is proposed that a 12-month transitional period will apply to the mandatory addition of iodised salt, in place of non-iodised salt, in key cereal-based foods.
This transitional period will allow time for the salt industry to increase the production of iodised salt and for manufacturers of the key cereal foods to make the required changes to manufacturing and labelling. Additionally, a transitional period will allow for consumers to be informed about the changes.

FSANZ has prepared a strategy to guide communication and education initiatives to raise awareness and understanding of the proposed standard for mandatory fortification with iodine and its implementation. In implementing this strategy, FSANZ will collaborate with other organisations that play an important role in providing information and education to consumers, industry and other key stakeholders.

CONTENTS

SEPARATE DOCUMENTS:

INVITATION FOR PUBLIC SUBMISSIONS

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

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment of this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel +64 4 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ by 6pm (Canberra time) 18 September 2006.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

INTRODUCTION

This Draft Assessment Report (the Report) considers mandatory fortification with iodine as a means of addressing the re-emergence of iodine deficiency in Australia and New Zealand.

Historically, New Zealand and parts of Australia have experienced iodine deficiency due to domestic food supplies being grown in the naturally low iodine soils. Between the 1960s and 1980s, as a result of additional sources of dietary iodine being available, both populations were replete and iodine deficiency was no longer a problem. 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. Australia and New Zealand are signatories 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* provided as Attachment 2. At that time, Ministers also requested that Food Standards Australia New Zealand (FSANZ) give priority consideration to mandatory fortification with iodine. 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:

- 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 Panel[1] convened by AHMAC concluded that mandatory fortification fulfilled their criteria[2] of effectiveness, equity, efficiency, certainty, feasibility and sustainability.

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.

A monitoring framework for mandatory fortification has recently been developed by a FRSC working group. FSANZ has adapted this framework and outlined the potential elements that will be needed to assess the impact of mandatory fortification of the food supply with iodine (see Attachment 3). However, agreement on the exact nature of an iodine monitoring system is yet to be reached with other health and regulatory agencies at the Commonwealth, State and Territory level in Australia and with the New Zealand Government.

This Report therefore, provides a description of the current iodine status of Australian and New Zealand populations and the implications for health and performance. It details the dietary iodine intake assessment conducted to establish the impact of potential mandatory fortification scenarios developed to address existing iodine deficiency and the expected benefits arising from the resulting improvement in iodine status. Further, the Report discusses safety issues that can be associated with iodine fortification, cost-benefit analysis, associated communication, education, monitoring, and implementation issues and presents a preferred regulatory approach. Issues arising from public submissions and targeted stakeholder consultation have also been addressed where possible in this 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.

On the basis of Ministerial advice that mandatory fortification with iodine is an effective strategy, FSANZ has reduced the number of regulatory options being considered at Draft Assessment. This Report has narrowed consideration of regulatory options to maintenance of *status quo*, (including existing voluntary use of iodised salt) and mandatory fortification; but does not consider extension and promotion of permissions for voluntary iodine fortification.

This approach reflects the relative success of international experience with mandatory iodine fortification programs as well as international guidelines for addressing iodine deficiency.

1. Background

1.1 Sources of Iodine

Iodine is not normally found in its elemental state in nature; instead it occurs bound to other elements to form various iodates and iodides (Freake, 2000). The oceans are considered to be the most important source of natural iodine. Iodine in seawater enters the air and from there is deposited onto soil, surface water and vegetation. 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 hormones thyroxine and triiodothyronine (thyronine) (Freake, 2000; Gibson, 2005). These hormones play a key role in regulating cellular metabolism and metabolic rate including the regulation of body temperature. They are also essential for brain and nervous system development in the foetus and young child. Because the foetus is dependent on the mother for iodine and for some of the thyroid hormones, this leads to an increased dietary iodine requirement for pregnant women (Delange, 2000). An exclusively breastfed infant is completely dependent on breast milk for iodine, which also leads to further elevations in the iodine requirement of lactating women; 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 it is taken up primarily 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 (EAR[4]), the recommended dietary intake (RDI[5]) and the upper level of intake (UL[6]). In the absence of sufficient data to determine an EAR and RDI, an adequate intake (AI[7]) was established instead. The most recent NRVs, released in May 2006, are higher than in 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

[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.

	Age	AI	EAR	RDI	UL
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 Upper Level of Intake for Iodine

The UL is based on disturbed thyroid function, i.e. an underproduction of thyroid hormone known as hypothyroidism, observed in supplementation studies in adults given 1700-1800 µg of iodine per day. An uncertainty factor of 1.5 is 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 these physiological states. Individuals with thyroid disorders or a long history of iodine deficiency may still respond adversely at levels of intake below the UL. Further explanation of iodine induced hypothyroidism is provided in Section 6.2.1.

1.3 Assessment of Iodine Status

As the iodine content of foods is dependent on the iodine content of the environment in which it is produced, and this can be highly variable across regions, it is difficult to construct appropriate food composition databases. Further, iodine status is not only a reflection of iodine intake but also the amount of goitrogens in the diet. Goitrogens are substances that inhibit absorption or utilisation of iodine by the thyroid (Gibson, 2005). Goitrogens have only been reported as being a problem where intakes are unusually high, e.g. diets very high in cassava or high levels of naturally occurring fluoride in water (Delange and Hetzel, 2005; BEST, 2006). Therefore, the assessment of dietary iodine intake is considered a less reliable indicator of population iodine status than physiological measures (Gibson, 2005).

Iodine status is more accurately assessed by urinary iodine concentration, except for neonates where blood concentrations of thyroid-stimulating hormone are measured (Gibson, 2005). Thyroid volume increases in response to prolonged iodine deficiency and is used to determine long-term iodine status. Increased thyroid volume is also known as goitre, which can range is size from being only detected by ultrasound to being clearly visible. Current international classification defines an enlarged thyroid as being a goitre only once a subclinical relative size is reached.

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

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 excretion can be highly variable from day to day, this methodology based on single urine samples is best suited for population measurement but not 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

Although the MUIC of school children is considered a marker for whole population iodine status, evidence from Australia, New Zealand and elsewhere suggests that women of childbearing age have poorer iodine status than school children (Chan *et al.*, 2003; Gunton *et al.*, 1999; Hamrosi *et al.*, 2003; Hamrosi *et al.*, 2005; McElduff *et al.*, 2002; Travers *et al.*, 2006).

1.4 Iodine Deficiency Disorders

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

1.5 History of Iodine Deficiency in Australia and New Zealand

1.5.1 Australia

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

In 1966, potassium iodate began to be used in bread improvers, but this practice was discontinued in 1976 due to unacceptably high rates of iodine-induced hyperthyroidism, particularly in those with a lifelong history of deficiency. The unexpected rates of iodine-induced hyperthyroidism were caused, at least in part, by unplanned increases in the iodine content of the food supply. These increases were attributed to the use of iodine containing sanitisers by the dairy industry leading to iodine contamination of milk products, and greater availability of food from regions of Australia with higher soil iodine and hance higher iodine in local produce.

In mainland Australia, endemic goitre has been recognised in certain regions since the middle of last century; specifically in the Atherton Tableland in Queensland and along the Great Dividing Range extending through New South Wales into Victoria (Clements 1986). Goitre has also been recorded in the Canberra region, the township of West Wyalong in New South Wales and in the Gippsland region of Victoria. In response, the Australian government in 1947 provided funding for iodine tablets as part of a goitre prevention program. In 1953 the recommendation to add iodised salt to bread was adopted in the ACT and continued until the 1980s. From the 1960s a major source of iodine, if not the prime source, in the Australian food supply was obtained from milk as a result of iodine contamination from iodine-based disinfectants by the dairy industry. These have gradually been replaced by more effective non-iodine containing disinfectants. These changes in the iodine content of the food supply, together with the declining use of iodised salt, have led to falling levels of iodine intake by the Australian population and precipitated the re-emergence of iodine-deficiency in some areas of Australia (Eastman, 1999).

1.5.2 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 but 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

Universal salt iodisation, i.e. the iodisation of *all* salt used for human and animal consumption, is the recommended strategy for the control of global iodine deficiency (ICCIDD *et al.*, 2001). However, universal salt iodisation has not been adopted by developed countries such as the United States, Canada, Switzerland, Belgium, the Netherlands, Denmark and Germany. 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 not clear 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 4.

1.7 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*[8] state that essential nutrients may be added to foods for the purposes of restoration, nutritional equivalence of substitute foods, fortification[9], 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 parts of Australia and in New Zealand and the negative implication for population health and performance. A more detailed description of the iodine status of Australians and New Zealanders and of potential consequences is at Attachment 5.

2.1 Iodine Status of Australian and New Zealand Populations

2.1.1 Current Iodine Status in Australia

The results of the Australian National Iodine Nutrition Study (NINS) conducted during 2003-2004 in school-aged children in all jurisdictions except Tasmania and the Northern Territory are shown in Table 3 (Li *et al.*, 2006).

Table 3: Australian NINS Median Urinary Iodine Concentration Data

State	Median Urinary Iodine Concentration (µg/L)[10]	Interquartile Ranges	Iodine Status
New South Wales	89	65.0-123.5	Mild deficiency
Victoria	73.5	53.0-104.3	Mild deficiency
South Australia	101	74.0-130.0	Borderline deficiency
Western Australia	142.5	103.5-214.0	Adequate
Queensland	136.5	104.0-183.8	Adequate
All Surveyed States	**104**	**104.0-147.0**	

8 Codex Alimentarius Commission, 1991.

9 '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.

10 According to the WHO and ICCIDD, an MUIC of 50-99 ug/L indicates mild iodine deficiency in a population.

Applying the international criteria in Table 3, more than 50% of the samples in Victoria and New South Wales had urinary concentrations <100 ug/L thus were classified overall as mildly deficient. South Australia had slightly fewer than half below 100 ug/L and was borderline. Queensland and Western Australia had smaller percentages below the 100 ug/L and were assessed as adequate overall.

The results of the NINS were consistent with an earlier study in New South Wales school children that also indicated a state of mild deficiency (Guttikonda *et al.*, 2003). Other studies conducted in recent years indicate various degrees of iodine deficiency amongst pregnant women in Melbourne and Sydney, and mild iodine deficiency amongst school children in Melbourne and NSW (Chan *et al.*, 2003; Gunton *et al.*, 1999; Guttikonda *et al.*, 2003; Hamrosi *el al*, 2005; Li *et al.*, 2001; Travers *el al*, 2006). Two out of three studies also suggest iodine deficiency amongst neonates in NSW (Chan *et al.*, 2003; McElduff *et al.*, 2002; Travers *et al.*, 2006).

In 1998-99, prior to intervention, children in Tasmania were mildly iodine deficient (Hynes *et al.*, 2004). In 2001-01, also prior to intervention, the proportion of children below the cut-off for moderate deficiency had increased, despite no apparent change in MUIC. This is an important piece of evidence relevant to the future if no action to address deficiency is taken; it suggests a continuing downward trend in iodine status, especially amongst those who already have poor iodine status.

Iodine status clearly shows geographic and demographic variations in Australia. The NINS clearly shows that iodine deficiency in school children is not uniformly distributed across the States, but is concentrated in south-eastern Australia. From the surveys undertaken in south eastern Australia, pregnant women and those of childbearing age generally have poorer iodine status than school-aged children. Furthermore, any iodine deficiency prior to or during pregnancy would become worse during lactation when iodine requirements are at their highest, as outlined in Section 1.2.1. This potential disparity between population groups means that pregnant and lactating women in any part of the country may be at greater risk of deficiency than indicated by the NINS data.

2.1.2 Current Iodine Status in New Zealand

The 2002 New Zealand Children's Nutrition Survey (CNS) involving a geographically and demographically representative sample of 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 <50 ug/L (Ministry of Health, 2003). This indicates that the population as a whole is mildly approaching moderately iodine deficient.

A separate survey of iodine status in Dunedin and Wellington children aged 8-10 years showed enlarged thyroids in approximately 30% according to revised international guidelines, indicating prolonged iodine deficiency in this group (Skeaff *et al.*, 2002; Zimmerman *et al.*, 2004).

Studies have also shown mild and moderate iodine deficiency in formula-fed and breastfed infants respectively (Skeaff *et al.*, 2005), and moderate iodine deficiency in both pregnant and non-pregnant women (Thomson *et al.*, 2001). Adult males have also been shown to have mild to moderate iodine deficiency (Thomson *et al.*, 1997).

Iodine deficiency appears to be geographically evenly distributed across New Zealand. As in Australia, some groups including pregnant and breastfeeding women, and breastfed infants have poorer iodine status than school-aged children.

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. However, increased thyroid volume is not necessarily caused by iodine deficiency, but can also be caused by iodine excess and or have causes unrelated to iodine intake.

From research and public health interventions undertaken throughout the iodine deficient parts of the world, it is very clear that the poorer the iodine status of a population, the greater the extent and severity of its impact on health and performance. Also, the more severe the iodine deficiency in a population and therefore its impact, the more easily its impact can be quantified. However, 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 5 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 can 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-to-Moderate Iodine Deficiency during Pregnancy and Early Childhood

The cognitive and motor skill impacts in the offspring of Australian and New Zealand pregnant and breastfeeding women experiencing mild-to-moderate iodine deficiency have not been specifically researched. However, comparably deficient overseas populations have shown evidence of impaired mental function in children born to mothers with suboptimal thyroid hormone production resulting from iodine deficiency or other causes. Insufficient maternal thyroid hormone can lead to offspring having cognitive problems, e.g. poorer verbal, perceptual, mental and motor skills, and lower intelligence quotient (Galan *et al.*, 2005; Haddow *et al.*, 1999). Infants with iodine deficiency may have poorer information processing skills (Choudhury and Gorman, 2003). Such children may also be at substantially increased risk of attention-deficit and hyperactivity disorders (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, 2000; van den Briel, 2000).

Children with moderate iodine can 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. Raising of the auditory threshold[11] has been reported in mild and moderate iodine deficiency, and has been shown to track closely with poorer performance in both verbal and non-verbal tests of mental function as well as poorer fine motor control (Valeix *et al.*, 1994; Soriguer *et al.*, 2000; van den Briel, 2001).

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

2.2.2 Consequences of Mild to Moderate Iodine Deficiency in Adults

Iodine deficiency over a prolonged period of time can lead to adverse changes in the thyroid, including various forms of goitre, which 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 6.2.1. (Hetzel and Clugston, 1998). 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 The Current Food Standard

Current provisions in Standard 2.10.2 – Salt and Salt Products of the *Australia New Zealand Food Standards Code* (the Code) 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

Industry estimates indicate only 1% of all salt produced in Australia is used in food for humans and animals. Of that, between 10-12% of salt produced for food use is sold as household table and cooking salt and of that, only about 15% is iodised. Current use of iodised salt in processed foods appears minimal. In New Zealand approximately 50% of salt sold as table and cooking salt is iodised.

[11] The volume below which a given frequency of sound can no longer be heard.

2.4.1 Tasmania

In the late 1980s, the Tasmanian population was considered iodine replete. 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 program in October 2001 (Seal J, *in press*) 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 TDHHS and those in the baking industry willing to participate. Salt manufacturers also signed a MoU agreeing to supply the baking industry in Tasmania with iodised salt at about 40 mg iodine/kg.

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 statues improved Tasmanian School Children. Details of the interim fortification program are given at Attachment 6.

The interim Tasmanian fortification program 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.

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 and in parts of Australia. Iodine deficiency is associated with a wide range of adverse health effects; with the most detrimental involving the developing brain, especially during foetal growth and infancy 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, iodine deficiency increases the risk of thyroid dysfunction 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, wellbeing and productivity of the Australian and New Zealand community now and in the future.

Sufficient iodine in the diet can prevent iodine deficiency disorders. Internationally a number of countries have successfully reduced the risk from iodine deficiency through food fortification programs involving the use of iodised salt.

Therefore increasing the iodine content of the Australian and New Zealand food supply is important to reduce the prevalence of iodine deficiency and the adverse effects that this can have 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 Australia and New Zealand, especially in children.

The goal is to reduce the prevalence of iodine deficiency in the Australian and New Zealand populations to the maximum extent possible 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 10 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 Australia and 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 perform 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 IQs only marginally lower than those that lived in iodine sufficient areas (Qian *et al.*, 2005). This illustrates 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), as well as that of goitre in children as well as adults and subsequent thyroid dysfunction, e.g. hyper or hypothyroidism (Delange and Hetzel, 2005). An improvement in the prognosis for thyroid cancer would also be anticipated (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 – 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 7 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 greater and better defined than those of the latter. Iodine induced hypothyroidism is generally subclinical, transient, and even in the event that it does not clear spontaneously 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 Grave's disease previously treated with iodine; women who have post-partum thyroiditis; or those who have subacute thyroiditis. Globally more common cause of hypothyroidism is however not excess iodine, but iodine deficiency (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). Where iodine-induced hyperthyroidism has been observed following iodine fortification, it has been found to be transient.

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. 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 8.

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.

7.1.1 Regular Consumption of Salt in Australia and New Zealand

In evaluating potential food groups for fortification with iodine, the major contributors to salt intakes from processed foods were determined. In western countries, about 75-85% of dietary salt is estimated to come from processed foods (James *et al.*, 1987). Quantitative estimates of the major contributors to total salt consumption are lacking in Australia and New Zealand, however, similar proportional contributions to overseas estimates are expected.

From the Australian 1995 National Nutrition Survey (NNS), approximately 50% of salt in processed foods came from cereals and cereal products[12] as well as cereal-based products and dishes[13]. This was the case for the whole population aged 2 years and over as well as for children aged 2-3 years and women aged 16-44 years. From the 1997 New Zealand NNS, bread (including rolls and specialty breads), bread-based dishes[14], and grains and pasta[15] account for approximately 45% and 39% of the salt intake from processed foods by women aged 16-44 years and the population aged 15 years and above respectively. Further details about these surveys are given in Section 8 and Attachment 9.

The remainder of salt intakes comes from discretionary salt of which about 15% is iodised in Australia and 50% in New Zealand. Discretionary salt refers to the consumption of salt added during cooking and or at the table. Sixty-two percent of Australian NNS respondents reported adding discretionary salt to cooking and/or at the table with varying degrees of frequency. The proportion of those using cooking/table salt increased from 36% of 2-3 year olds to 75% of those 70 and over, however, those who used *iodised* salt were not identified. The 1997 New Zealand NNS did not record habits of table and cooking salt use but the 2002 Children's Nutrition Survey (CNS) of children aged 5-14 years reported approximately 60% of this group usually or sometimes consumed food that had been salted during preparation whereas just under 50% reported usually or sometimes adding salt at the table. No data on quantified consumption of *iodised* salt has been published.

On this basis, FSANZ decided that the use of iodised salt in particular groups of processed foods should be further investigated. Iodine intakes from consumption of discretionary salt intakes were also taken into account given the potentially significant contribution to overall iodine intake.

---

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

[13] 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.

[14] Includes pizzas, sandwiches, filled rolls and hamburgers, taco and tortilla-based dishes, dim sims, spring rolls, wontons and stuffings

[15] Includes plain cooked rice, pasta, and noodles, filled pastas, savoury rice-based dishes, pasta-based dishes (e.g. lasagne, macaroni cheese), instant noodles, noodle-based dishes (e.g chow mein), flours, bran and germ

8. Dietary Intake Assessment

Although population iodine status is best assessed by measuring urinary iodine concentration, the determination of an appropriate level of fortification in food requires the decision to be based on estimates of dietary intakes. 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 Australian and New Zealand populations as outlined in Section 2.1, a two-to-three-fold increase in MUIC and hence increase in mean intake of the deficient populations is desirable. In dietary terms, the goal is ideally to have no more than 3% of the population with iodine intakes below the EAR. However, this target needs to be moderated by the need to also minimise the proportion of the population whose iodine intakes exceed the relevant UL.

8.1 Dietary Intake Assessment

A dietary intake assessment was conducted to assess the potential impact of mandatory iodine fortification of food on iodine intakes. The scope of the assessment included children aged up to 3 years and women of childbearing age (assumed to be 16-44 years) as well as the Australian population aged 2 years and above and the New Zealand aged 15 years and above. Dietary intake assessments for New Zealand children aged 5-14 years will be included when the data derived from the 2002 CNS are provided to FSANZ.

The aim of the dietary intake assessment was to determine a level of fortification that maximised the proportion of the population iodine intakes meeting or exceeding the EAR while minimising the proportion whose intakes exceeded the UL.

8.1.1 Sources of Data

Food consumption data were sourced from the 1995 NNS, the 1997 New Zealand NNS, and theoretical diets. The 1995 Australian NNS surveyed 13,858 people aged 2 years and above, and the 1997 New Zealand NNS surveyed 4,636 people aged 15 years and above. Due to the absence of survey data, theoretical diets were used to assess dietary iodine intakes for Australian children aged 1 year and New Zealand children aged 1-3 years. Baseline iodine concentrations for foods were derived from four major sources:

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

Although food consumption data was sourced from the 1995 Australian NNS and 1996-7 New Zealand NNS, the salt and iodine content of food in the respective food composition databases were updated, with the help of the New Zealand Food Safety Authority, to contain the latest information just prior to the analysis. Thus taking into account any recent voluntary reductions in the salt content of some products.

8.2 Fortification Scenarios Using Iodised Salt in Different Processed Food Categories

Two options for using iodised salt in processed foods were investigated in detail. First, in line with international recommendations, the option of replacing salt in all processed foods was selected for investigation. Second, as cereal-based foods contributed about half the salt intake from all processed foods, the option to replace non-iodised with iodised salt was explored in cereal-based foods was explored. Where an amount of iodine is specified it is as atomic iodine, not the amount of iodine containing compound added to salt.

Several concentrations of iodine in the salt to be used in processed foods or cereal-based foods were initially considered ranging from 10 – 20 mg/kg in processed foods, and 15 – 40 mg/kg in cereal-based foods. At the higher concentrations of iodine, a sizable proportion of the iodine intakes of 2-3 and 4-8 year old were predicted to exceed the UL. This occurred because the salt intakes in this age group are relatively similar to that of adults, whereas their UL, being based on body weight, is several-fold lower. Two scenarios with very similar impact on dietary iodine intake were explored in more detail.

These scenarios were:

Scenario 1: Cereal- based foods manufactured using iodised salt containing 30 mg iodine per kg of salt, replacing non-iodised salt ('Scenario 1 – Cereal- based foods').

Scenario 2: Processed foods manufactured using iodised salt containing 15 mg iodine per kg of salt, replacing non-iodised salt ('Scenario 2 – Processed foods')

In both scenarios, the current levels of non-iodised salt replace iodised salt in the selected food vehicles with unsalted processed products remaining unaffected. Iodised table and cooking salt was included in the dietary intake assessments due to its significant contribution to iodine intake in those who consume it. Due to uncertainties around the consumption of iodine from iodised discretionary salt was reduced to 20 mg iodine per kg of salt. See Section 8.3.1 for further explanation of the uncertainties concerning iodised discretionary salt.

8.2.1 Use of Iodised Salt in Cereal-Based Foods

For the purposes of dietary intake assessment, cereal-based foods containing added salt include: breads (plain, sweet and savoury), breakfast cereals, pizza bases, doughnuts, cakes, sweet biscuits, crackers/savoury biscuits, slices, hotplate products (pikelets, scones, crumpets etc.) and pastry.

Cereal-based foods that contain negligible quantities of salt (e.g. plain dried pasta, flour, rice grains etc.) did not change in iodine content.

8.2.2 Use of Iodised Salt in Processed Foods

For the purposes of dietary intake assessment, processed foods refers to all foods manufactured commercially, these included the products listed in cereal-based foods above as well as included: meat, poultry and game products and dishes; milk, milk products and dishes; snack foods; and savoury sauces and condiments.

Processed foods that contain negligible quantities of salt did not change in iodine content.

8.3 Key Uncertainties in the Dietary Intake Assessment

For a full list of the assumptions and uncertainties inherent in dietary intake assessment, see Attachment 9. This section addresses the uncertainties that are specific to this proposal.

8.3.1 Uncertainties in Relation to Discretionary Salt

Discretionary salt refers to salt added during cooking and/or at the table. The Australian and New Zealand NNS do not contain data on the amount of discretionary salt consumed, iodised or otherwise. As iodised salt represents a major source of iodine for those who consume it, accounting for it in the dietary assessment was important. Therefore recent annual cooking and table salt sales data were used to calculate a daily per capita salt intake. For further explanation of how discretionary salt intakes were calculated, see Attachment 9.

In the Australian NNS, only those individuals reporting that they added salt for cooking or at the table (62%) were assigned an equal portion of the salt sold for this purpose, i.e. 2.7 g per day. This general figure does not take into account the frequency with which they reported using discretionary salt and assumes for example, that young children would consume as much of this salt as adults

The New Zealand NNS did not identify consumers of cooking and/or table salt. Retail sales data give a daily per capita discretionary salt consumption of 1g. In the dietary intake assessment it was assumed that all individuals consume this amount. This is likely to overestimate consumption by some and underestimate consumption by others.

As consumers of *iodised* salt could not be identified individually in the consumption surveys, the dietary intake assessment scenarios considered both and no addition of discretionary salt and the addition of iodised discretionary salt according to the assigned consumption. This approach produces dietary intake estimates with an upper and lower bound for each scenario. Because only a proportion of discretionary salt is iodised, the actual iodine intakes from fortification would be expected to fall within the estimated bounds. However, since the upper bound represents a regular consumer of a per capita amount of iodised salt, high consumers of iodised salt would have iodine intakes beyond the upper bound of the range.

The range of estimated iodine intake resulting from the possible use of iodised discretionary salt was very wide, resulting in considerable uncertainty with respect to the proportion of the population likely to be below the EAR or above the UL. By approximately halving the concentration of iodine in discretionary salt to an average of 20 mg iodine per kg salt, the range of likely mean intakes is reduced markedly. As a result the certainty around the proportion of people below the EAR or above the UL improves considerably. It was therefore decided to use this reduced iodine concentration in discretionary salt for both fortification scenarios.

8.3.2 Geographic Variations in Iodine Status in Australia

It is apparent from the Australian NINS described in Section 2.1.1 that there is considerable variation in the iodine status among the different Australian States.

Although survey respondents can be identified by State, the available food composition data represent average national values that cannot be used to account for variations in the iodine content of food and water between different regions. The results of the intake assessment therefore represent only average Australian intakes. Therefore, the iodine intakes in States which are classed as iodine deficient are likely to be overestimated, whereas the intakes in those States regarded as currently having an adequate intake are likely to be underestimated.

There is no evidence for large variations in iodine status across geographic regions in New Zealand.

8.3.3 Pregnancy and Lactation

Pregnancy and lactation are accompanied by an increased requirement for iodine; see Sections 1.2, 1.4 and 2.2. Given the small number of pregnant and lactating women surveyed in the Australian and New Zealand NNS, it was not appropriate to analyse these groups separately. Therefore, the elevated EAR for each of these two life stages has been applied to the food consumption data from all women of childbearing age, defined as being 16-44 years. As pregnant and lactating women are likely to be eating more than they would normally, the analysis may be slightly underestimating iodine intake. On the other hand, this group might avoid certain iodine-rich foods such as seafood because of public health advice. This approach introduces another facet of uncertainty.

8.4 Results of Dietary Intake Assessment

The results of the dietary intake assessment for Australia are shown in Table 4 and those for New Zealand in Table 5. Columns on the left show assume no iodised discretionary salt, those on the right shows results assume iodised discretionary salt. Given that only ~15% of discretionary salt in Australia is iodised, the columns on the left are probably more representative. In New Zealand where iodised salt accounts for ~50% of discretionary salt, it is less certain which part of the range best reflects the most likely impact of fortification.

Table 4: Proportion of the Australian Population that Have Iodine Intakes < Ear Currently and Following Fortification of Processed or Cereal-Based Foods, with and without the Use of Iodised Discretionary Salt

	No Iodised Discretionary Salt			Iodised Discretionary Salt		
	Current	Cereal-based	Processed	Current	Cereal-based	Processed
Group	% < EAR	% < EAR	% < EAR	% < EAR	% < EAR	% < EAR
2-3	18	1	1	12	1	0
4-8	22	1	< 1	12	< 1	0
9-13	29	< 1	1	13	< 1	0
14-18	41	5	2	15	3	1
19-29	47	9	3	20	4	2
30-49	54	8	3	22	3	1
50-69	61	9	3	17	2	< 1
70+	72	12	5	17	3	< 1
Women 16-44 years	65	14	6	28	6	3
pregnant	95	74	60	42	43	31
lactating	98	89	81	57	68	55

Table 5: Proportion of the New Zealand Population that have Iodine Intakes < EAR Currently and Following Fortification of Processed or Cereal-Based foods, with and without the use of Iodised Discretionary Salt

	No Iodised Discretionary Salt			Iodised Discretionary Salt		
	Current	Cereal-based	Processed	Current	Cereal-based	Processed
Group	% < EAR	% < EAR	% < EAR	% < EAR	% < EAR	% < EAR
15-18	91	6	4	11	0	0
19-29	91	13	7	23	1	1
30-49	90	10	7	21	< 1	< 1
50-69	92	9	7	20	1	< 1
70+	96	8	8	25	< 1	< 1
Women 16-44 years	95	18	11	35	2	< 1
pregnant	99	87	80	96	73	64
lactating	99	94	92	98	90	85

The results of the dietary intake assessment are discussed in more detail below with particular reference to vulnerable population groups.

8.4.1 Very Young Australian Children

In the absence of national nutrition survey data, the mean dietary iodine intakes for Australian children aged 1 year were calculated using a theoretical diet that did not include discretionary iodised salt. Dietary iodine intakes were estimated accounting for the consumption of toddler milk as it is permitted to be fortified with iodine. The current estimated mean daily iodine intake is 79-96 μg, rising to 96-113 μg and 96-113 μg following fortification of cereal-based foods and processed foods respectively. The lower bound of the range assumes no toddler milk is consumed and the upper bound represents where 1 serve (226 g) of toddler milk is consumed per day. The estimated average intake for iodine in 1 year-olds currently, and following fortification, is above the EAR of 65 μg per day.

As these estimates are based on theoretical diets, the proportion of 1 year-olds exceeding the UL cannot be calculated. In these cases, it is accepted that the average intake can be multiplied by 2.5 to obtain the 95th percentile (WHO, 1985), i.e. the amount of daily iodine consumption that the top 5% of the population are likely to exceed. The predicted 95th percentile of daily iodine intake is 198-240 μg currently, rising to 238-280 μg and 238-283 μg following fortification of cereal-based foods and processed foods respectively. This suggests that some 1 year olds in Australia exceed the UL (200 μg/day) on the basis of the current diet, with the proportion being higher following fortification.

8.4.2 Very Young New Zealand Children

Mean dietary iodine intakes for New Zealand children aged 1-3 years were calculated using a theoretical diet that did not include discretionary iodised salt. A range of dietary iodine intakes were estimated to account for the consumption of toddler milk. The current estimated mean daily iodine intake is 48-72 μg, rising to 84-109 μg and 89-113 μg following fortification of cereal-based foods or all processed foods respectively. The lower bound of the range assumes no toddler milk is consumed and the upper bound represents where 1 serve (226 g) of toddler milk is consumed per day. The average intake following mandatory fortification is predicted to be above the EAR of 65 μg per day.

Using the same adjustment as described for Australian children above, the 95th percentiles of iodine intakes are 119-180 µg, 210-272 µg and 221-283 µg currently and following fortification of cereal-based foods and processed foods, respectively. This suggests some 1-3 year-olds in New Zealand exceed the UL on the basis of the current diet, with the proportion being higher following fortification.

8.4.3 Australian Children and Adolescents

Both fortification scenarios lead to an approximate one-and-a-half-fold increase in iodine intake in Australian children and adolescents. Assuming all States experience this same relative increase in iodine intakes, New South Wales, Victoria and South Australia are predicted to achieve an adequate average iodine intake, whereas intakes in Western Australia and Queensland might shift to above adequate.

Assuming no consumption of iodised discretionary salt, 6% or 10% of 2-3 year olds would exceed the UL following fortification with cereal-based or processed foods respectively. This proportion rises to 16% and 20% respectively if the consumption of iodised discretionary salt at levels described in Section 8.3.1 is assumed. A small proportion of 4-8 year olds, between <1 - 2%, would also exceed their UL. It is salient to note that at current intakes, between <1- 24% of 2-3 year olds and up to 1% of 4-8 year olds exceed their ULs. The larger range of current exceedances of the UL for 2-3 year olds is due to the iodine concentration in discretionary salt being higher than according to the fortification scenarios.

Given that only about 15% of discretionary salt is iodised and that not many 2-3 year olds are likely to consume the per capita amount of 2.7 g salt per day, the upper bound of the range exceeding the UL is likely to be an overestimate. The amount by which 2-3 year olds are expected to exceed the UL is, in the majority of cases, less than 100 µg. It seems likely that a greater proportion of those exceeding the UL would be found in the States that may currently have adequate dietary iodine. This would be consistent with the possibility of higher iodine concentrations in the water of some areas as outlined in Section 7 of Attachment 9. The implications of exceeding the UL are addressed in Section 9.2 below.

8.4.4 New Zealand Children and Adolescents

The dietary intake assessment for New Zealand children aged 5-14 years is being provided by the New Zealand Food Safety Authority and is currently pending. The data will be incorporated into the Final Assessment Report for this Proposal if received within the necessary timeframe.

8.4.5 Australian and New Zealand Women of Childbearing Age

The iodine status of Australian women of childbearing age (16-44 years) has been assessed only in New South Wales and Victoria where it was found to be poorer than that of school-aged children. Although both fortification scenarios without discretionary iodised salt show an average one-and-a-half-fold increase in iodine intake in this group, it is unclear if they would shift iodine status sufficiently for the south eastern Australian States to no longer be classed as iodine deficient. There are no predicted intakes that exceed the UL.

New Zealand women of childbearing age are estimated to approximately double their iodine intake relative to current levels assuming no iodised discretionary salt intake.

This will represent a substantial improvement in iodine status although it may not fully address the current deficiency. As with other groups, those consuming iodised discretionary salt will increase their iodine intake further.

The proportion of women below the EAR for pregnancy and lactation is highest in New Zealand. Given available iodine status data New South Wales and Victoria would account for the highest proportion of women below the EAR in Australia, but neither the iodine status nor estimated intake has been assessed in the other States.

In the context of pregnancy and lactation, it is important to recall that the relevant EAR has simply been applied to the intakes of all women of childbearing age. The increase in energy intake due to these physiological states has not been taken into account, neither has any tendency to change dietary habits that may increase or decrease iodine intake. Despite these uncertainties, it is clear that the majority of Australian and New Zealand women are unlikely to meet the EAR for pregnancy or lactation. However, a large proportion would be likely to enter pregnancy in an iodine replete state following mandatory fortification.

8.4.6 Australian and New Zealand Adults

The adult population in both countries would experience a one-and-a-half to two-fold increased in iodine intake, not taking discretionary salt into account. The additional consumption of iodised discretionary salt would further increase intake. This represents a substantial shift towards adequate iodine intake. The outcome in terms of addressing iodine deficiency is likely to vary by State and between the two countries with Australia being more likely to achieve an adequate iodine intake across the population. Male iodine status will improve more than female status because of their greater food consumption relative to the same EAR. There is a trend for iodine intake to drop with age after the teenage years. No proportion of the adult population in either country is predicted to exceed the UL.

8.5 Dietary Intake Assessment Conclusions

The dietary intake assessment indicates that both scenarios deliver similar increases in dietary iodine intakes. Fortification of processed foods results in a slightly greater proportion of the population meeting the EAR but also results in a greater proportion exceeding the UL. Neither scenario entirely meets the needs of pregnant and lactating women. Consistent with the iodine status data described in Section 2, New Zealand has an estimated iodine intake approximately one third lower than Australia. As a result, a greater proportion of the New Zealand population intakes, while experiencing a proportionately greater increase in intake than Australia, are predicted to stay below the EAR.

9. Assessment of the Health Outcomes from Mandatory Iodine Fortification

This section outlines the anticipated improvement in health and performance of the Australian and 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 Australian Children and Adolescents

Following mandatory fortification, the iodine intake of Australian children aged 2 -13 years is predicted to be below the EAR in only less than 1% of children. As the mean iodine intake in 1 year-olds are also likely to be well above the EAR this group are also likely to have an adequate iodine intake. As a result the risk of children having: impaired hearing, fine motor control, reaction times, visual problem solving, abstract reasoning, verbal fluency, reading proficiency, spelling, mathematical skills, or general cognition due to poor iodine status during childhood will be substantially reduced. Where one or more of these impairments are already present and caused by iodine deficiency a substantial improvement would be expected within several weeks to several months of fortification. This is assuming that the impairment(s) arose due to iodine deficiency after the age of 2-3 years. Those impairments that arose earlier will not be reversed, but will be prevented in future generations.

The exact impact of fortification will vary between States due to the differences in current iodine status, but the exact differences cannot be predicted from the data available except to say the better the current iodine status the larger the portion of the population that will be replete.

In those aged 14-18 years approximately 4-5%, predominantly female, the average would fall below the EAR for iodine intake. The specific impact of iodine deficiency and the outcome of alleviating it in this age group are largely unknown. The positive outcome predicted is a reduction in the risk of goitre and other negative changes to the thyroid predisposing to thyroid disease later in life. In young women an adequate iodine intake is also important to ensure those who become pregnant do not do so with depleted iodine stores.

9.1.2 Australian and New Zealand Women of Childbearing Age

The proposed fortification of scenarios would substantially decrease the proportion of 16-44 year old women whose iodine intakes fall below the EAR. The health implications for this include a substantial reduction in the risk of iodine deficiency-related goitre and future thyroid problems. The majority of women would still have iodine intakes below the EAR for pregnancy and lactation. However, an 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 following mandatory fortification.

9.1.3 Australian and New Zealand Adults

The proposed fortification scenarios would lead to a large shift towards iodine adequacy throughout the adult population in both countries. 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 introduction of mandatory iodine fortification it is estimated that a small percentage of young children may exceed the UL which is described in Section 1.2.1.1. The magnitude of the exceedance depends on the amount of discretionary iodised salt in the diet, which is likely to be low (see Section 8.3.1). 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 for iodine 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 mean an adverse effect will result. 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.

Further, 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, 1981 48 /id}, this over four times the highest predicted intake following mandatory fortification. Thus it is unlikely that those children exceeding the UL would be adversely affected.

However, it also needs to be acknowledged that the UL is based on healthy populations. Those with existing thyroid disease or with long-term iodine deficiency are more susceptible to problems arising from increased iodine intakes including iodine-induced hyperthyroidism. However, 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.

Those States with better current iodine status, i.e. Queensland and Western Australia, and therefore highest current iodine intakes will most likely have the highest iodine intakes following fortification. While a greater proportion of those exceeding the UL would be expected to be in these States, they would also be likely to have the smallest number of people sensitive to small increases in iodine intake due to pre-existing iodine deficiency.

Given the evidence, reviewed in detail in Attachment 7 and applied to the proposed mandatory fortification in Attachment 10, it is likely that the risk of adverse health consequences due to the proposed increase in iodine intake is small across all groups, but is slightly elevated in those with pre-existing thyroid disease, those living in States with higher iodine intakes, and in the small portion of 1-3 year olds whose iodine intakes exceed the UL.

10. Risk Assessment Summary

There is now strong evidence showing widespread re-emergence of mild-to-moderate iodine deficiency throughout much of the New Zealand and parts of the Australian population.

In Australia iodine deficiency has been identified in several groups including school children, pregnant women, neonates, patients with diabetes, and healthy adult volunteers. Data from a survey in school-aged children indicates Queensland and Western Australia have an adequate iodine intake. The iodine status of other groups is not known in these States. On the other hand New South Wales and Victoria have widespread iodine deficiency in both children and adults. In New Zealand iodine deficiency has been identified in all groups studied encompassing school children, pregnant women, non-pregnant women of childbearing age, breast and formula fed infants and toddlers, as well as adult males.

Mandatory fortification with iodine would be expected to reduce the risk of children having poorer verbal and information processing skills, lower scores of perceptual, mental and motor assessment, and 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 thyroid problems in later life.

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. An estimated 75-85% of daily salt intake in western countries is from processed foods and a sizeable proportion of this comes from cereal-based products. To address this uncertainty it was decided to model a reduced iodine concentration in discretionary salt of 20 mg of iodine per kg salt.

The final fortification scenarios selected for consideration were: use of salt iodised at 15 mg of iodine per kg of salt in all processed foods, or use of iodised salt at 30 mg of iodine in cereal-based foods. The considerable uncertainty surrounding distribution of iodised discretionary salt consumption resulted in broad ranges in predictions of efficacy and exceedance of the UL. To address this uncertainty, it was therefore decided to model a reduced iodine concentration in discretionary salt to 20 mg of iodine per kg salt.

On average both scenarios would result in less than 1% of Australian children aged 2- 13 years not consuming the EAR for iodine. Based on theoretical diets the iodine intake in 1 year–olds is also very likely to be adequate. Both would also result in less than 15% of Australian and less than 18 % of New Zealand women of childbearing age not consuming sufficient iodine to reach their EAR for iodine. This represents a large improvement from the estimates of current intakes, which are below the EAR for well over half this group. The iodine intake would still not be sufficient for the majority of women during pregnancy or lactation, with the problem being greatest in New Zealand, Victoria and New South Wales, and not known in other States and Territories. A small proportion of children aged 1-3 and an even smaller proportion of those aged 4-8 would exceed the UL. The improvement in iodine intake would be slightly greater following fortification of all processed foods, but the proportion of children exceeding the UL would also be slightly higher.

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 key cereal-based foods. These issues include social, consumer 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

The Risk Assessment showed that the replacement of non-iodised salt with iodised salt in all processed foods or in cereal-based foods could deliver a similar outcome. However, the use of iodised salt in cereal-based foods is less trade restrictive and costly for industry when compared with iodised salt in all processed foods. On this basis, the preferred option is to replace non-iodised salt with iodised salt in cereal-based foods.

11.1.1 Limiting the Food Vehicle to Key Cereal-Based Foods

Initially, dietary intake assessments were undertaken whereby all cereal-based foods replaced salt with iodised salt. When attempting to translate this scenario into regulation, it was difficult to provide regulatory certainty with respect to the definition of 'cereal-based foods'. Also, this scenario encompassed a large range of foods and yet approximately 95% of salt in cereal-based foods was derived from three main categories, bread, breakfast cereals and biscuits. The remaining 5% of salt contained in 'miscellaneous' foods had a larger trade impact and resulted in greater costs for industry. On this basis, it was decided to restrict the food vehicle to the three key cereal food categories mentioned above.

11.1.2 Defining the 'Key Cereal-Based Foods'

It is intended that bread, breakfast cereals and biscuits will be required to replace non-iodised salt with iodised salt:

Bread is defined in Standard 2.1.1 – Cereals and Cereal Products of the Code as:

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

This definition includes foods such as bread, bread rolls, buns, English muffins, fruit bread, yeast-leavened flatbreads and bread products such as bread crumbs and stuffing.

Breakfast cereals are traditionally grain-based foods promoted as being suitable for the first meal of the day and frequently consumed with milk/milk substitutes. The primary ingredient(s) is typically a type of cereal, such as wheat, oats, millet, barley, rye and maize. It is not intended that foods positioned and marketed as a meal replacement, as defined in Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods be included in this category of 'breakfast cereal'. These are special purpose foods and currently have permissions to contain iodine.

Biscuits are ordinarily defined as a sweet or savoury product, prepared from a stiff mixture of flour, liquid, shortening and other ingredients. Examples of such items include crispbreads, crackers and sweet biscuits but do not include cakes, slices, muesli bars and flans.

FSANZ will prepare an Implementation Guide if further clarification is required to determine the scope of cereal-based foods included in the fortification scenario.

11.2 Appropriateness of Using Iodised Salt in the Key Cereal-Based Foods

As outlined in Section 7.1, the suitability of using iodised salt as the food vehicle has been assessed against international criteria. The dietary intake assessment (at Attachment 9) showed that the target population would regularly consume the key cereal-based foods containing iodised salt without risk of excessive consumption by the target and non-target population. An assessment of the remaining criteria is outlined below.

11.2.1 Stability of Iodised Salt

Studies on 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, see Attachment 8. Generally, salt is a very stable carrier for iodine. The permitted forms, as prescribed in Standard 1.1.1 of the Code, are potassium iodide or potassium iodate or sodium iodide or sodium iodate.

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, see Attachment 8. 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.

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 program, 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, 2006).

Similarly, it is expected that the bioavailability of iodine from iodised salt in key cereal-based foods would be high.

11.2.3 Economical Feasibility of Iodised Salt

The salt industries of Australia and New Zealand indicated that the iodisation of salt would result in only a small price increase. The Cost Benefit Analysis, at Attachment 11, 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. It is estimated that the proposed mandatory iodine fortification would cost A$0.17 and NZ$0.11 per person per year in Australia and New Zealand respectively.

11.2.4 Centralised Production Allowing for Quality Control

Salt production in Australia and New Zealand is mostly controlled by a few major producers who manufacture nearly all the food grade salt used in both countries. These companies have in place appropriate analytical testing procedures and routinely monitor levels of salt iodisation to ensure they are within specifications.

11.2.5 Technological Feasibility of Iodised Salt in Key Cereal-Based Foods

As outlined in Attachment 8, iodised salt has been successfully used in a variety of foods, including cereal-based foods. 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. Based on the available research, it is technologically feasible to add iodised salt to cereal-based foods.

11.2.6 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 key cereal-based foods is the preferred a food vehicle for delivering additional amounts of iodine to the food supply.

11.3 Technical and industry considerations

11.3.1 Salt Production in Australia and New Zealand

The main salt manufacturers in Australia and New Zealand include Cheetham Salt Limited, including Salpak, Western Salt Refinery in Western Australia, Dominion Salt and Cerebos-Skellerup in New Zealand and Olssons Pacific. In Australia and New Zealand, there is minimal household salt importation, with only small amounts of retail and gourmet salt products being imported. In Australia, the bulk of commercial salt for the food industry comes from Australia with the exception of salt manufactured for cheese and dairy foods being imported from New Zealand.

11.3.2 Industry Capacity for Salt Iodisation

In some instances, additional machinery and equipment will be needed to expand outputs. Currently iodised salt is manufactured at only a few sites in Australia and at one of two sites in New Zealand. The increased demand for iodised salt and the associated transport costs may require additional sites to be established. However, salt manufacturers have advised that this could be accommodated within the proposed implementation timeframes.

11.3.3 Accommodating process variations in the salt industry

Australian and New Zealand salt manufacturers have indicated that there would be minor losses from production and have recommended a 'working range' of ±10 mg of iodine per kg of salt be established to compensate for normal process variation in manufacturing. Setting a range also prevents large amounts of additional iodine being added.

11.3.4 Labelling

All bread, breakfast cereal and biscuit manufacturers will be required to list iodised salt in the ingredient list of their product label. Iodised salt will be required to be listed as an ingredient unless it is part of a compound ingredient[16] making up less than 5% of the food, for example in bread crumbs. Labelling for iodised salt will necessitate labelling modifications and as a result incur costs for manufacturers.

11.3.5 Niche Products

Mandatory iodine fortification may be an issue for food manufacturers producing products using only 'natural ingredients' or organic products. These manufacturers may consider the fortification of their products will not fit with their niche market, and could detrimentally affect sales. Iodised salt may not be considered a 'natural ingredient', and may also conflict with organic industry certification requirements.

11.4 Consistency with Ministerial Policy Guidance

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:

---

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

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 from the Ministerial Council is that mandatory fortification with iodine is an effective public health strategy to address the re-emergence of iodine deficiency in New Zealand and parts of Australia, subject to assessment of clinical safety and cost effectiveness. In recognition of this significant population health problem, FSANZ was asked to consider mandatory iodine fortification. Therefore within the context of the 'High Order' Policy Principles, which are FSANZ's statutory objectives, the remaining 'Specific Order' Policy Principles are considered as follows.

11.4.1 Consistency with Australian and New Zealand National Nutrition Guidelines

The Australian and New Zealand national nutrition guidelines[17] for all age groups 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 cereal-based products. This option is not intended to promote increased salt intake as iodised salt will replace non-iodised salt currently used in manufactured foods.

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.

Although salt is the primary carrier for iodine, it will be present in bread, breakfast cereals or biscuits. In this way, these cereal-based foods will be considered to be sources of iodine, rather than the salt itself. The national nutrition guidelines for Australia and New Zealand encourage consumption of breads and cereals; they also encourage limiting fat, salt and sugar intakes. Consistency with these guidelines has been ensured as far as possible while balancing the effectiveness of the proposed mandatory fortification option. The selection of biscuits as a carrier of iodised salt could be considered inconsistent with these nutrition guidelines as some biscuits, for example chocolate biscuits, can be high in fat and/or sugar. The inclusion of biscuits as a food vehicle for iodised salt is not intended to promote the increased consumption of biscuits, which may contain higher than desired fat, sugar and salt contents. Instead the preferred option provides an effective food vehicle to improve the iodine intakes of the target population, in combination with breads and breakfast cereals.

---

[17] NHMRC. Dietary Guidelines for Australian Adults. Commonwealth of Australia, 2003; Ministry of Health. Food and Nutrition Guidelines for Healthy Adults: A background paper. Wellington. Ministry of Health, 2003.

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 need to ensure significant proportions of the population, especially children, do not exceed the UL.

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.

11.5 Consumer Issues

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

- choice and availability of non-iodised products;
- 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 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 key cereal-based foods 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 (Attachment 6) also provides some evidence of consumer response to the widespread fortification of bread products with iodised salt. 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).

11.5.1 Choice and Availability of Non-Iodised Products

The mandatory requirement to replace non-iodised salt with iodised salt in key cereal-based foods is expected to reach a large proportion of the population (see Attachment 9). Some individuals may choose to avoid iodised products. The availability of some salt-free options, particularly for breakfast cereals and unleavened breads, will provide non-fortified options for those who choose them. Additionally, ingredient labelling will provide information for consumers. However, some unpackaged breads will not be required to be labelled and consumers can request information about the presence of iodine.

The Tasmanian (interim) Iodine Supplementation Program was well received by the community (Seal, 2006). 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 there were a handful of public inquiries with individuals being readily reassured (Seal, 2006).

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 key cereal-based foods 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.

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). Unlike Australia, which mandates the fortification of bread-making flour with thiamin and fat spreads with vitamin D, New Zealand currently has no mandatory fortification requirements.

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. Exposure to previous fortification and supplementation initiatives, as in Tasmania, is also likely to increase levels of awareness. 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 key cereal-based foods as part of the *Bi-national monitoring system to track the impact of regulatory decisions on mandatory iodine fortification* (Attachment 3).

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. However, it is possible that 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 are 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 key cereal-based products are widely and regularly consumed (Attachment 9).

11.5.4 Labelling and Product as a Basis for Informed Choice.

Consumers will be informed about the addition of iodised salt to cereal-products through general labelling requirements that require all ingredients of a product to be identified in the ingredient list (see Section 15.2). This information will enable consumers to either select products fortified with iodine or to avoid those products depending upon their individual choice.

While the majority of breads, breakfast cereals and biscuits will be required to list iodised salt in the ingredient list, there will be a small number of foods exempt from this requirement, unpackaged bread in particular. In these instances, consumers can request information as to the presence of specific ingredients in these foods.

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 the key cereal-based foods;
- the salt levels in the key cereal-based foods; and
- the use of iodised salt in other commercial foods.

If the future consumption of the designated cereal-based foods 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 key cereal-based foods. If these salt levels vary in processed food, for example they are lowered in response to public health campaigns; this would reduce the effectiveness of the mandatory fortification scenario. Various industry campaigns are currently examining ways to reduce the salt content of salted processed foods. 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.

Various food manufacturers have indicated that if they are required to use iodised salt in the cereal-based food they produce, they are unlikely to purchase non-iodised salt for 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 this mandatory fortification scenario.

Question to Submitters

If manufacturers of breads, breakfast cereals and biscuits are required to use iodised salt, would iodised salt also be used in the processing of other food products? If so, please indicate which products.

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 this fortification scenario to promote increases in salt intake, including iodised salt intakes. As part of the Communication and Education Strategy, FSANZ will reiterate support for the dietary guidelines which focus on reducing salt intakes.

FSANZ examined the possibility of removing the voluntary permissions for iodised salt. In effect, this would mean that all discretionary salt would be non-iodised; and would prevent manufacturers from adding iodised salt to any food products, except breads, breakfast cereals and biscuits.

Removing voluntary permissions would provide greater certainty in estimating iodine intakes, given the lack of quantitative data on discretionary salt intakes. FSANZ has estimated the range of iodine intakes from discretionary salt intakes based on sales data which provides a general indicator of likely intakes. While acknowledging the limitations of these estimates, in some instances, the addition of iodised salt makes significant contributions to the effectiveness of the fortification scenario, especially in geographical locations with more severe iodine deficiency. The dietary intake assessments also show that predicted intakes are safe.

Conversely the removal of the voluntary permission for iodisation of salt would further restrict consumer choice and potentially create consumer confusion by removing a well established source of iodine from the food supply. It would also require modification of the New Zealand dietary guideline on salt which currently advises consumers to select iodised salt in preference to non-iodised salt. It could potentially increase costs for those bread, breakfast cereal and biscuit manufacturers who produce other food as it would require them to purchase both iodised and non-iodised salt.

FSANZ believes that maintaining current voluntary permission for iodisation of salt in conjunction with the mandatory fortification of cereal-based foods with iodised salt provides a number of benefits. These include enhancing the effectiveness of the fortification scenario and providing alternative iodine sources for people who do not consume salted cereal-based foods. However, FSANZ is proposing to reduce the concentration of iodine in iodised salt from 25-65 mg per kg to 20-45 mg per kg to help reduce the uncertainty in iodine intakes. This is the same level as proposed for the mandatory iodine requirement.

This voluntary permission will also allow manufacturers to add iodised salt to other processed foods. Currently, very few commercial foods contain iodised salt but as a consequence of the mandatory fortification requirements, the use of iodised salt in commercial foods may increase.

Question to Submitters

Should the voluntary iodine permission for the iodisation of salt be removed?

11.6.3 Increased Iodine Requirements of Pregnant and Breastfeeding Women

The level of iodisation in salt has been selected to maximise iodine intakes in the target group, while preventing significant proportions of the non-target group exceeding the upper safe levels of intake. However, the UL for children is approximately one fifth of the adult UL and yet salt intakes for children are over half that of women. Thus, the amount of additional iodine that can be delivered to pregnant and breastfeeding women, using iodised salt, is constrained by the need to ensure that young children do not receive too much iodine.

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. If a woman is iodine replete before pregnancy, her iodine stores may be adequate to provide sufficient iodine for her child. However, if the mother is deficient before pregnancy, there is a greater risk the child will be iodine deficient. Therefore, at least in the short term, until the population is iodine replete, supplementation for pregnant and breastfeeding women may be necessary.

11.6.4 Geographical Variation in Iodine Status

As stated in Section 8, there are geographical variations in the iodine status of the Australian population. The predicted increases in iodine status reflect an average increase across the entire Australian population. Thus, in those States with iodine deficiency, the increase in iodine status may be less than predicted and conversely States with adequate iodine status may have higher intakes. This raises the question as to effectiveness and/or safety of the fortification scenario for the different States.

While data exists indicating that school aged children in some States are replete, there is a lack of data on the iodine status on pregnant and breastfeeding women in these States. Advice from FSANZ's Iodine Scientific Advisory Group is that even in iodine replete States the amount of additional iodine being delivered from fortification would not place these populations at undue risk. This conclusion was supported by further analysis of FSANZ's dietary intake assessments, examining the iodine water levels from different States, as outlined in Attachment 9.

Different risk management approaches may be required for individual States and Territories in response to variations in iodine status. This would maximise effectiveness and reduce risk of iodine excesses resulting from the fortification scenario.

11.7 Impact on Trade

The impact on trade of using iodised salt in cereal-based foods is anticipated to be minimal. The majority of the designated cereal-based foods, namely bread, breakfast cereals and biscuits, are manufactured locally for the Australian and New Zealand markets. Biscuits may be more affected by this Proposal, as some biscuit products are produced for both local and export markets.

11.7.1 Exports

FSANZ is only aware that Japan restricts the imports of food containing added iodine and this will potentially affect Australian and New Zealand exports to this country. The cost to provide additional lines of non-iodised products for export markets has been estimated at between 10% and 30%, and this cost has been incorporated into the Benefit Cost Analysis (see Section 13.2). Additionally, to assist trade with countries that do allow importation of iodised products, it is preferable that the selected level of salt iodisation be consistent with international guidelines.

11.7.2 Imports

Very little food grade salt is imported into Australia or New Zealand, with only small amounts of gourmet non-iodised products imported. These products would be unaffected by the mandatory fortification scenario. FSANZ is unaware of the importation of any iodised salt products but if there were, these products would need to comply with the revised iodisation range of 20-45 mg per kg.

It is intended that all breads, breakfast cereals and biscuits imported into Australia and New Zealand will need to comply with the proposed standard for mandatory fortification with iodine.

If this does not occur it will undermine the health objective and effectiveness of the proposed fortification option. In addition, it will disadvantage local manufacturers who will have added costs associated with fortification, and unlike their importer counterparts could not offer a non-iodised product to consumers.

Question to Submitters

What impact, if any, would the mandatory requirement for the replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits have on the import of these foods into Australia and New Zealand?

11.8 Summary

A number of risks and issues arising from the mandatory requirement to replace salt with iodised salt in key cereal-based foods have been identified. Strategies for the management of these risks as they relate to the preferred regulatory option are addressed later in this Report (see Section 15).

12. Regulatory Options

FSANZ selected iodised salt as an ingredient in processed cereal-based foods including bread and bread products, breakfast cereals and sweet and savoury biscuits 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 the selection of bread products, breakfast cereals and biscuits as the food vehicle to which the addition of iodised salt is to be mandated, consideration was given to adding iodised salt to all manufactured processed food. Bread and bread products, breakfast cereals and biscuits were chosen because they are the least trade restrictive measure and because there was little difference between the overall iodine intake by the target population under either scenario.

Consequently at Draft Assessment the following two options have been identified.

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 discretionary salt. 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 addition of iodised salt to bread, bread products, breakfast cereals and biscuits

This option proposes that non-iodised salt be replaced with iodised salt in the manufacture of bread, biscuits and breakfast cereals. The salt iodisation level is to be in the range of 20 – 45 mg iodine per kg salt. This concentration will address mild to moderate deficiency in iodine intake for the population of Australia and New Zealand. In addition the voluntary permission on the level of iodine in discretionary salt will remain but the level will be reduced to be consistent with the mandatory range.

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 and Attachment 3 of this report.

13. Impact Analysis

13.1 Affected Parties

- Industry:
  - Iodine importers
  - Salt manufacturers
  - Manufacturers of selected foods: breads, cereal products and biscuits
  - Importers of the selected foods

- Government:
  - New Zealand and Australian state and territory government enforcement agencies
  - Australian Quarantine Inspection Service

- Consumers generally, and particularly the following sub-groups:
  - Infants during foetal development and up to 3 years of age
  - Pregnant and lactating women

13.2 Cost Benefit Analysis

FSANZ commissioned Access Economics to investigate the costs and benefits of replacing salt with iodised salt in key cereal-based products. The Cost-Benefit Analysis prepared by Access Economics is provided in full at Attachment 11.

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 benefits that are possible would be worthwhile in relation to the costs that would be incurred. This approach is acceptable to the Office of Regulation Review.

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 the selected cereal based products (bread, breakfast cereals and biscuits).

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. Changes to other standards would be required to allow for organic production.

The upfront costs associated with machinery and labelling for salt manufacturers in Australia would be A$159,000 and for New Zealand, NZ$303,000. Most indicated they would use potassium iodate which costs A$30 to A$40 per kilogram in Australia and NZ$55 to NZ$65 per kilogram in New Zealand.

Industry has indicated that the amount of product undergoing analytical testing ranges from 6% to 20%. In addition the cost for this testing depends on whether the tests are carried out in-house or in a laboratory. Based on company estimates of test costs and the number of tests, costs of analytical testing in Australia for all salt manufacturers are A$22,000 per year.

There are likely to be other costs for salt manufacturers including the cost of warehousing the iodised salt separately to non-iodised salt. Also one Australian salt manufacturer indicated that they would incur extra transport costs because it would expand its plant in one state but not in another, and would therefore need to transport salt from the expanded plant to customers in the other state. These transport costs are estimated to comprise 72% of annual ongoing outlays associated with fortification.

13.2.2.3 Cereal Processing Industry

Manufacturers of processed cereal products affected by the proposed iodine fortification strategy would include makers of breakfast cereals, bread and biscuits.

The categories of cereal processing costs affected by this fortification proposal include additional costs of iodised salt, changes to labels, analytical testing and trade related costs.

It is estimated that iodised salt would cost cereal processing firms 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.

With mandatory fortification, cereal processing firms would be obliged to redesign label templates to ensure compliance with labelling standards for food containing iodised salt.

Estimates received by Access Economics of the costs of label redesign for pre-packaged products in Australia were in the range of A$500 per stock keeping unit for simpler changes and around A$1,000 to A$2,000 per stock keeping unit for more complex changes. In New Zealand it is estimated that these costs would range from NS$500 to NZ$1,000 per stock keeping unit depending on the complexity of the change. On a per kilogram of salt input basis, pre-packaged labelling estimates ranged from A$0.06 to A$0.33 to A$2 in Australia and on average NZ$0.11 in New Zealand.

Estimates of the costs of changing information manuals, cardboard inserts and label stickers providing this information, were between 1 cent and 7 cents per kilogram of salt input.

The upfront costs of labelling changes required if fortification is introduced would be around A$15.5 million in Australia and NZ$341,000 in New Zealand. These cost estimates were calculated from information provided by industry in both countries and reflect higher labelling costs reported by Australian industry.

If mandatory fortification is introduced at a time when labels are redesigned in the normal course of business, then the incremental labelling costs would be minimal. For example, one firm advised Access Economics that print runs usually last three to six months. A transition period, of 12 months, would also moderate – although not eliminate – the problem of disposing of unused labels, or unfortified products.

Costs estimates for analytical testing by cereal processing firms varied from 0.3 to 3 cents per kilogram of salt purchased. The average of these, 1.65 cents per kilogram of salt was used and applied to total salt used in cereal processing. Ongoing costs per year of analytical testing are estimated at A$413,000 for Australia and NZ$51,000 for New Zealand.

Submissions received by FSANZ indicated that iodine fortification would increase trade related costs because imports of foods fortified with iodine are prohibited in some countries. Thus, companies exporting to these countries need to maintain separate product lines, with the associated ongoing warehousing and label switching costs. In calculating these trade related costs, Access Economics had to make assumptions based on information from industry about the proportion of exports to countries that do not permit iodine-fortified products. Trade related costs are estimated at over A$2.3 million in ongoing outlays per year in Australia and more than NZ$280,000 in ongoing outlays per year in New Zealand. Some countries may require some or all imported food to be fortified with iodine.

13.2.2.4 Government – Administration and Enforcement of Regulation

The costs estimates considered in this section reflect only the value of resources allocated to activities that would not otherwise be undertaken if mandatory fortification was not introduced, ignoring costs already sunk in developing the proposal thus far.

In Australia, the states and territories would be responsible for the enforcement of this regulation. Their costs would include awareness raising and training, auditing and surveillance, administration and responding to complaints. These costs were estimated by calculating a per capita cost for the entire Australia population based on some figures received from two Australian jurisdictions.

13.2.2.5 Government – Monitoring

An effective fortification program will require monitoring costs. Although monitoring is not part of FSANZ's responsibilities under the *Food Standards Australia New Zealand Act 1991,* 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 detail at Attachment 3. The costs discussed here are assumed to be the same for both countries, on the basis of available information.

The costs of ensuring manufacturers, retailers and importers are aware of the new fortification requirement are approximately A$36,000 per year for Australia and NZ$43,200 for New Zealand. The costs of updating the National Food Composition Database, maintaining a reporting system for the food industry on voluntarily fortified products, monitoring labels and label compliance analytical surveys are estimated to be about A$62,400 per year for Australia and NZ$74,880 for New Zealand.

The costs of consumer attitude and behaviour research and market basket store surveys are estimated to be about A$118,000 per year for Australia and NZ$141,600 for New Zealand. To conduct the National Nutrition Survey in relation to changes in iodine intakes is expected to cost A$20,000 per year in Australia and NZ$24,000 per year in New Zealand.

In addition it is estimated costs of monitoring relating to testing of the levels of iodine in the Australian and New Zealand population through blood and urine testing are estimated to be A$168,000 per year in Australia and NZ$201,600 per year in New Zealand. Finally a cost has been assumed of an officer to provide overall system support in each country, at a cost of approximately A$100,000 per year in Australia and NZ$120,000 per year in New Zealand.

An approximate total of the monitoring costs outlined in the attachment is A$504,400 per year for Australia and NZ$605,280 per year for New Zealand. This is included in the summary of total costs table set out below.

13.2.2.6 Summary of Total Costs

Overall, the total upfront costs from this proposal are A$15,797,000 for Australia and NZ$651,556 for New Zealand. The total ongoing costs per year are A$3,319,000 and NZ$434,000 for Australia and New Zealand respectively.

In Australia, these costs equate to $0.17[18] per person per year for the ongoing costs. In New Zealand ongoing costs are $0.11[18] per person per year.

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

Summary of total costs	Australia (A$)	New Zealand (NZ$)
Upfront costs		
Salt industry (machines and labelling)	159,000	303,000
Cereal processing industry (labelling)	15,500,000	341,000
Government – administration and enforcement of regulation	138,000	7,800
Total upfront	**A$15,797,000**	**NZ$651,556**
Ongoing costs (per year)		
Salt industry (maintenance, iodine, analytical testing, transport and storage)	488,000	18,170
Cereal processing industry (analytical testing and trade related costs)	2,675,000	331,500
Government – administration and enforcement of regulation	156,000	84,800
Total ongoing (per year)	**A$3,319,000**	**NZ$434,000**
Monitoring costs (per year)*	**A$504,400**	**NZ$605,280**

Costs of iodine fortification per person	Australia	New Zealand
Population	20,111,297	4,120,900
Upfront cost per head	A$0.79	NZ$0.16
Ongoing cost per head (per year)	A$0.17	NZ$0.11
Monitoring cost per head (per year)*	A$0.03	NZ$0.15

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

13.2.3 The Benefits

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

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

[18] 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.

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. Thus, it is also plausible that without intervention there would be an inter-generational decline in iodine status. As noted in Section 9.1.1.3, addressing iodine deficiency will reduce the risk of iodine-induced hyperthyroidism and can lead to an improvement in the prognosis of thyroid cancer.

13.2.3.2 Benefit of Avoiding Harm of Cognitive Impairment

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 Australians and 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.

14. Comparison of Options

Introducing mandatory fortification as proposed in this report, is expected to result in ongoing costs of $3.3 million in Australia and NZ$434,000 in New Zealand. This equates to about $0.17 per person per year in Australia and $0.11 per person per year in New Zealand. The important benefits of this Proposal relate to halting a generation-to-generation depletion of iodine and improvements in cognitive function. While quantifying the dollar values of these benefits proved extremely difficult, they nonetheless would be worthwhile, especially in relation to the small cost to the community that would be incurred. FSANZ considers that the proposal would deliver net-benefits to Australia and New Zealand.

Hence FSANZ considers that Option 2, to fortify selected foods with iodine, provides net benefits superior for the populations of Australia and 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 Australia and New Zealand.

On the basis of the available evidence FSANZ recommends that mandatory fortification of salt with iodine for addition to bread, breakfast cereals and biscuits would deliver substantial benefits to Australia and New Zealand. These principal benefits relate to halting a generation to generation depletion of iodine and improvements in cognitive function. At a cost of about $0.17 per person per year in Australia and $0.11 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 key cereal-based foods 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 scenario

<u>15.1.1.1 Iodine Supplement Use</u>

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 will refer this issue to the relevant health authorities and liaise with the Royal Australian and New Zealand College of Obstetricians and Gynaecologists.

<u>15.1.1.2 Tailoring Education Messages for Specific Geographical Locations</u>

Given the geographical variations in the iodine status across the States/Territories of Australia, and New Zealand, it will be important that education messages are tailored by local governments to reflect their regional iodine status.

In potentially iodine replete populations, such as Queensland and Western Australia, the education messages should support the national nutrition guidelines to use less salt, including iodised salt. It may also be advantageous to promote the use of iodine supplements by pregnant and breastfeeding women in these populations.

Similarly, in deficient populations, such as New Zealand and New South Wales, the education messages should support the national nutrition guidelines to use less salt, and in New Zealand should encourage choosing iodised salt if salt is used. In addition, a recommendation that pregnant and breastfeeding women take iodine supplements should be a key education message for these populations.

In both replete and deficient populations the need for supplements will need to be monitored to determine on going need for education messages promoting iodine supplement use by pregnant and breastfeeding women.

15.1.2 Safety Considerations

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 the proposed mandatory fortification scenario. FSANZ has adopted a conservative approach to mandatory fortification, which incorporates a prescribed level of fortification and recommends a comprehensive monitoring system. In addition, FSANZ will inform endocrinologists of the potential low risk of iodine-induced hyperthyroidism due to this mandatory fortification scenario.

15.1.2.2 Pre-Existing Thyroid Disease

Individuals with pre-existing thyroid disease, for example Grave's 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, though it is acknowledges that it may in some. However 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. As part of the education and communication strategy, endocrinologists will be informed of the possible risk of adverse reactions in some individuals with these conditions.

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. Even where there is some form of heightened sensitivity to iodine, it is unlikely the amounts of additional iodine resulting from this fortification scenario will cause any adverse reactions.

Advice to this effect will be incorporated into the FSANZ education and communication strategy. For further discussion of this issue see Attachment 7.

15.1.2.4 Children Above the Upper Level of Intake

A small proportion of young children, aged less than 3 years, will exceed the upper level of intake for iodine (see Section 7). Though 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 young children, although the margin of safety is reduced. 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 education and communication strategy. In addition, the iodine intake and status of this age group will be monitored as part of the monitoring program.

15.1.3 Impact on Future Iodine Levels in the Food Supply

The causes of the re-emergence of iodine deficiency are not fully understood but may be related to:

- the dairy industry minimising the use of iodine-based cleaning products, leading to lower concentrations of iodine in milk;
- decreased consumption of iodised salt, due to greater use of non-iodised salt and a reduction in total salt intakes; and
- variations in iodine levels in drinking water.

As mentioned in Section 11.5, there are a number of other variables that may also influence the future levels of iodine in the food supply, namely the consumption of the key cereal-based foods, the salt levels in these foods, the 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 to monitor changes in the key sources of dietary iodine and the impact on iodine status in both the target and non- target population groups as part of the monitoring program outlined in Section 21.

15.2 Labelling and Information Requirements

The purpose of food labelling is to provide consumers with information about food to enable them to make informed food choices. Labelling provides an important source of information for consumers regarding fortification, 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 making nutrition claims (Standard 1.2.8); and
- the conditions applying to nutrition claims about vitamins and minerals (Standard 1.3.2).

Under mandatory fortification, foods containing iodised salt will be required to list iodised salt as an ingredient in the ingredient list, with the exception of those covered under subclause 2 (1) of Standard 1.2.1, for example unpackaged foods. However, in the case of unpackaged foods consumers may request ingredient information. In accordance with the Ministerial Policy Guideline for mandatory fortification, *there is no mandatory requirement to label a food product as fortified*. The policy guidance further states that, *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 NIP is warranted. The ingredient listing of iodised salt will alert consumers to the presence of iodine, 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.

15.2.1 Use of Nutrition and Health Claims

Mandatory fortification presents the opportunity for food manufacturers to make nutrition and health claims, as permitted under the Code, related to the iodine content of cereal products in labels and related information. The iodine content of the key cereal-based products using iodised salt may in some cases reach sufficient levels to enable manufacturers to make a nutrition claim about the presence of iodine. For example a 'source' claim could be made on bread if the iodine content was 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.

A new Standard (draft Standard 1.2.7 – Nutrition, Health and Related Claims) is currently under development and will permit a wider range of claims in the future.

15.2.2 'Natural Foods' and Related Descriptor Labels

Food labelling or promotional claims must be factually correct and not misleading or deceptive under the fair trading legislation of Australia and New Zealand[19]. FSANZ intends 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.

15.3 Practical Considerations of Implementing the Dietary Intake Assessment Outcomes

15.3.2 Level of iodine fortification in iodised salt

In determining the appropriate level of iodisation in salt to address the re-emergence of mild iodine deficiency, the Risk Assessment has proposed the following:

---

[19] *Trade Practices Act 1974*, State and Territory Fair Trading legislation and *Fair Trading Act 1986*.

- 30 mg per kg of iodised salt in cereal-based products; and
- 20 mg per kg of iodised salt in table salt.

Due to the uncertainty surrounding discretionary salt intakes in both Australia and New Zealand, it was decided to reduce the level of iodisation in discretionary salt from an average 45 mg per kg to 20 mg per kg.

Salt manufactures have indicated a preference for one level of salt iodisation instead of two. Although it is technically possible to produce two levels, production costs would be increased and could potentially result in a level of confusion for small manufactures purchasing small quantities more suited to the retail packaging sizes.

Salt manufacturers have recommended a working range of ±10 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 ±10 mg per kg accommodates the normal distribution range. The application of the suggested range to the two salt iodisation levels results in significant overlaps occurring. In practical terms this creates a situation whereby it is difficult to easily distinguish between the two levels.

FSANZ has determined that one level of salt iodisation is the most practical solution. The advantages of having one level of salt iodisation include:

- consistency with the recommended level set by WHO and ICCIDD;
- less impost for salt manufacturers;
- easier to enforce[20];
- less confusion for manufacturers purchasing small quantities of iodised salt;
- 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.

As stated in Section 11.2.1, an average loss of 10% should be accommodated in the fortification range to account for any expected losses in processing. On the basis of these findings, FSANZ has prescribed a fortification range of 20-45 mg of iodine per kg of salt.

15.3.3 Conclusion

The introduction of the one level of salt iodisation and limiting the food vehicle to the three key cereal categories does deviate slightly from the initial dietary intake assessment. While this is unlikely to significantly alter the predicted outcomes, it does introduce a slightly greater level of uncertainty with respect to the dietary intake assessment. It should be noted however, that the dietary intake assessment scenarios are based on conservative assumptions providing high safety margins. To confirm that these adjustments will not undermine the effectiveness and/or safety of the revised fortification scenario, FSANZ will undertake further dietary intake assessment and report these results in the Final Assessment Report.

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

COMMUNICATION AND CONSULTATION

16. Communication and Education

Mandatory iodine fortification is well supported, particularly by health professionals and government agencies in Australia and New Zealand. It is acknowledged as an effective means of delivering a substantial improvement in iodine intakes across the population, and alleviating the current deficiency and preventing future deficiency, especially among children.

16.1 Education and Communication Strategy

FSANZ has prepared a strategy to guide communication and education initiatives to raise awareness and understanding of the proposed standard and its implementation. This strategy draws on our discussions with key stakeholders about the most effective ways of communicating information about the proposed standard to consumers, industry, health professionals, governments and the media.

In implementing this strategy, FSANZ will continue to collaborate with other organisations that play an important role in providing information and education to consumers, industry and other key stakeholders. Given the conservative approach adopted by FSANZ in determining the level of iodine fortification, additional measures will be needed to complement this initiative, including supplementation for pregnant and lactating women and ongoing health promotion activities.

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

A full summary of the issues raised in submissions is provided in Attachment 12. Key issues identified in submissions have been addressed where possible in the main body of this Report and focus on:

- the selection of appropriate food vehicles for fortification;
- potential risks associated with increasing iodine intakes;
- success of current fortification strategies to increase iodine intake;

- potential export trade barriers associated with mandating the use of iodised salt in manufactured goods;
- the lack of consumer choice associated with mandatory fortification;
- costs associated with mandatory fortification;
- the need for the current salt permissions to be reviewed;
- the importance of education campaigns to raise awareness of the re-emergence of mild iodine deficiency and the proposed regulatory solution;
- the need for additional measures to be used in conjunction with mandatory fortification to ensure population groups with increased requirements (e.g. pregnant women) have adequate iodine intakes; and
- the need to establish a national monitoring and surveillance system, prior to the implementation of mandatory iodine fortification.

17.2 Targeted Consultation Process

Issues identified from public submissions formed the basis of further targeted consultation with key stakeholder groups, including salt manufacturers and suppliers and manufacturers of bread, breakfast cereals and biscuits products. Information received has informed FSANZ's consideration of the appropriateness of the food vehicle, identification and investigation of risk management issues, the cost-benefit analysis, the recommendations for the implementation phase, and the monitoring requirements for mandatory fortification.

As part of this 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 the following sectors; public health nutrition, food manufacturing, enforcement, food policy, health promotion and consumer education.

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 both in Australia and New Zealand.

In addition, FSANZ commissioned an independent economic consultancy organisation, Access Economics, to investigate the benefits and costs of replacing salt with iodised salt in key cereal-based products in Australia and New Zealand. Access Economics held further consultations with key stakeholders, particularly industry groups, in regard to the financial and health implications of mandatory fortification.

18. World Trade Organization

As members of the World Trade Organization (WTO), Australia and New Zealand are 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 to mandatory fortify salt with iodine used in the manufacture of cereal-based products. 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 the imports of foods fortified with iodine are proscribed in some countries for example Japan. Requirements to mandatory fortify salt used in the manufacture of cereal-based products, which include some staple foods, may have trade implications not yet identified. Therefore, notification of the proposed mandatory fortification regulations will be made to the WTO in accordance with the WTO Technical Barriers to Trade Agreement. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

CONCLUSION

19. Conclusion and Preferred Option

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, breakfast cereals and biscuits (Option 2) (prescribed at a fortification range of 20-45 mg of iodine per kg of salt) would deliver net-benefits to Australia and New Zealand.

This approach maintains the current voluntary permission for iodised salt but the level of iodisation has been reduced from the current range of 25-65 mg per kg to be consistent with the prescribed mandatory range.

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.

FSANZ concluded that Option 2 is the preferred approach at Draft Assessment for the following reasons:

- the replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits would contribute considerably to alleviating the consequences of existing deficiency, and prevent it from becoming even more widespread and serious in the future;

- the use of iodised salt to reduce the prevalence of iodine deficiency is consistent with international guidance and experience;

- in Tasmania, the recent use of iodised salt in bread was a successful initiative to increase the iodine status of a mildly deficient population;

- on the available evidence, including overseas experience with mandatory fortification, the proposed level of fortification does not pose a risk to general public health and safety. The level has been set to minimise any potential health risks. In groups that are generally more sensitive to increases in iodine intake, e.g. individuals with existing, thyroid conditions, the risk of a negative impact on health is still considered to be very low;

- the replacement of salt with iodised salt in key cereal-based food is effective and technologically feasible;

- FSANZ considers that the proposal would deliver net-benefits to Australia and New Zealand:

  - while quantifying the dollar values of the benefits proved extremely difficult, the identified benefits are considered to be valuable, especially in relation to the small cost likely to be incurred by the community;
  - the cost to industry and government in the first year would be $A15.8 million and $NZ0.7 million in Australia and New Zealand respectively, but would be lower in each subsequent year at $A3.3 million and $NZ0.4 million respectively;
  - these costs may be passed on to consumers and in the first year would amount to A$0.79 per person in Australia and NZ$0.16 per person in New Zealand, but in each subsequent year would fall to A$0.17 per person in Australia and NZ$0.11 per person in New Zealand;

- consumers will be provided with information through ingredient labelling to identify the presence of iodised salt in the key cereal-based food; and

- 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 and parts of Australia.

20. Implementation and Review

If the FSANZ Board approve the proposed draft variations to the Code following the completion of a Final Assessment for this Proposal, the Ministerial Council will be notified of that decision. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code are expected to come into effect 12 months from gazettal.

It is proposed that a 12-month transitional period will apply to the mandatory addition of iodised salt, in place of non-iodised salt, in key cereal-based foods. This transitional period will allow time for the salt industry to increase the production of iodised salt and for manufacturers of the key cereal foods to make the required changes to manufacturing and labelling.

Additionally, a transitional period will allow for consumers to be informed about the changes. The mandatory requirement for the replacement of salt with iodised salt in bread, breakfast cereals and biscuits will therefore come into effect 12 months from gazettal of the proposed draft variations to the Code.

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. A proposed approach to monitoring is discussed below in Section 21.

20.1 Communication and Education Strategy for the Preferred Regulatory Option

FSANZ has prepared a strategy to guide communication and education initiatives to raise awareness and understanding of the proposed standard for mandatory fortification with iodine and its implementation.

The strategy aims to increase awareness among all target audiences of the proposed standard for mandatory fortification with iodine; and to promote iodine supplementation among pregnant and breastfeeding women. Target audiences identified for the strategy are: consumers, particularly pregnant and breastfeeding women and care providers of young children, industry; health professionals; government agencies that are responsible for monitoring, enforcement and education; and the media.

To implement this strategy, FSANZ will collaborate with other organisations that play an important role in providing information and education to consumers, industry and other key stakeholders. This collaborative approach will increase public awareness of the proposed standard and fortification issues, ensure consistency of information, and maximise the effectiveness of available resources. For this strategy to be most effective, communication and education activity will need to be sustained over time.

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 in 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 and will require the concomitant involvement of health and regulatory agencies at a Commonwealth, State and Territory level in Australia and the New Zealand Government.

For the purposes of progressing discussion on the proposal to mandate iodine fortification, FSANZ has adapted the draft monitoring framework prepared by the FRSC working group for mandatory fortification of nutrients and outlined the potential elements that could be considered for inclusion in a monitoring system for assessing the impact of iodine fortification on consumers (see Attachment 3).

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 would also be 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 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.

In order to determine the impact of mandatory fortification on iodine intake, it is also necessary to collect data on the range of food products available using iodised salt mandatorily and voluntarily, and their iodine content, consumer attitudes and purchase behaviour in relation to fortified foods, actual consumer food and supplement consumption patterns and on biochemical markers of iodine status. Attachment 3 gives details on possible data collection methods for each of these elements of a more comprehensive monitoring system. These data collections would provide extremely valuable information on how the fortification policy has affected the whole food system. This would be particularly important if implementation of mandatory fortification did not achieve the desired end outcome of reducing the prevalence of iodine deficiency or if there was evidence that it was adversely affecting the population in general. A comprehensive monitoring system should provide sufficient data to answer the question 'why is it not working?' and be able to identify the best intervention point for improving the system in the future to achieve a better outcome.

FSANZ recognises that the costs for establishing an ongoing monitoring system have not been included in the cost-benefit analysis presented elsewhere (see Section 21) because the inter agency discussion on the elements (and hence costs) to be included in such a system has yet to take place. However, the cost of a monitoring system will need to be considered by the Ministerial Council when making their final decision on the proposal.

Preliminary costings for various elements of a monitoring system based on current estimates have been included in Attachment 3 as a basis for future discussion with key stakeholders, including the food industry as well as the government agencies involved.

As part of its ongoing work, FSANZ will contribute directly to 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;
- updating the food composition databases;
- 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 in the population, including uptake of iodised table salt;

- tracking regional differences in iodine status and iodine levels in the food supply; and
- researching changes in consumers' attitudes and behaviour towards fortified foods.

FSANZ may also be involved indirectly in other program activities.

References:

ATSDR (2004). Toxicological profile for iodine. U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Atlanta, GA. http://www.atsdr.cdc.gov. Accessed on 23 March 2006.

Board on Environmental Studies and Toxicology (BEST) (2006). Fluoride in Drinking Water: A Scientific Review of EPA's Standards, The National Academies Press. http://www.nap.edu/catalog/11571.html?onpi_newsdoc03222006. Accessed on 16 August 2006

Brown, E. (2004) *Research into food fortification. For the baking industry research trust.* Brand Development Research Limited, Auckland.

Chan, S.S., Hams, G., Wiley, V., Wilcken, B. and McElduff, A. (2003) Postpartum maternal iodine status and the relationship to neonatal thyroid function. *Thyroid*, 13(9):873-876.

Childs, N. M. and G. H. Poryzees (1998). 'Foods that help prevent disease: consumer attitudes and public policy implications.' *British Food Journal*, 100(9): 419-426.

Choudhury, N. and Gorman, K.S. (2003) Subclinical prenatal iodine deficiency negatively affects infant development in Northern China. *J. Nutr.*, 133(10):3162-3165.

Clements, F.W. (1986) A History of Human Nutrition in Australia. Longman Cheshire, Melbourne, Victoria.

Codex Alimentarius Commission. (1991) General principles for the addition of essential nutrients to foods. CAC/GL 09-1987 (amended 1989, 1991) www.codexalimentarius.net/searchindex.doc.

Cook, T., Rutishauser, I. and Allsopp, R. (2001) *The Bridging Study: comparing results from the 1983, 1985 and 1995 Australian national nutrition surveys*. Australian Food and Nutrition Monitoring Unit, Commonwealth Department of Health and Aged Care, Commonwealth of Australia, Canberra.

Cooper, G.J.S., Croxson, M.S., Ibbertson, H.K. (1984) Iodine intake in an urban environment: a study of urine iodide excretion in Auckland. *N. Z. Med. J.*, 97:142-145.

Cox, D. N. and A. S. Anderson (2004) Food choice. In: Gibney, M. J., Margetts, B. M, Kearney J. M., Arab, L., eds. *Public health nutrition*. Blackwell Science Ltd, Oxford, pp 144-166.

Darnton-Hill, I. (1998) Rationale and elements of a successful food-fortification program. In: Scrimshaw, N.S. eds. Food and nutrition bulletin. 2,Vol 19, United Nations University Press, Tokyo.

Delange, F. and Hetzel, B.S. (2005) The Iodine Deficiency Disorders. http://www.thyroidmanager.org/Chapter20/20-frame.htm. Accessed on 13 March 2006.

Delange, F. (2000) The role of iodine in brain development. *Proc. Nutr. Soc.*, 59**:** 75-79

Delange, F. (2001) Iodine deficiency as a cause of brain damage. *Postgrad. Med. J.,* 77(906):217-220.

Eastman, C. (1999) Where has all our iodine gone? Editorial. *Med. J. Aust.*, 171: 455-456.

Freake, H.C. (2000) Iodine. In: Stipanuk, M.H., ed. *Biochemical and physiological aspects of human nutrition.* W.B. Saunders Company, Philadelphia, Penn, pp 761-781.
FSANZ (2006). Draft Assessment Report Proposal P295. Consideration of Mandatory Fortification with Folic Acid. Food Standards Australia New Zealand, Canberra.

Galan, I.R., G., I, Sanchez, M.P., Pilar Mosteiro, D.M. and Rivas Crespo, M.F. (2005) Psycho-intellectual development of 3 year-old children with early gestational iodine deficiency. *J. Pediatr. Endocrinol. Metab.*, 18 Suppl 1:1265-1272.

Gibson, H.B (1995). Surveillance of iodine deficiency disorders in Tasmania 1949-1984. Dept. of Health Services, Hobart, Tasmania.

Gibson, R.S. (2005) Principles of Nutritional Assessment 2nd ed. Oxford University Press, New York, NY.

Gunton, J.E., Hams, G., Fiegert, M. and McElduff, A. (1999) Iodine deficiency in ambulatory participants at a Sydney teaching hospital: is Australia truly iodine replete? *Med. J. Aus.,t* 171(9):467-470.

Guttikonda, K., Travers, C.A., Lewis, P.R. and Boyages, S. (2003) Iodine deficiency in urban primary school children: a cross-sectional analysis. *Med. J. Aust.,* 179(7):346-348.

Haddow, J.E., Palomaki, G.E., Allan, W.C., Williams, J.R., Knight, G.J., Gagnon, J., O'Heir, C.E., Mitchell, M.L., Hermos, R.J., Waisbren, S.E., Faix, J.D. and Klein, R.Z. (1999) Maternal thyroid deficiency during pregnancy and subsequent neuropsychological development of the child. *N. Engl. J. Med.,* 341(8):549-555.

Hamrosi, M.A., Wallace, E.M. and Riley, M.D. (2003) Iodine status in early pregnancy: ethnic variations. *Asia Pac. J. Clin. Nutr.,* 12 Suppl:S15.

Hamrosi, M.A., Wallace, E.M. and Riley, M.D. (2005) Iodine status in pregnant women living in Melbourne differs by ethnic group. *Asia Pac. J. Clin. Nutr.,* 14(1):27-31.

Hawthorne, P. (2005) *Research into consumer attitudes to fortification of foods. Report prepared for the New Zealand Food Safety Authority*. Peter Glen Research, Lower Hutt.
Hetzel, B.S. (1994) Iodine deficiency and fetal brain damage. *N. Engl .J. Med.*, 331(26):1770-1771.

Hetzel, B.S. (2000) Iodine and neuropsychological development. *J. Nutr.* 130(2S Suppl):493S-495S.

Hetzel, B., Clugston, G. (1998). *Iodine.* In: Shils *et al.*, eds. *Modern nutrition in Health and Disease* 9th ed. Lippincott Williams & Wilkins, pp 253-264.

Huda, S.N., Grantham-McGregor, S.M., Rahman, K.M. and Tomkins, A. (1999) Biochemical hypothyroidism secondary to iodine deficiency is associated with poor school achievement and cognition in Bangladeshi children. *J. Nutr.* 129(5):980-987.

Hynes, K.L., Blizzard, C.L., Venn, A.J., Dwyer, T. and Burgess, J.R. (2004) Persistent iodine deficiency in a cohort of Tasmanian school children: associations with socio-economic status, geographical location and dietary factors. *Aust. N. Z. J. Public Health*, 28(5):476-481.

ICCIDD, UNICEF, WHO. (2001). *Assessment of Iodine Deficiency Disorders and Monitoring their Elimination*. Second edition, WHO Publishing, Geneva

Ikeda, J. P. (2004). Culture, food, and nutrition in increasingly culturally diverse societies. A sociology of food and nutrition. The social appetite. J. Germov and L. Williams. Melbourne, Oxford University Press, pp 288-313.

James, W.P., Ralph, A. and Sanchez-Castillo, C.P. (1987) The dominance of salt in manufactured food in the sodium intake of affluent societies. *Lancet*, 1(8530):426-429.

Joint FAO/WHO Expert Committee on food additives (JECFA). (1989) *Toxicological Evaluation of certain food additives and contaminants. WHO food additive series N024* Geneva: World Health Organization.

Jooste, P.L., Upson, N., Charlton K.E. (2005). Knowledge of iodine nutrition in the South African adult population. *Public Health Nutr.*, 8(4):382-386.

Kearney, M., M. J. Gibney, *et al.*. (1997). 'Perceived need to alter eating habits among representative samples of adults from all member states of the European Union.' *Eur. J. Clin Nutr.,* 51(Suppl 2): S30-S35.

Khoja, S., Luby, S., Ahmed, Z., Akber, A. (2000). Effectiveness of health education in promoting the use of iodized salt in Lotkoh, Tehsil Chitral, Pakistan. *J. Pak. Med. Assoc*, 50(9):296-300.

Li, M., Eastman, C.J., Waite, K.V., Ma, G., Zacharin, M.R., Topliss, D.J., Harding, P.E., Walsh, J.P., Ward, L.C., Mortimer, R.H., Mackenzie, E.J., Byth, K. and Doyle, Z. (2006) Are Australian children iodine deficient? Results of the Australian National Iodine Nutrition Study. *Med. J. Aust.,* 184(4):165-169.

Li, M., Ma, G., Boyages, S.C. and Eastman, C.J. (2001) Re-emergence of iodine deficiency in Australia. *Asia Pac. J. Clin. Nutr.,*10(3):200-203.

Mann, J.I. and Aitken, E. (2003) The re-emergence of iodine deficiency in New Zealand? *N. Z. Med. J.,* 116(1170):U351.

McElduff, A., McElduff, P., Gunton, J.E., Hams, G., Wiley, V. and Wilcken, B.M. (2002) Neonatal thyroid-stimulating hormone concentrations in northern Sydney: further indications of mild iodine deficiency? *Med. J. Aust.,* 176(7):317-320.

Ministry of Health (2003). NZ Food NZ Children: Key Results of the 2002 National Children's Nutrition Survey. Ministry of Health, Wellington.

Mohapatra, S.S., Bulliyya, G., Kerketta, A.S., Geddam, J.J., Acharya A.S. (2001) Elimination of iodine deficiency disorders by 2000 and its bearing on the people in a district of Orissa, India: A knowledge-attitude-practices study. *Asia Pacific J. Clin. Nutr.*, 10(1):58-62.

Nathoo, T., Holmes, C.P. and Ostry, A. (2005) An analysis of the development of Canadian food fortification policies: the case of vitamin B. *Health Promot. Int.,* 20(4):375-382.

North, K.A.K., Fraser, S. (1965). Iodine intake as revealed by urinary iodide excretion. *N. Z. Med. J.*, 65:512-513.

Nutrivit. (2000) Fortification basics: choosing a vehicle. http://www.nutrivit.org/vic/staple/index.htm.

Park, Y.K., Harland, B.F., Vanderveen, J.E., Shank, F.R. and Prosky, L. (1981) Estimation of dietary iodine intake of Americans in recent years. *J. Am. Diet. Assoc.,* 79(1):17-24.

Qian, M., Wang, D., Watkins, W.E., Gebski, V., Yan, Y.Q., Li, M. and Chen, Z.P. (2005) The effects of iodine on intelligence in children: a meta-analysis of studies conducted in China. *Asia Pac. J. Clin. Nutr.,* 14(1):32-42.

Sarker, F.H., Taufigun-Nessa, U.K., Chowdhury, S.A. (2002) Use of iodised salt and the prevalence of goitres in an endemic area of Bangladesh. *Mymensingh Med. J.*, 11(1):22-25.

Sarne, D. (2004) Effects of the Environment, Chemicals and Drugs on Thyroid Function. http://www.thyroidmanager.org/Chapter5/5a-frame.htm. Accessed on 15 August 2006.

Seal, J. (In Press). The Makings of the Tasmanian (interim) Iodine Supplementation Program 2001-2004. In: Richards, P. ed. *Goitre Monitor: History of Iodine deficiency Disorders in Tasmania from Pre-British Settlement to the Present Day*. Australian Society for the History of Medicine, Launceston.

Simpson, F.O., Thaler, B.I., Paulin J.M., Phelan E.L., Cooper, G.J.S. (1984) Iodide excretion in a salt-restriction trial. *N.Z. Med. J.*, 97:890-893.

Skeaff, S.A., Ferguson, E.L., McKenzie, J.E., Valeix, P., Gibson, R.S. and Thomson, C.D. (2005) Are breast-fed infants and toddlers in New Zealand at risk of iodine deficiency? *Nutrition* 21(3):325-331.

Skeaff, S.A., Thomson, C.D. and Gibson, R.S. (2002) Mild iodine deficiency in a sample of New Zealand schoolchildren. *Eur. J. Clin. Nutr.,* 56(12):1169-1175.

Soriguer, F., Millon, M.C., Munoz, R., Mancha, I., Lopez Siguero, J.P., Martinez Aedo, M.J., Gomez-Huelga, R., Garriga, M.J., Rojo-Martinez, G., Esteva, I. and Tinahones, F.J. (2000) The auditory threshold in a school-age population is related to iodine intake and thyroid function. *Thyroid,* 10(11):991-999.

Teng, W., Shan, Z., Teng, X., Guan, H., Teng, D., Jin, Y., *et al.* (2006) Effect of Iodine Intake on Thyroid Disease in China. *N. Engl. J. Med.*, 354:2783-2793.

Thomson, C.D. (2003) Australian and New Zealand Reference Values for Iodine, A report prepared for the Ministry of Health. New Zealand Ministry of Health.

Thomson, C.D. (2004) Selenium and iodine intakes and status in New Zealand and Australia. *Br. J. Nutr.,* 91(5):661-672.

Thomson, C.D., Colls, A.J., Conaglen, J.V., Macormack, M., Stiles, M. and Mann, J. (1997) Iodine status of New Zealand residents as assessed by urinary iodide excretion and thyroid hormones. *Br. J. Nutr.,* 78(6):901-912.

Thomson, C.D., Packer, M.A., Butler, J.A., Duffield, A.J., O'Donaghue, K.L. and Whanger, P.D. (2001) Urinary selenium and iodine during pregnancy and lactation. *J. Trace. Elem. Med. Biol.,* 14(4):210-217.

Travers, C.A., Guttikonda, K., Norton, C.A., Lewis, P.R., Mollart, L.J., Wiley, V., Wilcken, B., Eastman, C.J. and Boyages, S.C. (2006) Iodine status in pregnant women and their newborns: are our babies at risk of iodine deficiency? *Med J. Aus.,* 184(12):617-620.

Valeix, P., Preziosi, P., Rossignol, C., Farnier, M.A. and Hercberg, S. (1994) Relationship between urinary iodine concentration and hearing capacity in children. *Eur. J. Clin. Nutr.,* 48(1):54-59.

van den Briel, T., West, C.E., Bleichrodt, N., Ategbo, E.A. and Hautvast, J.G. (2000) Improved iodine status is associated with improved mental performance of schoolchildren in Benin. *Am. J. Clin. Nutr.,* 72(5):1179-1185.

van den Briel.T., West, C.E., Hautvast, J.G. and Ategbo, E.A. (2001) Mild iodine deficiency is associated with elevated hearing thresholds in children in Benin. *Eur. J. Clin. Nutr.,* 55(9):763-768.

Vermiglio, F., Lo, P., V, Moleti, M., Sidoti, M., Tortorella, G., Scaffidi, G., Castagna, M.G., Mattina, F., Violi, M.A., Crisa, A., Artemisia, A. and Trimarchi, F. (2004) Attention deficit and hyperactivity disorders in the offspring of mothers exposed to mild-moderate iodine deficiency: a possible novel iodine deficiency disorder in developed countries. *J. Clin. Endocrinol. Metab.,* 89(12):6054-6060.

West, CE, de Koning, FLHA & Merx, RJHM 1995, Effect of Iodized salt on the colour and taste of food, UNICEF, New York.

Wilson, C.G., Evans, G., Leppard, P. and Syrette, J. (2004) Reactions to genetically modified food crops and how perceptions to risks and benefits influences consumers' information gathering. *Risk Analysis,* 24(5):1311-1321.

Winger, RJ, Koenig, J, Je Lee, S, Wham, C, and House, DA., (2005), Technological Issues with Iodine Fortification of Foods, Final Report for New Zealand Food Safety Authority.
Worsley, A. and G. Skrzypiec (1998). 'Personal predictors of consumers' food and health concerns.' *Asia Pac. J. Clin. Nutr.,* 7(1): 15-23.

Worsley, A. and V. Scott (2000). 'Consumers' concerns about food and health in Australia and New Zealand.' *Asia Pacific Journal of Clinical Nutrition* 9(1): 24-32.

United Nations (1990). World Declaration On The Survival, Protection And Development Of Children And A Plan Of Action For Implementing The World Declaration On The Survival, Protection And Development Of Children In The 1990s. New York.

Zimmermann, M.B., Connolly, K., Bozo, M., Bridson, J., Rohner, F. and Grimci, L. (2006) Iodine supplementation improves cognition in iodine-deficient schoolchildren in Albania: a randomized, controlled, double-blind study. *Am. J.Clin. Nutr.,* 83(1):108-114.

Zimmermann, M.B., Hess, S.Y., Molinari, L., (2004) New reference values for thyroid volume by ultrasound in iodine sufficient schoolchildren: a WHO/NHD Iodine Deficiency Study Group Report. *Am. J. Clin. Nutr.,* 79: 231-237.

ABBREVIATIONS AND ACRONYMS

ABS	Australian Bureau of Statistics
AHMAC	Australian Health Ministers' Advisory Council
AHMC	Australian Health Ministers' Conference
CNS	New Zealand Children's Nutrition Survey
DALY	Disability adjusted life year
EAR	Estimated average requirement
FRSC	Food Regulation Standing Committee
FSANZ	Food Standards Australia New Zealand
ICCIDD	International Council for the Control of Iodine Deficiency Disorders
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
NZ 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 (1000th of a milligram)
mg	milligrams (1000th of a gram)
g	grams

Attachment 1

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

To commence: 12 months from gazettal

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

[1.1] *omitting the* Purpose, *substituting –*

This Standard regulates the addition of vitamins and minerals to foods, and the claims which can be made about the vitamin and mineral content of foods. Standards contained elsewhere in this Code also regulate claims and the addition of vitamins and minerals to specific foods, such as, the addition of iodised salt to certain foods and the addition of thiamin to 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, 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, qualifies the use of the term 'bread', requires the mandatory fortification of flour for making bread with thiamin (Australia only) and requires the mandatory replacement of non-iodised salt with iodised salt in certain foods.

[2.2] *inserting after clause 4 –*

5 Mandatory addition of iodised salt to certain foods

(1) Subclause 1(2) of Standard 1.1.1 does not apply to this clause.

(2) Where salt is added to –

- (a) biscuits;
- (b) bread; and
- (c) breakfast cereals

it must be iodised salt.

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 biscuits, bread and breakfast cereals.

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.

[3] ***Standard 2.10.2*** *of the Australia New Zealand Food Standards Code is varied by –*

[3.1] *omitting clause 6, substituting –*

6 Composition of iodised salt

(1) Subclause 1(2) of Standard 1.1.1 does not apply to this clause.

(2) Iodised salt must contain iodine in a permitted form equivalent to –

(a) no less than 20 mg/kg of iodine; and
(b) no more than 45 mg/kg of iodine.

[3.2] *omitting clause 7, substituting –*

7 Composition of iodised reduced sodium salt mixtures

(1) Subclause 1(2) of Standard 1.1.1 does not apply to this clause.

(2) Iodised reduced sodium salt mixtures must contain iodine in a permitted form equivalent to –

(a) no less than 20 mg/kg of iodine; and
(b) no more than 45 mg/kg of iodine.

Editorial note:

The Schedule to Standard 1.1.1 specifies the permitted forms for iodine.

Attachment 2

Policy Guideline
Fortification[21] 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 were 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:

[21] 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.
5. 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 restoration[22]).

    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.

---

[22] 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.

Attachment 3

Development of a Bi-National Monitoring System to Track the Impact of Regulatory Decisions on Mandatory Iodine Fortification

Contents

Introduction

Monitoring is a fundamental component of mandatory and voluntary fortification programs, to ensure that fortification is effective, both in meeting the objectives of improving the nutritional intake and status of the target population as well as ensuring the public health and safety of target and non-target groups (Stanley at al 2005, Nexus 2006). Information from an ongoing monitoring system will also provide evidence for future policy decision making on whether to continue a mandatory fortification program or not. In the case of iodine it is particularly important to monitor iodine levels in iodised salt and an indicator of the impact of fortification on health on a regular basis as the level of iodisation of salt may need altering from time to time to achieve the desired population health outcome (WHO 2001, Dunn 1996, Zimmermann 2005).

The Australia and New Zealand Food Regulations Ministerial Council *Policy Guideline on the Fortification of Food with Vitamins and Minerals* (Policy Guideline, ANZFRMC 2004) provided guidance on monitoring for both mandatory and voluntary fortification.

1. Policy Guideline

1.1 Mandatory Fortification Programs Monitoring Framework

The Policy Guideline states for mandatory fortification that:

> *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.*

In December 2004, Food Standards Australia New Zealand (FSANZ) sought advice from the Food Regulation Standing Committee (FRSC) in relation to monitoring the impact of mandatory fortification, as required by the Policy Guideline. A FRSC sub-group working on this advice provided a draft framework in December 2005 for the development of monitoring systems to complement mandatory fortification programs. The FRSC sub-group met in June 2006 to further progress this draft framework for consideration by FRSC at its next meeting (FRSC sub group 2006). An agreement was also made at the FRSC sub group meeting to establish an expert group to develop the monitoring system specifically required for iodine.

The draft framework notes that for any given mandatory fortification program a monitoring program will need to be developed and will vary from nutrient to nutrient. The purpose of this monitoring will be to assess the effectiveness of and continuing need for the specific mandatory fortification program.

1.2 Monitoring the Impact of Food Standards Decisions on the Voluntary Addition of Vitamins and Minerals to Specific Foods

Similarly for voluntary fortification, the Policy Guideline states:

> *A permission to voluntarily 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.*

As part of its role in developing food standards that permit voluntary addition of vitamins and minerals to specific foods, FSANZ has agreed to develop a five year monitoring system to assess the impact of these decisions over time on the nutritional status of the Australian and New Zealand populations.

For nutrients such as iodine, where there is likely to be a mandatory requirement to fortify salt used in some processed foods with iodine as well as voluntary permissions to fortify table and cooking salt, the monitoring system will need to include information on the impacts of both mandatory and voluntary fortification.

2. Proposed Monitoring System

Monitoring the impact of fortification of foods with iodine extends beyond FSANZ's responsibilities under the *Food Standards Australia New Zealand ACT 1991*, and will require the concomitant involvement of health and regulatory agencies at a Commonwealth, State and Territory level in Australia and the New Zealand Government.

FSANZ has adapted the draft generic monitoring framework for mandatory fortification prepared by the FRSC working group and outlined the potential elements of a monitoring system that aims to assess the impact on consumers of mandatory fortification of the food supply with iodine.

As with 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.

2.1 Objective of the Monitoring System

The main objective of a comprehensive monitoring system for iodine would be to investigate the impact of cumulative fortification permissions for iodine (mandatory and voluntary) on the:

- food supply; and
- population as a whole and on population subgroups in relation to health (assessed in terms of level of thyroid function, urinary iodine for the target groups of young children, women of child bearing age and/or an indicator group of school age children[23], adequacy of nutrient intakes, safety of nutrient intakes and prevalence of adverse health affects linked to excessive iodine intakes for the general population).

2.2 Clarification of Questions to be Asked and Answered by Data Collected via the Monitoring System

In developing a monitoring system the FRSC sub group notes that the questions to be answered need clarification (FRSC sub group 2006). Figure 1 is an outcomes hierarchy outlining process, impact and outcome questions to be considered.

---

[23] Pregnant/lactating women and breastfed infants appear to have the poorer iodine status than school age children. The WHO recommendation to use school age children as an indicator population is based on the ease of access to this population group compared to women or young children.

The draft FRSC sub group framework identifies three areas relating to the development of a monitoring system for the addition of vitamins and minerals to the food supply:

1. Monitoring components, for example nutritional status of the target and non-target population, nutrient composition and variability in fortified foods, industry and consumer awareness and support/acceptance of the fortification program.
2. Data collection and mechanisms, noting to use routine data collections if available and the need for specific market research regarding industry and consumer awareness.
3. Timeliness, noting that baseline data on health status, nutritional status and nutrient intake should ideally be collected prior to implementation of a fortification program.

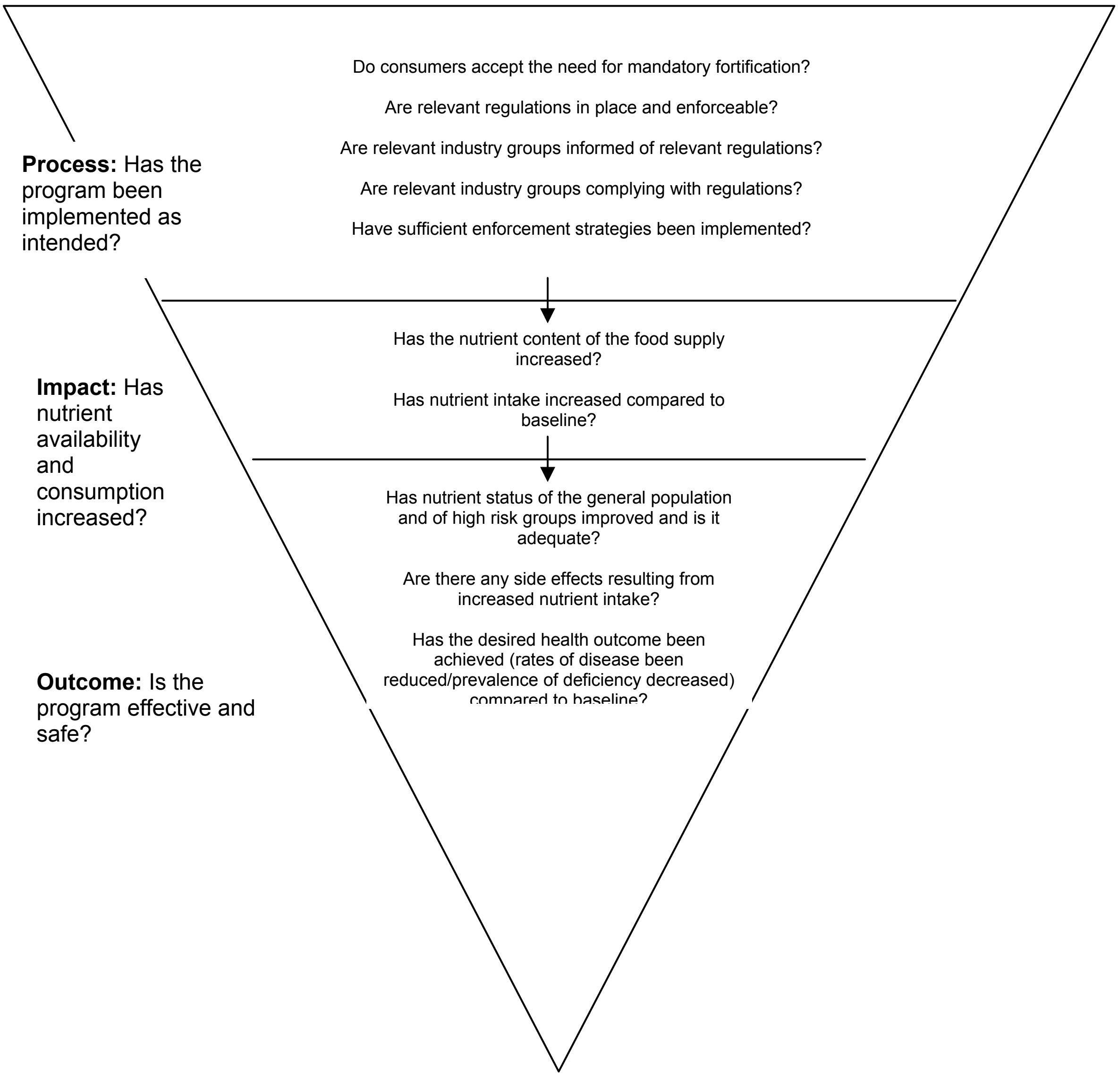


Figure 1: Outcomes hierarchy for monitoring mandatory fortification programs (adapted from Abraham B, Webb K 2001)

2.3 Developing a Monitoring System for Iodine Fortification

Ideally, most of the data required to monitor the impact of iodine fortification would be collected as part of an existing ongoing national food and nutrition monitoring system (Nexus 2006, Marks *et al.* 2001, Stanley 2005). In New Zealand national nutrition surveys are conducted on a regular basis. However, as such a system has not been established to date in Australia, the proposed monitoring system for iodine fortification taps into existing data collections where possible and identifies where new work is required, similar to the approach taken in Canada to evaluate their folic acid fortification program (PHAC, 2005). Parts of the monitoring system outlined here will be common to all monitoring systems for nutrients, for example, the collection of data on food consumption patterns.

Characteristics of good iodine monitoring systems have been developed by WHO and adapted as part of the Tasmanian Iodine Monitoring Program and address issues such as acceptability, compatibility, cost, equity, performance and technical feasibility of the elements selected to form part of the comprehensive system (Appendix 1). Consideration of these and other characteristics provides a useful checklist for the development of monitoring systems in a health environment designed to support fortification programs.

2.3.1 Steps Required to Achieve an Effective Increase in Iodine Status of the Population

In achieving the end objective of iodine fortification of the food supply, protecting public health and safety by reducing the prevalence of iodine deficiency in the Australian and New Zealand populations whilst maintaining the safety of the general population, it is useful to take a program logic approach to identify the interim steps and objectives that must be achieved before this end objective is reached, as shown in Figure 2 (UNDP, 2002). This framework also indicates a timeline, in that each step has to be in place before the next step can be achieved or measured. For example, the food industry will be given a transition period to implement mandatory fortification and may take time develop new products if voluntary permissions to fortify are given. Measurement of impact on consumer awareness, behaviour, food and supplement consumption patterns and ultimately on iodine status must therefore be undertaken at a reasonable time interval after the products appear on the shelves for purchase.

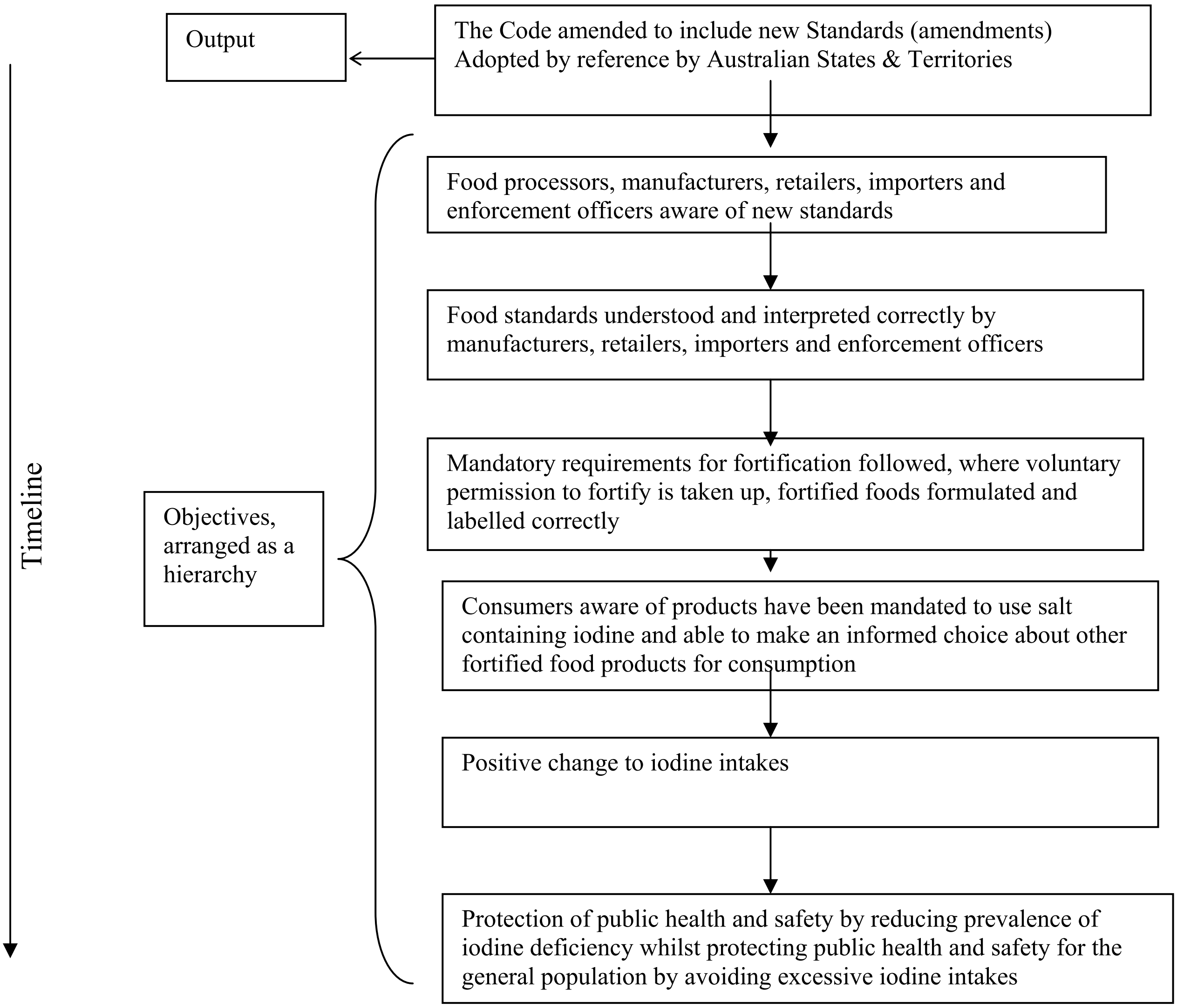


Figure 2: Evaluation of Permissions to Fortify Foods Against FSANZ Act Section 10, Objectives

2.3.2 Assessing Interim Outcomes

The main objective of a mandatory fortification program for iodine in Australia and New Zealand is to reduce the prevalence of iodine deficiency. Direct measurement of the end effect of iodine deficiency over a period of time on brain development and IQ is difficult in populations with mild to moderate levels of deficiency (WHO 2001, Dunn 1996, Zimmermann 2004). However, measurement of indicators of iodine status, such as urinary levels of iodine, is relatively easy. Although the main target group for iodine fortification is young children and women of child bearing age because their iodine status is generally lower than other population sub-groups, it is recognised that these groups may be hard to access for testing in some countries. An alternative recommended by WHO is to select an ‘indicator’ population group who are easier to access, such as primary school age children (WHO 2001).

2.3.3 Indicators of Iodine Status

Measurement of urinary iodine levels is recognised as a reliable indicator of the level of iodine deficiency in a given population because levels are expected to increase as iodine intakes increase and is an essential component of any monitoring system that aims to assess the effectiveness of an iodine fortification policy (Dunn 1996, Zimmermann 2004, 2005, WHO 2001).

Other indicators of thyroid function such as thyroid size, thyroid stimulating hormone (THS) concentrations in neonates or thyroglobulin concentrations in adults and children may also provide useful monitoring data, all of which are expected to decrease once iodine repletion is achieved (Zimmermann 2004, WHO 2001). In populations with mild to moderate deficiency, the best method of measuring thyroid size is by ultrasound rather then palpitation (WHO 2001). However, as thyroid size changes slowly these measurements can only assess long-term impacts of a fortification program not short-term effects and may in fact show different trends from urinary concentration data in the first few years of a iodine fortification program (WHO 2001, Zimmermann 2004). In addition some symptoms of iodine deficiency such as the formation of nodules in the thyroid are irreversible in adults, despite iodine fortification, one of the reasons for the preferred choice of children as an indicator group for monitoring. The measurement of neonatal TSH levels as a sensitive indicator of iodine status of the mother during pregnancy is also not straightforward as other factors can influence results, such as the timing of specimen collection, exposure to antiseptics containing iodine in the hospital environment, assay equipment used (Zimmermann 2005).

Currently there are no systems in place in Australia or New Zealand to collect any clinical indicators of iodine status on a regular basis, although studies have been undertaken that indicate a re-emergence of iodine deficiency in both the Australian population (Li at al 2006, 2001) and the New Zealand population (Thomson al 2001). In an ongoing monitoring system it would also be necessary to collect information on potential unintended adverse health effects of increasing iodine intakes for all population groups, particularly on people with hypothyroidism, who are sensitive to sudden increases in iodine intake from food or supplements and may develop iodine-induced hyperthyroidism.

Although not absolutely essential it would also be very useful for future policy decision making on whether to continue a mandatory fortification program or not, to collect additional data on how the fortification policy has affected the whole food system, particularly in this case on changes in the level of iodine in salt, the use of iodised salt in manufactured foods including processing, storage and food preparation losses of iodine in different food matrices and consumers' discretionary salt use (WHO 2001).

This would be particularly important if implementation of the mandatory fortification program did **not** achieve the desired end outcome of increasing urinary iodine levels or decreasing thyroid size, thyroglobulin blood levels in children and adults or THS levels of neonates by the expected amount, or if there was evidence that it was adversely affecting the population in general.

A comprehensive monitoring system should provide sufficient data to answer the question *'why is it not working?'* and be able to identify the best intervention point for improving the system in the future to achieve a better outcome.

2.3.4 Interpretation of Results

In many cases it is difficult to interpret data to assess the effect of implementing a food standard against the end objective of setting that standard. The external influences on public health and safety as a whole are so complex and influenced by many external factors that a measured change to the level of health and safety of a given population group cannot generally be attributed to a single influence, a single agency or action by an agency, such as a change in food regulatory measures. However, reasonable performance measures (indicators) can be developed for interim objectives to assess if they have been achieved.

In selecting performance measures for specific monitoring activities in a fortification monitoring system it is important to determine priority setting criteria and assign a relative importance to them (see Appendix 1, adapted from Reardon 2002). The determination of priorities for different elements of the monitoring system for assessing the impact of iodine fortification will be the subject of discussion for the expert group to be established under the FRSC sub group. Selection of elements will be dependent on the usefulness of the data collected to measuring the success of the fortification program as well as the funds agreed and set aside for this purpose.

2.3.5 Proposed Monitoring Activities for Iodine Fortification

The questions posed by the FRSC sub group that need to be asked and answered as part of any monitoring system for fortification (Figure 1) have been linked to the interim steps identified in Figure 2 that need to be in place to achieve a decrease in iodine deficiency in Table 3. Performance measures are suggested for each step, with the method of measurement and the agency(ies) with potential responsibility for undertaking the proposed program activities outlined. Further details of each proposed program activity is given in Appendix 1.

It is apparent that an increasing number of external factors that may affect the outcome come into play as you go down the flow chart that shows the hierarchy of outcomes and that it will not be feasible for FSANZ on its own to develop a means of measuring all interim outcomes. The funding and staff resources required need to be considered for each option, as does the role and responsibilities of each agency and the potential usefulness of the information collected to FSANZ, other Commonwealth agencies and the jurisdictions.

Obviously, one of the most important data sources on the overall impact of fortification of the food supply on nutritional status will be that obtained from national nutrition surveys (NNS) as outlined in Table 2, Interim objective 6, providing a baseline and follow up survey are undertaken. The usefulness of the nutrient intake data obtained will depend on an up to date food composition database being available for iodine to combine with collected food consumption data. For iodine the NNS data will be particularly valuable if data on discretionary salt use is captured and current levels of iodisation are known. Suggestions for other data collections to assess interim objectives 1-5 are intended to complement NNS data, not replace these data.

Table 3: Monitoring the Impact of Regulatory Decisions to Add Iodine to Salt in Cereal-Based Foods

Interim objective	Questions to be answered	Performance measure	Method	Responsibility
1. New standards in place (mandatory and/or voluntary requirements)	Are relevant regulations in place and enforceable?	Standards implemented in States & Territories, New Zealand.	Report back from jurisdictions when standards adopted into their food laws, with assessment of enforcement capability.	FSANZ, NZFSA, State & Territory agencies with food regulatory responsibilities
2 & 3. Food processors, manufacturers, retailers, importers and enforcement officers aware of new standards **Food standards understood and interpreted correctly by manufacturers, retailers, importers and enforcement officers**	Are relevant industry groups informed of relevant regulations? Have sufficient enforcement strategies been implemented?	Proportion of food processors, manufacturers, retailers, importers and enforcement officers who know about and interpret standard correctly.	Stakeholder surveys	FSANZ
4. **Mandatory requirements for fortification followed, where voluntary permission to fortify is taken up, fortified foods formulated and labelled correctly**	Are relevant industry groups complying with regulations? Has iodised salt been used in manufacture of required foods instead of ordinary salt and labelled correctly? Is iodised table salt available and labelled correctly?	**Foods available:** Proportion of different categories of foods that have used iodised salt in manufacture (mandated foods and others) **Labelling requirements**: Proportion of cereal foods and table salt labelled correctly. Proportion of fortified foods where actual content reflects label claims. **Nutrient content:** Changes in iodine concentrations in salt, food, water and supplements (including use of erythrosine as colouring, as it is iodine rich, Zimmermann 2005).	Data from manufacturers on brands available in market with iodised salt, to be updated annually. Proportion of iodised and non-iodised table salt used from salt disappearance data. Analytical survey of level of iodine at manufacture, after food processing and compared with label information. Update Australian and NZ national food composition databases on regular basis, including information on losses of iodine during food preparation.	FSANZ/AFGC/NZFGC to coordinate States & Territories, NZ could assist with analysis of foods vs. labelling claim FSANZ NZFSA with NZ Crop and Food Institute

Interim objective	Questions to be answered	Performance measure	Method	Responsibility
5. Consumers aware of products that have been mandated to contain iodine and able to make an informed choice about other fortified food products for consumption	Do consumers change their attitudes and behaviour in relation to food purchases? Why? Do consumers accept the need for mandatory fortification? How do consumers use iodine supplements?	**Research consumer attitudes and behaviours towards fortified foods:** Changes in consumer understanding and behaviour in relation to products containing iodised salt, discretionary use of table salt (added at table and/or use in cooking) and food labelling.	Consumer attitudes to food standards issues tracking survey. Targeted consumer surveys on specific issues incl response to education campaigns, substitution patterns for new products, consequential behaviour change. Call back surveys to sub set of respondents in Roy Morgan Single Source survey and Young Australian survey on specific foods/issues.	FSANZ, NZFSA
	Do consumers change food consumption patterns?	**Food consumption patterns**: Proportion of consumers consuming foods containing iodised salt. Use of discretionary salt in cooking or added at table. Changes in food purchase patterns for Aboriginal and Torres Strait Islander groups **Supplement consumption** Proportion of target and non target group consuming iodine supplements, amounts consumed	Survey of individuals (type of food and supplements consumed, frequency, amount): a) National nutrition survey of individuals (Food Frequency survey and 24-hour recall) every 10 years. b) Roy Morgan Single Source survey (Australia and NZ) and Young Australian survey, frequency of food consumption for individuals every 3 months. c) Market basket surveys of remote area stores National nutrition survey of individuals (as above). Other national, S&T surveys.	DoHA with jurisdictions, FSANZ NZFSA/MOH NZ FSANZ as coordinating agency States & Territories As above Inclusion of relevant questions to be negotiated

Interim objective	Questions to be answered	Performance measure	Method	Responsibility
6. Positive change to iodine intakes	Has iodine intake increased compared to baseline? Is iodine status of the general population and target groups improved and adequate compared with nutrient reference values?	Changes in proportion of consumers meeting reference health standards for iodine (EAR)	Nutrient intake assessments: a) NNS 24- hour recall survey with repeat 24 hour record for second day nutrient adjustments, combined with an up to date iodine concentration database, preferably with information on iodine supplements consumed.	Inter-agency (incl TGA), FSANZ NZFSA/MOH NZ
7. Protection of public health & safety by increasing iodine status and no adverse effects for general population	Has the desired health outcome been achieved for target group (i.e. proportion of population with desirable level of urinary iodine increased, thyroid function improved compared to baseline)	Increases in urinary iodine levels (proportion population below 50 µg/L, below 100 µg/L, above 300 µg/L) Decreases in thyroid size and/or blood spot thyroglobulin levels, newborn thyroid stimulating hormone levels as indicator of status in pregnancy Changes in proportion of consumers exceeding upper levels (UL) of iodine intake	Urine collection and tests Blood tests (thyroid stimulating hormone for neonates, blood spot thyroglobulin for adults and children) Thyroid size (by ultrasound) NNS 24- hour recall survey with repeat 24 hour record for second day nutrient adjustments, preferably with information on iodine supplements consumed.	AHMAC Some tests could be incorporated in existing studies by negotiating extra funding for add on component Inter-agency (incl TGA), FSANZ NZFSA/MOH NZ
	Are there any side effects resulting from increased intake for target or non target groups?	Changes in other health indicators to which links to excessive iodine intake have been made (e.g. impact on people with hypothyroidism)	Health statistics of people with iodine-induced hyperthyroidism Literature review of existing health programs with published data	AIHW

AFGC Australian Food and Grocery Council, AIHW Australian Institute of Health and Welfare, AHMAC Australian Health Ministers Advisory Council, DoHA Department of Health and Ageing, EAR Estimated Average Requirements, MOH NZ Ministry of Health New Zealand, NZFGC New Food and Grocery Council, NZFSA New Zealand Food Safety Authority, TGA Therapeutic Goods Administration.

3. Key Consumer Issues

There is a growing evidence base on Australian and New Zealand consumer attitudes and behaviour in relation to general food labelling issues (FSANZ 2001, 2003a, 2003b, 2003c, 2004a, 2004b, 2005c, 2005d). However, there is a paucity of data and research covering consumer response to fortification of the food supply and in particular to voluntary fortification, where there may be a choice of fortified and non-fortified products within a given food category (Frewer 2003, Health Canada 2005a, 2005b, Zimmermann 2005, Dunn 1996). The situation is further complicated when considering voluntary fortification, as additional opportunities for consumer choice may be provided in a fluid and evolving marketplace. The nature and scale of impacts on public health and safety as a consequence of mandatory and voluntary fortification will be determined in part by the actions and behaviour of consumers. However the behaviour of consumers is complex, difficult to predict, and is influenced by many factors.

With respect to fortification some of the key consumer issues that have been raised include (in no specific order):

- awareness and understanding of the fortification of foods;
- likely consumption patterns including degrees of substitution of existing foods by new fortified foods, and of the addition of fortified foods to diet;
- impacts of product consumption on other lifestyle/health behaviours (e.g. alcohol use and exercise levels)
- likely consumption patterns within demographic and cultural groups;
- degrees of consumer choice/autonomy;
- advertising claims and the construction of fortified foods as healthy;
- complexity of health and diet messages and potential for conflicting advice; and
- ensuring informed consumer choice.

A monitoring study provides an opportunity to collect relevant data and research on consumer attitudes and behaviour and to substantiate or qualify the assumptions made in risk assessments undertaken by FSANZ in preparing standards on fortification on how consumers may behave when faced with a choice of fortified and unfortified products, for example, what consumers think about using iodised salt in the light of other health messages about cutting down total salt intake, and to assess the overall impact of these decisions on the resultant nutritional status of the population.

4. Costs and Resources

Comprehensive monitoring systems are expensive and difficult to resource on an ongoing basis, however an ongoing system is much more effective, minimising the costs of lost expertise and resources overtime compared to one off systems (Nexus 2006). As mentioned above there will be a need for joint sharing of costs and resources for a monitoring system between Commonwealth, State, Territory and New Zealand agencies. Wherever possible data collections should be added onto existing surveys or data collection systems as this will minimise the overall costs.

Table 5 gives some indicative costs for assessing the outcome of each component in the proposed monitoring system, drawn from current costs for consumer research, predicted costs for the proposed Australian national children's nutrition and physical activity survey indicative costs for States and Territories to establish and run a national urinary iodine reporting system under the Australian Ministers Advisory Council (AHMAC) funding agreement and possibly measure thyroid size and/or test blood for the nominated target or indicator population groups.

Further details are given in Appendix 2, noting that for each interim objective there may be several program activities that will contribute to the collection of data for performance measures, each with a different allocation of funds. The priority accorded to each program activity will need to be agreed by all participating jurisdictions and agencies and used as a guide to allocate funding overall. As this monitoring system will generate a large amount of baseline and follow up data, funding for a program support officer has been included in the costs to provide a coordinating role for system establishment, data collation, reporting and communication of outcomes.

Table 5: Indicative Costs for the Proposed Monitoring Program Activities for Australia

Interim objective	**Program activities**	**Costs over 5 years**
1. New standards in place (mandatory and/or voluntary requirements)	Report from jurisdictions to FSANZ	NIL
2 & 3. Food processors, manufacturers, retailers, importers and enforcement officers aware of new standards Food standards understood and interpreted correctly by manufacturers, retailers, importers and enforcement officers	Baseline and follow up stakeholder attitude and behaviour surveys (email or computer aided telephone interviews)	$ 180 000
4. Mandatory requirements for fortification followed, where voluntary permission to fortify is taken up, fortified foods formulated and labelled correctly	Update National Food Composition Database regularly Reporting system for food industry on products available, Label monitoring survey Label compliance analytical surveys	$ 312 000 country (Excl label compliance surveys)
5. Consumers aware of products that have been mandated to contain iodine and able to make an informed choice about table salt and other fortified food products for consumption	National nutrition survey (costed in (6), Food frequency surveys (Roy Morgan) Market basket store surveys in remote communities Consumer attitude and behaviour research State and Territory surveys	$ 590 000 (Excl State & Territory, NZ surveys)
6. Positive changes to iodine intakes	National Nutrition Survey	$ 100 000* per country (Excl State & Territory, NZ surveys)
7. Protection of public health & safety by reducing prevalence of iodine deficiency	National nutrition survey (as above) Urine collection Add on to existing blood surveys for neonates, children and adults, other health data collections	$ 840 000 (Excl thyroid function tests)
Overall system support	Project support officer	$ 500 000

* It should be noted that the cost of reporting one nutrient from an Australian National Nutrition Survey has been included here, assuming a national nutrition survey program is in place, by diving the total cost of a survey by the number of nutrients to be reported. If a food consumption survey had to be established as a one-off cost for the iodine monitoring system the costs would be much higher (see Appendix 2).

4.1 FSANZ's Contribution to the Monitoring System

As part of its ongoing work, FSANZ will contribute directly to the following elements of the monitoring system:

- tracking changes in the food supply for salt, fortified/unfortified foods in key food categories in consultation with the food industry (interim step 2/3);
- updating the food composition databases via the Key Foods Analytical Program and entry of results into the Australian National Nutrient Database that FSANZ manages and subsequent national nutrition survey databases, including iodine levels in table salt and water supplies (interim step 4);
- tracking labelling changes on fortified foods via the ongoing FSANZ label monitoring survey (interim step 4);
- tracking changes in food consumption patterns for different demographic groups (food consumption frequency only) in key food categories that are likely to be fortified via purchase of Roy Morgan Single Source Survey data (interim step 5); and
- researching changes in consumers' attitudes and behaviour towards fortified foods (interim step 5).

FSANZ may also be involved indirectly in other program activities, possibly in an advisory capacity.

5. References:

General
Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC)(2004). Policy Guideline on the fortification of food with vitamins and minerals.

Monitoring
Abraham, B., Webb, K. (2000) Interim evaluation of the voluntary folate fortification policy, Australian Food and Nutrition Monitoring Unit, consortium of The University of Queensland, The University of Sydney and Deakin University.

Anderson. E., Perloff, B., Ahuja, J.K.C., Raper, N. (2001) Tracking nutrient changes for trends analysis in the United States. *J. Food Comp. Analysis,* 14:287-294.

Cameron, A. (2003) First report on the Tasmanian Iodine Monitoring program for the period 1 July 2002 to 31 December 2002, prepared for the Tasmanian Department of Health and human services by Broad Street Consultants, January 2003.

Cook, T., Rutishauser, I.H.E., Seelig, M. (2001) Comparable data on food and nutrient intakes and physical measurements from the 1983, 185 and 1995 national nutrition surveys, Australian Food and Nutrition Monitoring Unit, consortium of The University of Queensland, The University of Sydney and Deakin University.

Dunn, J.T. (1996) Seven deadly sins in confronting endemic iodine deficiency and how to avoid them, *J. Clin. Endocrinol. Metab.*, 81(4):1332-1335.

FRSC sub group on Addition of Substances (2006) Mandatory fortification: a framework for developing monitoring systems (draft).

Gill, T., Holden, K., Taylor, A., Carter, P. (2003) Status of indicators and monitoring of nutrition and food behaviour in South Australia, Report prepared for Health Promotion SA, December 2003.

Li, M., Creswell, J.E., Waite, K.V., Ma, G., Zacharin, M.R., Topliss, D.J., Harding, P.E., Walsh, J.P., Ward, L.C., Mortimer, R.H., MacKenzie, E.J., Byth, K., Doyle, Z. (2006) Are Australian children iodine deficient? Results of the Australian National Iodine Nutrition Study. *Med. J Aus.*, 184(4); 165-169.

Li, M., Ma, G., Boyages, S.C., Eastman, C.J. (2001) Re-emergence of iodine deficiency in Australia, *Asia. Pac. J. Clin. Nutr.*, 10:681-683.

Marks, G.C., Rutishauser, I.H.E., Webb, K., Picton, P. Key food and nutrition data for Australia 1990-1999, Australian Food and Nutrition Monitoring Unit, consortium of The University of Queensland, The University of Sydney and Deakin University.

Nexus Management Consulting (2006) A national food and nutrition monitoring surveillance system: a framework and business case, Final Report, April 2006.

Northern Territory Government (2005) Market Basket Survey of remote community stores in the Northern Territory, Department of Community Services, Northern Territory Government.

Public Health Agency of Canada (PHAC) (2003) Evaluation of food fortification with folic acid for the primary prevention of neural tube defects 1997-2003, Executive Summary and Full Report,.

Reardon, M.A. (2002) Iodine status of the Tasmanian population – development of a monitoring and surveillance program, Project presented as part of the requirement for award of the Master of Public Health of the Curtin University of Technology, October 2002.

Stanley, F., Eastman, C., Mann, J., Binns, C. (2005) The effectiveness of mandatory fortification as a public health strategy to increase nutrient intakes, with reference iodine and folate, expert public health advice, prepared for the Australia and New Zealand Food Regulation Ministerial Council, June 2005.

Thomson, C.D., Woodruffe, S., Colis, A.J., Joseph, J., Doyle, T.C. (2001) Urinary iodine and thyroid status of New Zealand residents. *Eur. J. Clin. Nutr.*, 55; 387-392.

United Nations Development Programme (UNDP 2002) Handbook on monitoring and evaluating for results, UNDP, Evaluation Office, New York, USA.

World Health Organisation (WHO) (2001) *Assessment of iodine deficiency disorders and monitoring their elimination: a guide for program managers, second edition*, WHO, Geneva, Switzerland.

Zimmerman, M.B. (2005) Increasing the iodine concentration in the Swiss iodised salt program markedly improving iodine status in pregnant women and children: a 5-y prospective study. *Am. J. Clin. Nutr.*, 82; 388-392.

Zimmerman, M.B. (2004) Assessing iodine status and monitoring progress of iodised salt programs, *J Nutr*; 134: 1673-1677.

Label monitoring

Food Standards Australia New Zealand (FSANZ) (2005a) Food label monitoring survey, July 2002-December 2003, Phase 1 report (incorporating Stages 1 and 2), Evaluation Report Series no 10, FSANZ
http://www.foodstandards.gov.au/mediareleasespublications/publications/evaluationreportseries/foodlabelmonitoringsurvey/flmsoverviewfactshee3077.cfm

Food Standards Australia New Zealand (FSANZ) (2005b) On going food label monitoring survey in Australia and New Zealand: report on the re-assessment of 2003 labels for nutrition, health and related claims (Phase 2), Evaluation Report Series no 14, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/evaluationreportseries/ongoingfoodlabelmonitoringsurveyno14/index.cfm

West Australian Food Monitoring Program (2005) Accuracy of nutrition information panels 2000-2002 – A Survey by the West Australian Food Monitoring Program. http://www.population.health.wa.gov.au/Environmental/resources/Accuracy%20nutrition%20info%20panels%20051024.pdf

Consumer research on labelling and fortification
Food Standards Australia New Zealand (FSANZ) 2001. Food Labelling Issues: Consumer Qualitative Research Report**,** December 2001, Evaluation Report Series No 2, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/foodlabellingissuesconsumerresearchdecember2001/index.cfm

Food Standards Australia New Zealand (FSANZ) 2003a. Food Labelling Issues: Quantitative Research with Consumers, June 2003**,** Evaluation Report Series No 4, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/foodlabellingissuesquantitativeresearchconsumersjune2003/index.cfm

Note – full results are given on website in interactive PowerPoint presentation (hard copy has enclosed disc)

Food Standards Australia New Zealand (FSANZ) (2003b) A Qualitative consumer study related to nutrient content claims on food labels, June 2003, Evaluation Report Series No 5, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/consumerstudyrelatedtonutritioncontentclaimsjuly2003/index.cfm

Food Standards Australia New Zealand (FSANZ) (2003c) A Qualitative consumer study related to food-type dietary supplement labelling, July 2003**,** Evaluation Report Series No 6, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/consumerstudyrelatedtofoodtypedietarysupplementlabellingjuly2003/index.cfm

Food Standards Australia New Zealand (FSANZ) 2004a. Food Labelling Issues: Quantitative Consumer survey on Allergen labelling: Benchmark 2003, Evaluation Report Series No 7, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/allergensurvey/index.cfm

Food Standards Australia New Zealand (FSANZ) (2004b) A qualitative consumer study related to food labelling of infant foods, Evaluation Report Series No 9, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/foodlabellingofinfantfoodsapril2004/index.cfm

Food Standards Australia New Zealand (FSANZ) (2005c) Food labelling issues: qualitative research on participants' perceptions and use of nutrient, health and related claims on packaged foods and associated advertising material, Evaluation Report Series no 12, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/evaluationreportseries/healthclaimsqualitat3069.cfm

Food Standards Australia New Zealand (FSANZ) (2005d) Food labelling issues: quantitative research on participants' perceptions and use of nutrient, health and related claims on packaged foods, Evaluation Report Series no 13, FSANZ http://www.foodstandards.gov.au/mediareleasespublications/publications/evaluationreportseries/healthclaimsquantita3070.cfm

Frewer, L., Scholderer, J., and Lambert, N. (2003) Consumer acceptance of functional foods: issues for the future. *British Food Journal.* Vol. 105:10, pp. 714-731.

Health Canada 2005. Understanding the forces that influences our eating habits: What we know and need to know. *Canadian Journal of Public Health*. Vol 96, supp. 3, pp. s1-s46.

Health Canada (2005) *Canadian consumer perspectives on food fortifications*. Health Canada.

Steptoe A, Pollard TM, Wardle J (1995) Development of a measure of the motives underlying the selection of food: the food choice questionnaire, *Appetite: 25: 267-284*.

Appendix 1

Table 1: General Characteristics of a Good Monitoring and Surveillance System in a Health Environment (adapted from Reardon 2002)

Characteristics	*Explanation*
Management structure	Access to an advisory committee or expert group A focus on building partnerships and providing leadership – links with both the research and practice sector, links with interventions to improve nutrient status and health outcomes Links with policies and other key client groups Sound data management processes and data confidentiality procedures and expertise in interpreting and analysing the data Commitment to data development and harmonisation, where required Sound understanding of data ownership
Communication	Regular reporting/publication of findings Results accessible to stakeholders (in a user-friendly form) Follow-up and feedback to participants and stakeholders Capacity to produce high quality, timely and accessible statistical reports and information
Sustainability	Adequate infrastructure to ensure ongoing monitoring and minimise loss of expertise) Commitment to and access to ongoing funding Retention of expertise and avoidance of start up costs resulting from intermittent funding Alignment with the broader health monitoring systems
Flexibility	Regular reviews to respond to scientific developments Capacity to identify and address data gaps and deficiencies

Table 2: Priority Setting Criteria for Selecting Performance Measures (adapted from Reardon 2002)

Priority setting criteria	**Explanation of meaning**	**Relative importance**
Acceptability	How acceptable is it to the target population? How acceptable is it to the field staff doing tests? Are there any ethical concerns?	High
Compatibility	Are selected measures compatible with other monitoring and surveillance programs on nutrient status?	Medium
Cost	What is overall cost (capital, recurring cost for consumables, maintenance costs, training, admin and salary costs)? Is cost of program proportionate to problem? Who gains benefits, who bears the cost? Will it save resources overall?	Medium-high
Equity	Will there be an unequal burden on sub groups of population? Are all sub groups considered? If not why not?	Medium
Interpretability	Will measures be reflective of whole population? Are there adequate reference data to interpret results? Is there capacity to provide data for evaluation of national and state programs?	High
Performance	How useful is measure in terms of sensitivity, specificity and reliability? What is validity of measure?	High
Technical feasibility	How practical is the performance measure? (sample collection, preparation and storage, access to subjects in sampling frame, skills and resources needed to interpret data)	High
Using a combination of indicators	What is the minimum number of performance measures needed to ensure an effective monitoring and surveillance program?	Medium

Appendix 2

Table 3: Indicative Costs for the Proposed Program Activities

Program activity	Establishment/baseline research cost first year	Costs over remaining 4 year period	Lead agency	Priority for funding*
2/3a Stakeholder surveys Attitudes, awareness and understanding of new requirements in Code CATI or email survey with two stakeholder groups (industry, enforcement officers)	Baseline survey $ 100 000 Education campaign for industry on need for iodine fortification and use of iodised salt (esp small to medium size businesses)	Follow up industry surveys $ 80 000 Education campaign (TBC)	FSANZ with salt and food industry	Medium
4a Food supply survey Data from manufacturers on brands available in market place with iodised salt, and content to be updated annually. Salt disappearance data.	$ 75 000 x 1 year APS6 project officer to set up system and collate data	$ 80 000 ongoing data purchase ($ 20 000 per year)	FSANZ with AFGC/NZFGC. Manufactured Foods Database (NZ) Total diet surveys (NZ and Australia) Salt industry	High
4b Label monitoring survey Collect data on labelling of foods with iodised salt via ongoing label monitoring survey.	$ 20 000 purchase of sales data (EAN or bar code data)	$ 40 000 ($ 10 000 per year)	FSANZ	Low
4c Update National Food Composition Database Analyse key foods, table salt, water for iodine on regular basis	FSANZ survey established, $ 17 000 to collect extra baseline data ($ 90 per single iodine analysis, $ 200 for 12 trace elements; 190 samples)	$ 80 000 each country	FSANZ/NZFSA with NZ Crop and Food Research Institute	High
4d Compliance survey Analyse iodine levels of salt and food products compared with label information.	TBC	TBC	S&T, NZFSA	Low - medium

Program activity	Establishment/baseline research cost first year	Costs over remaining 4 year period	Lead agency	Priority for funding*
5a) Consumer attitudes to food standards issues tracking survey.	Targeted consumer surveys on specific issues incl substitution patterns for new products, consequential behaviour change.	$ 100 000 follow up surveys (targeted foods, could be combined with folic acid follow up surveys?)	FSANZ	Low
5b) Food consumption patterns from National dietary survey of individuals (FFQ survey and 24-hour recall, repeat 24 hour survey, individual records of food, salt and supplements consumption)	Baseline data – no costs 1995 NNS 1997 adults NZNNS 2002 children's' NZNNS	See NNS costs for (6) Follow up: 2007 Australian children's' NNS 2007 NZ adults survey	DOHA, States & Territories NZFSA	High
5c) Roy Morgan Single Source survey (Australia and NZ) and Young Australian survey	$ 230 000 for back data for Jan 2001-Mar 2006 Frequency of key food consumption for individuals every 3 months.	$ 200 000 ($50 000 subscription per year for next 4 years for new data on 3 month basis)	FSANZ	Medium
5d) Other national, S&T surveys.	Assess current data holdings	TBC	States & Territories	Low-medium
5e) Store market basket surveys	Baseline audit of foods available in remote areas (minimal added costs) $ 60 000 baseline	Follow up survey	States & Territories	Low-medium

Program activity	Establishment/baseline research cost first year	Costs over remaining 4 year period	Lead agency	Priority for funding*
6a) Iodine intakes from NNS 24- hour recall survey with repeat 24 hour record for second day nutrient adjustments, preferably with information on salt, iodine supplements consumed. **6b) iodine intakes from existing State & Territory surveys**	Australian NNS data with updated iodine food content, salt intake (no supplements) 1997, 2002 NZNNS data with updated iodine food content (some supplement data) (as modelled by FSANZ in P300) State & Territory surveys costs TBC	Data from follow up NNSs ~ $ 100 000 per nutrient per country (assuming 36 nutrients reported per survey, $3.6 mill cost for whole survey incl development of a food composition survey database)** State & Territory Surveys costs TBC	DOHA, States & Territories, NZFSA States & Territories	High Low - medium
7a. Urine tests **7b Literature review of relevant health statistics** **7c Thyroid function (thyroid size, blood tests)**	$ 300 000 Establishment costs (assumes some costs in kind from S&T) $ 20 000 Add onto existing health surveys (cost effective)	$ 500 000 Ongoing costs, assuming 2 follow up surveys (2 years after end transition period, and 5 years after). $ 20 000 at end of 5 years TBC	AHMAC cost share DOHA/AIHW DOHA/ States& Territories, NZFSA	High Medium Medium (thyroid size, neonates testing) Low (adult, children blood tests)
Overall monitoring system support#	$ 100 000 (APS6 with some admin support) Project officer to assist in establishing system, collate data/prepare reports	$ 100 000+ inflation per year for next four years	FSANZ/AIHW, other agencies	High

*To be confirmed after discussion with relevant health and regulatory agencies
**It should be noted that the cost of reporting one nutrient from a national nutrition survey has been included here, assuming a national nutrition survey program is in place, by diving the total cost of a survey by the number of nutrients to be reported. If a food consumption survey had to be established as a one-off cost for the iodine monitoring system the costs would be much higher
Costs could be shared with national folate/folic acid monitoring system
AFGC Australian Food and Grocery Council, AIHW Australian Institute of Health and Welfare, AHMAC Australian Health Ministers Advisory Council, DoHA Department of Health and Ageing, EAR Estimated Average Requirements, MOH NZ Ministry of Health New Zealand, NZFGC New Food and Grocery Council, NZFSA New Zealand Food and Grocery Council, NZFSA New Zealand Food Safety Authority TGA Therapeutic Good Administration.

Attachment 4

International Experience With Iodine Fortification Programs

Contents

USA

Endemic goitre from iodine deficiency was common in Midwest and Northwest America until the 1920s. From 1920 through until the 1950s iodine intake increased by the voluntary use of iodised salt. Also the use of iodine in various forms was increasingly used in the food industry, as a bread conditioner, food colouring, and from dairy products. The past decade has seen a decrease in urinary iodine levels, although still comfortably above the lower limit for iodine sufficiency[24].

The only national monitoring studies are the National Health and Nutrition Examination Surveys (NHANES) conducted by the US Center for Disease Control (CDC). The NHANES III, 1988-94 survey (most recent) reported median urinary iodine of 145 μg/L, this was a marked decrease from the median of 321 μg/L in the NHANES I, 1971-74 survey (IDD Newsletter 2001). This decrease was thought to be related to the reduction of iodine in milk and the replacement of iodine by bromine salts as the dough conditioner in commercial bread production. It is unknown the extent to which voluntary salt reduction, secondary to concerns about sodium intake and hypertension, has contributed to lower urinary iodine concentrations (Hollowell *et al.* 1998).

The voluntary iodisation of salt continues in the US today. It is estimated that 50 – 60 % of total salt consumption is salt that has been iodised[25]. Salt contains 100 mg iodine/kg as potassium iodide (76 gm/kg as iodine). No quality control takes place at the consumer level.

The US population gets iodine from other sources. These include dairy products, meat, vitamin supplements, health foods (such as kelp), skin antiseptics and certain medications.

No official program for iodine nutrition exists. The CDC who conducts the national nutritional surveys has agreed to continue iodine monitoring in its ongoing surveys.

Canada

Mandatory table salt iodisation 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 (Nutriview 2003/1). Today, mandatory fortification of salt with iodine exists in the whole of Canada. In Canada, household salt is iodised at 76 μg iodine/g (100 gm/kg as potassium iodide). A survey of salt samples in Ottawa in 1980 showed the iodine content to range from 30-84 mg iodine/kg (IDD Newsletter 2001). The coverage of iodised salt in Canada has reached near 100 %. Milk has also been a significant source of iodine. From 1987 data, the iodine content of milk ranged from 122 μg/L in Newfoundland to 517 μg/L in Manitoba (IDD Newsletter 2001).

There is no formal government program and no regular monitoring exists, although the country has extensive capacity to assess thyroid size and urinary iodine and conducts regular neonatal screening (IDD Newsletter 2001). Although recent data is lacking, it is assumed that iodine deficiency is unlikely.

---

[24] www.people.virginia.edu/~jtd/iccidd/mi/idd_178.htm Accessed 11/8/04

[25] IDD Newsletter 17 (1):8, February 2001

Germany

It has been reported that iodine deficiency continues to exist in some areas of Germany. However, a national survey conducted in 2000 of 3065 school age children in 128 sites reported a national median urinary iodine excretion of 148 µg/L, i.e. iodine sufficiency (IDD Newsletter. 2002). Salt iodised with potassium iodate at 20 mg potassium iodate /kg is used on a voluntary basis in humans, animals and the food industry. In addition to salt, livestock mineral supplements contain 10-40 mg iodine/kg. This has contributed to the iodine content of milk which was reported to be 130 µg/L in 1996 (IDD Website. 2003a)

Industrial salt iodisation was first allowed in 1991, although in 1993 Government declared that iodised salt is not required for bakeries, meat, sausages, or industrial foods.

Regular monitoring of iodine nutrition exists and a national coordinating committee which has existed since 1984 has recommended universal salt iodisation become mandatory. This stance is supported by others who believe that 'liberal handling of the iodisation of foods is obviously not sufficient to adequately improve iodine status' and 'without appropriate legislative measures to enforce universal salt iodisation as recommended by WHO, the insufficient iodine status in Germany and in other European countries could become a never-ending story' (Remer, 1998).

Switzerland

Switzerland is iodine sufficient. Voluntary iodised salt was introduced in 1922 at the low level of 1.9 – 3.75 mg iodine/kg as potassium iodide. This level was slowly increased to 7.5 mg iodine/kg (1962), 15 mg iodine/kg (1980), and recently to 20 - 30 mg iodine/kg (1998). Iodised salt is permitted for use both at home and in the food industry. Iodised salt now has a market share of 92 % of household salt, and approximately 70 % of salt used in commercial food production (Delange *et al.*, 2002). Monitoring of salt and iodine nutrition is conducted at five year intervals (IDD Newsletter, 2002).

Denmark

Salt iodised with potassium iodide at 8 -13 mg iodine/kg became mandatory for household use and for commercial production of bread and cakes in Denmark in July 2000. This was expected to distribute sufficient iodine to the population and increase the median iodine intake by 50 to 60 µg per day (Laurberg *et al.,* 2003). Prior to 1998 iodised salt was prohibited. From 1998 until 2000 iodised salt was available on a voluntary basis (IDD website 2003b).

In 1994, a Danish working group was established to evaluate the need for an iodine enrichment program in Denmark. Among other issues, the group reported on the feasibility of iodine enrichment of food. Models were put forward on how iodisation of household salt, all salt for consumption including salt used by the food industry or salt in bread (approximately 1.25 g per 100 g of bread), would distribute iodine in the population (Laurberg *et al.*, 2003).

The iodisation program in Denmark is monitored through regular investigation of the iodine content and use of salt. Iodine intake and the occurrence of thyroid disorders are also tracked in population cohorts previously having mild or moderate deficiency. Participants were investigated in 1997 to 1998 before iodine enrichment of salt.

A similar cohort will be investigated in 2004 to 2005, and the original cohort reinvestigated if sufficient funding is obtained.

Recent measurements of the iodine content of samples of salt, bread and cake collected from retail stores nation-wide show that there is a tendency towards higher iodine contents of industry salt than aimed at (mean concentration 16 mg iodine/kg) and that the program has been effective (Laurberg *et al.,* 2003).

An on-going register of overt hyper- and hypothyroidism cases has shown an increase in the incidence rate of hyperthyroidism, but of an acceptable magnitude, and the incidence is expected to decrease after some years. This is because it may take many years after a change in population iodine intake before a new steady state in the occurrence of thyroid disease is reached. Thus excessive iodine enrichment may lead to an early large surge of hyperthyroidism in a previously iodine deficient population. No large alterations in the incidence of hypothyroidism have been observed but a tendency towards an increase after iodine enrichment exists (Laurberg *et al.*, 2003). Observations for a longer period are needed before conclusions can be made.

The Netherlands

In the Netherlands, salt has been iodised since 1969. Initially potassium iodide was added to table and cooking salt at 3-8 mg potassium iodine/kg and bakers salt at 23-29 mg potassium iodine/kg (West *et al.*, 1995). However, due to the deterioration in iodine status, possibly associated with a reduced bread intake, levels of iodine were increased in 1983 to 23-29 mg potassium iodine/kg in cooking salt and 55-65 mg potassium iodine/kg in baking salt. The new level of iodisation of baking salt is equivalent to 42-50 mg iodine/kg (West *et al.*, 1995). Although use is voluntary, practically all bakeries use iodised salt. Iodised salt is used in the production of bread and pasta products[26].

In order to assess the efficacy of the increases in iodisation in the Netherlands, a surveillance study of iodine intake and urinary iodide excretion was undertaken in 222 men and 222 women aged 20 to 79 years (Brussaard *et al.*, 1997). This study did not use a random sample and was primarily designed to investigate people with low vitamin B6 intakes and may also have over-represented those with low iodine intakes.

Iodine intakes were assessed using three day records. It was shown that mean iodine intakes in men were 196 μg/d (20-49 years) and 172 μg/ay (50-79 years) and for women 149 μg/day (20-49 years) and 140 μg/day (50-79 years). Iodine intakes were closely related to bread consumption and energy intake in both men and women (Brussaard *et al.*, 1997).

The prevalence of low iodine intake was highest in the older women and overall less than five percent of the sample had inadequate intakes. Prevalence of marginal iodide excretion was less than five percent of all groups investigated. Median urinary iodide excretion was in the range for mild iodine deficiency disorder (Brussaard *et al.*, 1997).

[26] Partnership for Sustained *Elimination of Iodine Deficiency*. Report of a Board Side-Meeting. November 2001, The Netherlands

An evaluation of the iodine intake and thyroid size in 937 Dutch school children aged 6 to 18 years was conducted by Wiersinga *et al* (2001). The median urinary iodine concentration of all investigated children was 154.4 μg/L, clearly above the threshold level of 100 μg/L for iodine deficiency.

This study indicates the absence of endemic goitre in the Netherlands according to WHO criteria: the prevalence of goitre (grade I or higher by inspection and palpation) was less than 5 %, the frequency of thyroid volume above the 97th centile by ultrasound was less than 5 % and the median urinary iodide concentration was greater than 100 μg/L among the investigated school children.

It was also found that bread was the main source of dietary iodine in the Netherlands. Boys and girls ate five and four slices of bread per day respectively (median values). One slice of bread is estimated to contain 20 μg of iodine in the Netherlands (Wiersinga *et al.*, 2001).

References:

Brussaard, J., Brants, H., Hulshof, K., Kistemaker, C., Löwik, M. (1997) Iodine intake and urinary excretion among adults in the Netherlands. *Eur. J. Clin. Nutr.*, 51,S59-S62.

Delange, F., Burgi, H., Chen, Z., Dunn, J. (2002) World Status of Iodine Deficiency Disorders Control Programs. *Thyroid,* 12(10), 915 – 924.

Hollowell, J., Staehling, N., Hannon, W., Flanders, D., Gunter, E., Maberly, G., Braverman, L., Pino, S., Miller, D., Garbe, P., DeLozier, D., Jackson, R. (1998) Iodine Nutrition in the United States. Trends and Public Health Implications: Iodine Excretion Data from National Health and Nutrition Examination Surveys I and III (1971-74 and 1988-1994). *J. Clin. Endocrinol. Metab.,* 83(10), 3401-3408.

IDD Newsletter. 2001. 17(1),8

IDD Website. (2003a). IDD Prevalence and Control Program Data – Germany. www.people.virginia.edu/~jtd/iccidd/mi/idd_062.htm. Accessed August 2004.

IDD Website. (2003b). IDD Prevalence and Control Program Data – Denmark www.people.virginia.edu/~jtd/iccidd/mi/idd_062.htm. Accessed August 2004.

ICCIDD. (2002) Europe is Still Iodine Deficient. IDD Newsletter Vol 18 (4), 51-55. www.iccidd.org.

ICCIDD. (2003) Implementation and Monitoring of Iodine Supplementation in Denmark: The Dan Thyr Program. IDD Newsletter Vol 19 (4), 55-59.

ICCIDD. (2003). IDD Prevalence and Control Program Data, The Netherlands. www.iccidd.org.

ICCIDD. (2003) IDD Prevalence and Control Program Data, Germany. www.iccidd.org.

ICCIDD. (2004) IDD Prevalence and Control Program Data. Accessed 04/02/2004 at: http://www.people.virginia.edu/~jtd/iccidd/mi/idd_062.htm

Laurberg, P., Jørgensen, T., Knudsen, N., Pedersen, I., Perrild, H., Rasmussen, L., Ovesen, L. (2003) Implementation and monitoring of iodine supplementation in Denmark: The Dan Thyr Program. *IDD Newsletter*, 19(4),55-59.

Remer, T, and Neubert, A. (1998) A Never-Ending Story of an Insufficient Status without Mandatory Iodization of Foods? – A German Experience. *J. Clin. Endocrinol. Metab.*, 83(10),3755-3756.

West, C., de Koning, F., Merx, R. (1995) Effect of iodized salt on the colour and taste of food. Report of a study carried out at the request of UNICEF, New York.

Wiersinga, W., Podoba, J., Srbecky, M., van Vessem, M., van Beeren, H., Platvoet-ter Schiphorst, M. (2001) A survey of iodine intake and thyroid volume in Dutch schoolchildren: Reference values in an iodine-sufficient area and the effect of puberty. *Eur. J. Endocrinol.*, 144,595-603.

Attachment 5

Iodine Status in Australia and New Zealand and Implications for Health and Performance

Contents

1. Assessment of Iodine Status

Assessing dietary intake of iodine is difficult and not considered a reliable indicator of iodine status both due to the inherent inaccuracy of dietary assessment and the interaction of iodine with iodine uptake inhibitors generically termed goitrogens, discussed in section 1.1 below. Status is more accurately reflected by urinary iodine concentration (ICCIDD, 2001). Thyroid volume, as assessed by neck palpitation or preferably ultrasonography, provides a measure of long-term iodine status with increased thyroid volume, known as goitre once thyroid volume in children exceeds the 97th percentile of age or body surface area specific World Health Organization (WHO) reference values (Gibson, 2005). 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 no visible or palpable, palpable but not visible, or visible enlargement respectively (Gibson, 2005).

Other indicators of iodine status include the thyroglobulin, thyroid-stimulating hormone , and the thyroid hormones: thyroxine and triiodothyronine (thyronine). Of these blood markers, thyroglobulin appears to be the most specific indicator of recent iodine status, but it is a relatively recently used biomarker still gaining acceptance amongst the research community (Gibson, 2005). Thyroid-stimulating hormone is relatively insensitive to mild and moderate iodine deficiency, but is appropriate for the diagnoses of congenital hypothyroidism in newborns (Gibson, 2005). The blood concentrations of thyroxine and thyronine are also quite insensitive to milder forms of iodine deficiency (ICCIDD, 2001; Gibson, 2005).

1.1 Goitrogens

Substances that inhibit the absorption and/or utilisation of iodine by the thyroid, or otherwise interfere with normal thyroid hormone synthesis, are collectively known as goitrogens (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, e.g. cabbage; they are also contained 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 (Gibson, 2005, Sarne 2004). High natural fluoride levels have also 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 is these substances is unusually high (BEST, 2004; Delange and Hetzel, 2005: Sarne, 2004).

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

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

The WHO and ICCIDD have developed a system of classifying populations into categories of iodine status based on their median urinary iodine concentration (MUIC) as shown in Table 1. For the purposes of surveys the WHO and ICCIDD recommend school-aged children as the most suitable group in which to measure iodine status (ICCIDD, 2001). WHO and the ICCIDD state that a median urinary iodine concentration of less than 100 μg/L and more than 20% of the population having a urinary iodine concentration of less than 50 μg/L together indicate mild iodine deficiency; and a median concentration of less than 50 μg/L is indicative of moderate iodine deficiency in that population. (ICCIDD, 2001). These categories are not entirely appropriate to pregnant or lactating women who require greater iodine intakes than other groups. Based on recommendations of iodine intake a MUIC of less than 150 μg/L would be considered insufficient (ICCIDD, 2001; Delange, 2004).

These categories of MUIC are not indicative of the iodine status of individuals and should only be used to assess populations. Individual urinary iodine concentrations are highly variable and a single urinary iodine concentration cannot be used to classify whether an individual is severely, moderately or mildly deficient. 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.

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

2. Evidence of Iodine Deficiency in the Australian and New Zealand Populations

It was reported in the early 1990s that there was no evidence of iodine deficiency anywhere in Australia at that time (Stanbury *et al.,* 1996). New Zealand has a history of iodine deficiency dating back to the 1920s when iodised salt was used to achieve a dramatic reduction in goitre rates (Mann and Aitken, 2003). Iodine deficiency in New Zealand was further reduced by the use of iodophors as sanitisers by the dairy industry in about the 1960s (Thompson, 2003; NHMRC and MoH, 2005). The use of iodophors by the dairy industry has also traditionally been an important source of iodine for the populations in parts of Australia (Gibson, 1995; Eastman 1999).

In more recent years however, a downward trend in iodine status has been noted in both Australian and New Zealand populations (Thomson, 2003). It has been estimated from a comparison of urinary iodine levels of Sydney residents in the early 1990s with levels from similar groups in the same city almost decade later that iodine intake appears to have halved over that decade (Eastman, 1999).

2.1 Australia

Several studies have been conducted since 1999 in Tasmania, New South Wales and Victoria following identification of a probable re-emergence of iodine deficiency in those parts of the nation. Iodine deficiency was observed in all investigated groups including school children and pregnant women.

The 2003-4 National Iodine Nutrition Study (NINS) measured the urinary iodine concentration of 1709 8-10 year olds from both rural and urban locations in New South Wales, Victoria, South Australia, Western Australia and Queensland (Li *et al.*, 2006). Tasmania was excluded because of its recent efforts to address local iodine deficiency, whereas the Northern Territory was excluded for logistical reasons. Findings indicate mild deficiency in New South Wales and Victoria with South Australia being borderline; for further details see Table 2.

Table 2: Australian NINS Median Urinary Iodine Concentration Data

State	MUIC (μg/L)	Iodine Status
New South Wales	89	mild deficiency
Victoria	73.5	mild deficiency
South Australia	101	borderline deficiency
West Australia	142.5	adequate
Queensland	136.5	adequate
All Surveyed States	**104**	

The NINS finding was consistent with an earlier Melbourne study of 607 school children showing a MUIC of 70 μg/L, with 27% having a urinary iodine concentration less than 50 μg/L (McDonnell *et al.*, 2001). A study in 301 5-13 year olds living in New South Wales in 2000 also had similar findings to the NINS with a MUIC of 84 μg/L, and 14% of children having an MUIC less than 50 μg/L (Guttikonda *et al.* 2003). For further details see Table 3.

The only study in Australia to assess the change in iodine status in the same group of children over time was undertaken in Tasmania (Hynes *et al.*, 2004). The urinary iodine concentration of 170 children was assessed in 1998-99 and then again in 2000-01. Although the MUIC did not change markedly in 2 years (76 μg/L to 75 μg/L), the study showed that the percentage of children with urinary iodine concentration below 50 μg/L increased from 13.5% to 21.2% over the two year period; confirming a state of mild iodine deficiency in the area.

The iodine status of adult populations, especially pregnant women, has also been a topic of recent research, though only in New South Wales and Victoria. Two independent Sydney studies of pregnant women conducted in 1998-99 showed approximately 20% had urinary iodine levels less than 50 μg/L with the MUIC of the groups being 100 μg/L or less (Gunton *et al.*, 1999; Li *et al.*, 2001).

A subsequent study involving 50 postpartum women attending a Sydney hospital reported a MUIC of 46 μg/L; 58% had a urinary iodine concentration of less than 50 μg/L (Chan *et al.*, 2003). The most recently published study measured urinary iodine concentration in 796 pregnant women from the Central Coast area of New South Wales (Travers *et al.,* 2006). The MUIC was 85 μg/L, with those women who gave birth at private hospitals having a higher MUIC than those who did so in public hospitals, 101 μg/L vs. 82 μg/L. Results of these studies are summarised in the Table 3. In Melbourne a study of 802 pregnant women between 1998 and 2002 showed an increased percentage of pregnant women, 38-48% according to ethnicity, had urinary iodine levels less than 50 μg/L, and MUIC levels of between 52 and 61 μg/L (Hamrosi *et al.*, 2005).

A study undertaken in over 2,500 Sydney neonates between 1998 and 2000 showed 5.4-8.1% of infants had whole blood thyroid-stimulating hormone concentrations greater than 5 mIU/L (McElduff *et al.,* 2002). The WHO suggests that less than 3% of neonates would be expected to have a blood thyroid-stimulating hormone concentration greater than 5 mIU/L in an iodine replete population. A subsequent study involving of 50 Sydney neonates reported 6% as having TSH levels exceeding 5mIU/L (Chan *et al.*, 2003). The most recent published work reported that 2.2% of 816 neonates from the Central Coast of New South Wales had thyroid-stimulating hormone concentrations of > 5 mIU/L (Travers *et al.*, 2006).

Two of the above studies also investigated normal healthy adult populations and patients with diabetes (Li *et al.* 2001; Gunton *et al.*, 1999). In both studies, the healthy populations and people with diabetes had similar MUICs of less than 100 μg/L, with greater than 20% of the study populations having levels less than 50 μg/L, indicative of mild iodine deficiency. For further details see Table 3.

Table 3: Summary of Recent Australian Research Assessing Iodine Status

Reference:	Group	n	MUIC (μg/L)	%< 50 μg/L	Iodine Status
McDonnell *et al.*, 2001	Males 11-18 years	167	82	17	mild deficiency
(Melbourne)	Females 11-18 years	410	64	31	mild deficiency
Guttikonda *et al.*, 2003 (NSW)	Males & females 5-13 years	301	82	14	mild deficiency
Chan *et al.*, 2003 (Sydney)	Postpartum women	50	47	58	insufficient
Travers *et al.*, 2006 (NSW)	Pregnant women	796	85	17	insufficient
	Children 6-13 years	94	84	14	mild deficiency
Li *et al.*, 2001	Pregnant women	101	88	21	insufficient
(Sydney)	Adult volunteers	86	88	18	mild deficiency
	Patients with diabetes	85	69	24	mild deficiency
	Pregnant women	81	104	20	insufficient
Gunton *et al.,* 1999	Postpartum women	28	79	19	mild deficiency
(Sydney)	Patients with diabetes	135	65	34	mild deficiency
	Adult volunteers	19	64	26	mild deficiency
	Pregnant – Caucasian	227	52	48	insufficient
Hamrosi *et al.*, 2005	Pregnant - Vietnamese	263	58	38	insufficient
(Melbourne)	Pregnant– Indian/Sri Lankan	262	61	41	insufficient

2.2 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 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 percent; females 31 percent). 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 insufficient iodine intake/mild iodine deficiency across genders and ethnicities in NZ children aged 4-14 years. For further details see Table 4.

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 the data suggests the goitre rate is actually closer to 30%.

The only published work examining the iodine status in infants and toddlers revealed that the MUIC of 43 breast-fed infants was 44 µg/L (inter quartile range 23-82 µg/L), which was less than half that of 51 formula-fed infants (99 µg/L (inter quartile range 86-167)) (Skeaff *et al.*, 2005). 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. For further details on see Table 4.

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 was measured at several time points throughout the study. The MUIC ranging from 33-52 µg/L for pregnant women and 49-60 µg/L for non-pregnant women with 55% of all women having a urinary iodine concentration of less than 50 µg/L. This indicates mild-to-moderate iodine deficiency in both these groups. For further details see Table 4.

Although data on iodine status is not available from nutrition surveys in New Zealand adults, two published studies involving individuals from a range of geographic locations have examined iodine status amongst non-pregnant/breastfeeding women. 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 percent 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) was reported a MUIC of 54 µg/L for 233 study participants form 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 limit of normal 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 *et al.*, 2003	Males 5-14 years	970	68	25	mild
	Females 5-14 years	823	62	31	mild
	All	1793	66	28	mild
Skeaff *et al.*, 2005	Breastfed Infants	43	44	51	moderate
	Formula Fed	51	99	14	mild
Thomson *et al.*, 2001	Pregnant women	35	33-52	55	insufficient
	Non-pregnant women	17	49-60		insufficient
Thomson *et al.*, 1997	Adult Males	169	49	50	moderate
	Adult Females	164	44		moderate
Thomson *et al.*, 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 and varies 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 (enlargement of the thyroid) and cretinism (severe mental retardation) to encompass all presentations of the deficiency disease including the most important effect of iodine deficiency is on neuropsychological development (Hetzel, 2000). 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 marginally able to cope with the adult world (Megafoundation, 2005).

The impact of IDD are described in greater detail according to population subgroup in the sections below.

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).

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). In its extreme form, iodine deficiency results in cretinism, but of much greater public health importance in Australia and New Zealand are the more subtle degrees of brain damage and reduction of cognitive function that could affect the entire population over time. The degree of health effect is related to the severity of the deficiency and the stage in life at which the deficiency occurs. Many of the effects of iodine deficiency shown in adults are usually the result of chronic iodine deficiency rather than of recent deficiency. In general, adverse effects of iodine deficiency on the central nervous system can be irreversible and compounded by continuing deficiency during infancy.

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 important. Before the introduction of weaning foods, the iodine intake of the infant solely 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 Neurological Consequences for Children of Mothers with Mild Iodine Deficiency during Pregnancy

The effect of mild iodine deficiency (MUIC 55-99 μg/L) 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. This study suggested a dose-response relationship between iodine deficiency and mental development so that small differences in the severity of deficiency results in small changes in mental development in a linear fashion (Choudhury and Gorman, 2003).

3.4 Neurological Consequences for Children of Mothers with Moderate Iodine Deficiency During Pregnancy

A number of publications have shown a definite association between moderate iodine deficiency (UI 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. An Italian cross sectional study investigated the incidence of attention deficit and hyperactivity disorder (ADHD) in the children of 16 women from a moderately iodine deficient area compared to 11 control women from an iodine sufficient area. Eleven of the 16 children born in the moderately iodine deficient area were diagnosed with ADHD compared with no children born in the sufficient area (Vermiglio *et al.,* 2004). Further research in this area is required to draw any firm conclusion about this apparent association. However, an earlier study showing a significantly increased risk of ADHD in those with generalised resistance to thyroid hormone adds support to this possible relationship between maternal iodine status and risk of ADHD in offspring (Hauser *et al.*, 1993).

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 percentile 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 went on to suggest that an effect on intelligence performance in the offspring of iodine deficient mothers could occur even when the women's hypothyroidism was mild and asymptomatic. However, subsequent journal correspondence indicated that the effects of mild iodine deficiency is a controversial topic and is still being debated.

3.5 Neurological Consequences of Mild Iodine Deficiency

A cross-sectional study of 1,221 school children in southern Europe (Spain) with a MUIC of 90 mcg/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 mcg/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/Lwere more likely to have an IQ below the 25th percentile, i.e. IQ below 87.3.

3.6 Neurological Consequences of Moderate Iodine Deficiency

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 (Boyages *et al.*, 1989). 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.

3.7 Iodine Deficiency and Goitre

When dietary intakes of iodine are low (<50 µg /day) (Delange and Hetzel, 2005), thyroid hormone synthesis is reduced and secretion declines; this is known as hypothyroidism. This stimulates a feedback mechanism, resulting in increased secretion of thyroid stimulating hormone, which in turn promotes iodine uptake by the thyroid. If iodine intakes are low over a period of time the thyroid grows in an attempt to absorb more iodine and produce more thyroid hormones, resulting in iodine deficiency goitre (Gibson, 2005). Goitre is the most visible sign of moderate to severe iodine deficiency.

Mild iodine deficiency for a sustained period of time can result in the development of autonomous nodular goitres that produce thyroid hormone in direct response to iodine intake regardless of the circulating thyroid hormone levels (Delange and Hetzel, 2005). When the dietary intake of iodine increases in a person with autonomous nodular goitres, the risk of developing iodine induced hyperthyroidism (IIH) increases substantially. However, even without an increase in iodine intake these autonomous nodules may lead to spontaneous hyperthyroidism in later life. The correction of iodine deficiency reduces the risk of autonomous thyroid nodules forming, and therefore minimises the occurrence of IIH in subsequent generations (Hetzel and Clugston, 1998).

References:

ATSDR (2004). Toxicological profile for iodine. U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Atlanta, GA. http://www.atsdr.cdc.gov/

Board on Environmental Studies and Toxicology (BEST) (2006). Fluoride in Drinking Water: A Scientific Review of EPA's Standards, The National Academies Press. http://www.nap.edu/catalog/11571.html?onpi_newsdoc03222006. Accessed on 16 August 2006

Bleichrodt, N., and Born, M. (1994). 'A Meta-Analysis of Research into Iodine and Its Relationship to Cognitive Development.' In *The Damaged Brain of Iodine Deficiency,* ed. J. B. Stanbury, 195 –200. Communication Corporation, New York, NY.

Chan, S.S., Hams, G., Wiley, V., Wilcken, B. and McElduff, A. (2003) Postpartum maternal iodine status and the relationship to neonatal thyroid function. *Thyroid* 13(9):873-876.

Choudhury, N. and Gorman, K.S. (2003) Subclinical prenatal iodine deficiency negatively affects infant development in Northern China. *J. Nutr.* 133(10):3162-3165.

Delange, F. and Hetzel, B.S. (2005) The Iodine Deficiency Disorders. 1-48. http://www.thyroidmanager.org/Chapter20/20-frame.htm. Accessed on

Delange, F. (2000) The role of iodine in brain development. *Proc. Nutr. Soc.* 59**:** 75-79

Delange, F. (2001) Iodine deficiency as a cause of brain damage. *Postgrad. Med. J.* 77(906):217-220.

Delange, F. (2004) Optimal Iodine Nutrition during Pregnancy, Lactation and the Neonatal Period. *Int. J. Endocrinol. Metab*. 2:1-12.

Dorea, J. (2002). Iodine nutrition and breast feeding. *J. Trace. Elements. Med. Biol.* 16**:**207-220

Eastman, C. (1999). Where has all our iodine gone? Editorial. *Med. J. Aust.* 171: 455-456.

Freake, H.C. (2000) Iodine. In: Stipanuk, M.H., ed. *Biochemical and physiological aspects of human nutrition.* W.B. Saunders Company, Philadelphia, Penn, pp 761-781.

Galan, I.R., G., I, Sanchez, M.P., Pilar Mosteiro, D.M. and Rivas Crespo, M.F. (2005) Psycho-intellectual development of 3 year-old children with early gestational iodine deficiency. *J. Pediatr. Endocrinol. Metab* 18 Suppl 1:1265-1272.

Gibson, H.B (1995). Surveillance of iodine deficiency disorders in Tasmania 1949-1984. Deptartment of Health Services, Hobart, TAS.

Gibson, R.S. (2005) Principles of Nutritional Assessment 2nd ed. Oxford University Press, New York, NY.

Gunton, J.E., Hams, G., Fiegert, M. and McElduff, A. (1999) Iodine deficiency in ambulatory participants at a Sydney teaching hospital: is Australia truly iodine replete? *Med. J. Aust.* 171(9):467-470.

Guttikonda, K., Travers, C.A., Lewis, P.R. and Boyages, S. (2003) Iodine deficiency in urban primary school children: a cross-sectional analysis. *Med. J. Aust.* 179(7):346-348.

Haddow, J.E., Palomaki, G.E., Allan, W.C., Williams, J.R., Knight, G.J., Gagnon, J., O'Heir, C.E., Mitchell, M.L., Hermos, R.J., Waisbren, S.E., Faix, J.D. and Klein, R.Z. (1999) Maternal thyroid deficiency during pregnancy and subsequent neuropsychological development of the child. *N. Engl. J. Med.* 341(8):549-555.

Hamrosi, M.A., Wallace, E.M. and Riley, M.D. (2003) Iodine status in early pregnancy: ethnic variations. *Asia. Pac. J. Clin. Nutr.* 12 Suppl:S15.

Hamrosi, M.A., Wallace, E.M. and Riley, M.D. (2005) Iodine status in pregnant women living in Melbourne differs by ethnic group. *Asia. Pac. J. Clin. Nutr.* 14(1):27-31.

Hetzel, B.S. (1994) Iodine deficiency and fetal brain damage. *N. Engl. Med.* 331(26):1770-1771.

Hetzel, B.S. (2000) Iodine and neuropsychological development. *J. Nutr.* 130(2S Suppl):493S-495S.

Hetzel, B., Clugston, G. (1998). *Iodine.* In: Shils *et al.* eds. *Modern nutrition in Health and Disease* 9th ed. Lippincott Williams & Wilkins pp 253-264.

Huda, S.N., Grantham-McGregor, S.M., Rahman, K.M. and Tomkins, A. (1999) Biochemical hypothyroidism secondary to iodine deficiency is associated with poor school achievement and cognition in Bangladeshi children. *J. Nutr.* 129(5):980-987.

Hynes, K.L., Blizzard, C.L., Venn, A.J., Dwyer, T. and Burgess, J.R. (2004) Persistent iodine deficiency in a cohort of Tasmanian school children: associations with socio-economic status, geographical location and dietary factors. *Aust. N.Z. J. Public Health* 28(5):476-481.

ICCIDD, UNICEF, WHO. (2001). *Assessment of Iodine Deficiency Disorders and Monitoring their Elimination*. Second edition, WHO Publishing, Geneva.

Joint FAO/WHO Expert Committee on food additives (JECFA) (1989) *Toxicological Evaluation of certain food additives and contaminants. WHO food additive series N024* Geneva: World Health Organization.

Li, M., Eastman, C.J., Waite, K.V., Ma, G., Zacharin, M.R., Topliss, D.J., Harding, P.E., Walsh, J.P., Ward, L.C., Mortimer, R.H., Mackenzie, E.J., Byth, K. and Doyle, Z. (2006) Are Australian children iodine deficient? Results of the Australian National Iodine Nutrition Study. *Med. J. Aust.* 184(4):165-169.

Li, M., Ma, G., Boyages, S.C. and Eastman, C.J. (2001) Re-emergence of iodine deficiency in Australia. *Asia Pac. J. Clin. Nutr.* 10(3):200-203.

Mann, J.I. and Aitken, E. (2003) The re-emergence of iodine deficiency in New Zealand? *N. Z. Med. J.* 116(1170):U351.

McElduff, A., McElduff, P., Gunton, J.E., Hams, G., Wiley, V. and Wilcken, B.M. (2002) Neonatal thyroid-stimulating hormone concentrations in northern Sydney: further indications of mild iodine deficiency? *Med. J. Aust.* 176(7):317-320.

Megafoundation (2005) *What Does 'IQ' Stand For, and What Does It Mean?* http://hiqnews.megafoundation.org/Definition_of_IQ.html

Ministry of Health (2003). NZ Food NZ Children: Key Results of the 2002 National Children's Nutrition Survey. Ministry of Health, Wellington.

Qian, M., Wang, D., Watkins, W.E., Gebski, V., Yan, Y.Q., Li, M. and Chen, Z.P. (2005) The effects of iodine on intelligence in children: a meta-analysis of studies conducted in China. *Asia. Pac. J. Clin. Nutr.* 14(1):32-42.

Skeaff, S.A., Ferguson, E.L., McKenzie, J.E., Valeix, P., Gibson, R.S. and Thomson, C.D. (2005) Are breast-fed infants and toddlers in New Zealand at risk of iodine deficiency? *Nutrition* 21(3):325-331.

Skeaff, S.A., Thomson, C.D. and Gibson, R.S. (2002) Mild iodine deficiency in a sample of New Zealand schoolchildren. *Eur. J. Clin. Nutr.* 56(12):1169-1175.

Soriguer, F., Millon, M.C., Munoz, R., Mancha, I., Lopez Siguero, J.P., Martinez Aedo, M.J., Gomez-Huelga, R., Garriga, M.J., Rojo-Martinez, G., Esteva, I. and Tinahones, F.J. (2000) The auditory threshold in a school-age population is related to iodine intake and thyroid function. *Thyroid* 10(11):991-999.

Stanbury, J. (1996). Iodine Deficiency and the Iodine Deficiency Disorders in Present Knowledge in Nutrition. Seventh Edition ILSI press, Washington DC.

Thomson, C.D. (2003) Australian and New Zealand Reference Values for Iodine, A report prepared for the Ministry of Health. New Zealand Ministry of Health.

Thomson, C.D. (2004) Selenium and iodine intakes and status in New Zealand and Australia. *Br. J. Nutr.,* 91(5):661-672.

Thomson, C., Smith, T., Butler K., Packer, M. (1996). An evaluation of urinary measures of iodine and selenium status. *J. Trace Elements Med. Biol.*, **10:** 214-222

Thomson, C.D., Colls, A.J., Conaglen, J.V., Macormack, M., Stiles, M. and Mann, J. (1997) Iodine status of New Zealand residents as assessed by urinary iodide excretion and thyroid hormones. *Br. J. Nutr.,* 78(6):901-912.

Thomson, C.D., Packer, M.A., Butler, J.A., Duffield, A.J., O'Donaghue, K.L. and Whanger, P.D. (2001) Urinary selenium and iodine during pregnancy and lactation. *J. Trace Elem. Med. Biol.,* 14(4):210-217.

Travers, C.A., Guttikonda, K., Norton, C.A., Lewis, P.R., Mollart, L.J., Wiley, V., Wilcken, B., Eastman, C.J. and Boyages, S.C. (2006) Iodine status in pregnant women and their newborns: are our babies at risk of iodine deficiency? *Med. J. Aus.,* 184(12):617-620.

Valeix, P., Preziosi, P., Rossignol, C., Farnier, M.A. and Hercberg, S. (1994) Relationship between urinary iodine concentration and hearing capacity in children. *Eur. J. Clin. Nutr.,* 48(1):54-59.

van den Briel, T., West, C.E., Bleichrodt, N., Ategbo, E.A. and Hautvast, J.G. (2000) Improved iodine status is associated with improved mental performance of schoolchildren in Benin. *Am. J. Clin. Nutr.* 72(5):1179-1185.

van den Briel,T., West, C.E., Hautvast, J.G. and Ategbo, E.A. (2001) Mild iodine deficiency is associated with elevated hearing thresholds in children in Benin. *Eur. J. Clin. Nutr.,* 55(9):763-768.

Vermiglio, F., Lo, P., V, Moleti, M., Sidoti, M., Tortorella, G., Scaffidi, G., Castagna, M.G., Mattina, F., Violi, M.A., Crisa, A., Artemisia, A. and Trimarchi, F. (2004) Attention deficit and hyperactivity disorders in the offspring of mothers exposed to mild-moderate iodine deficiency: a possible novel iodine deficiency disorder in developed countries. *J. Clin. Endocrinol. Metab.,* 89(12):6054-6060.

Zimmermann, M.B., Connolly, K., Bozo, M., Bridson, J., Rohner, F. and Grimci, L. (2006) Iodine supplementation improves cognition in iodine-deficient schoolchildren in Albania: a randomized, controlled, double-blind study. *Am. J. Clin. Nutr.,* 83(1):108-114.

Zimmermann, M.B., Hess, S.Y., Molinari, L., (2004) New reference values for thyroid volume by ultrasound in iodine sufficient schoolchildren: a WHO/NHD Iodine Deficiency Study Group Report. *Am. J. Clin. Nutr.,* 79: 231-237.

Attachment 6

Tasmanian (Interim) Iodine Supplementation Program

Introduction

During the late 1990s, the Menzies Centre for Population Health conducted research into the iodine status of Tasmanians. The research showed a re-emergence of mild iodine deficiency in the population. The matter was referred to FSANZ, however due to the time required to establish a new standard, an interim program was developed. The Tasmanian Department of Health and Human Services (TDHHS) put in place an iodine fortification program in October 2001. Bakeries were asked to use iodised salt in place of regular salt and a Memorandum of Understanding (MoU) was established between the TDHHS and those in the baking industry willing to participate. Salt manufacturers also signed a MoU agreeing to supply the baking industry in Tasmania with iodised salt at 40 mg iodine/kg.

1. Selection of an Appropriate Food Vehicle

Several options were considered for iodine fortification in Tasmania. Under consideration were; milk supplementation, deliberate milk contamination, bread supplementation, agricultural supplementation, water iodisation, iodised table salts and iodised salt in bread. The advantages and limitations of each option are summarised in Table 1.

1.1 Choice of Bread as the Preferred Food Vehicle

After consideration of the various options, bread was selected as the preferred food vehicle for iodine fortification. Bread was selected because it is widely consumed and produced predominantly within the State. Consultation with the bread/baking flour industry was encouraging and the bread industry expressed interest in helping to increase the iodine status of the population. Bread makers were prepared to exclusively use iodised salt in their bread making. A trial was undertaken to assess the effects of iodised salt use in the baking process and found that iodised salt had no effect upon the taste, texture or quality of the product.

The majority of commercial salt in Tasmania is sourced from one supplier. This supplier indicated their ability to supply the bread baking industry with iodised salt to meet the requirements of the fortification program.

2. Memorandum of Understanding for the Use of Iodised Salt in Bread

A MoU was established between the baking industry and the TDHHS for the use of iodised salt in bread making and another MoU with the salt supplier. It was agreed that:

- bakeries use iodised salt at 40 ppm for bread making;
- bakers signing the MoU be permitted to bake non-bread items with non-iodised salt;
- the TDHHS would monitor human iodine status and conduct random bread sampling to monitor the levels of iodine within bread products;

- bakers would be required to label their bread in accordance with the Code, but would have a 12 month period of grace to exhaust all existing labels; and

- the TDHHS would actively promote bread as a dietary source of iodine.

Of the 174 bakeries state wide, 4 major and 26 smaller signed the MoU. This was estimated to cover 80% of the bread produced for consumption in Tasmania.

Table 1: Advantages and Limitations of Options to Increase Iodine Intake of the Tasmanian Population, 2001

Option	Advantages	Limitations
Whole milk	Widely consumed nutritious food. Iodine naturally occurs in milk. Most milk consumed in Tasmania processed by two major plants. Iodine residues from sanitisers provided source of iodine in the past.	Milk industry not supportive, concerned about, product image, cost, oxidation of fats reducing shelf life. Iodine addition to milk not permitted under the Food Standards Code. Won't reach those with milk allergies and intolerances. Labelling changes required.
Bread baked with iodised salt	Widely consumed nutritious food. Bread consumed in Tasmania predominantly produced locally. Previously used for increasing iodine status. Bread industry supportive. Salt industry could supply iodised salt at comparable price. Potassium iodide or iodate to salt permitted under Code.	Won't reach those with wheat allergies and intolerances. Labelling changes required.
Bread using iodised flour	Widely consumed nutritious food. Bread consumed in Tasmanian predominantly produced locally. Previously used for increasing iodine status. Thiamin already added to flour.	Iodine addition to flour not permitted under the Code. Some bread making flour used in Tasmania is milled interstate.
Fortification of dairy cattle feed	No regulatory requirements. Addresses iodine status of stock as well as humans.	Animal feeds not currently regulated. Supplementary feeding of dairy cattle varies according to pasture availability and seasonal conditions. Many brands and types of supplemental feeds used. More research required to determine feasibility.
Iodine enriched fertilizer	Addresses iodine status of stock as well as humans. Get to the source of the problem. Iodine enriched fertilizer used elsewhere.	Fertilizer use variable including rates applied to pasture, source of fertilizer, soil characteristics. More research required to determine feasibility.
Banning sale of non-iodised salt		Requires regulation. Potential for confusion in public health messages regarding salt. Majority of salt consumption from manufactured foods. Salt consumption data inadequate for valid dietary modelling.
Iodisation of reticulated water supplied	Widely consumed on a daily basis.	Many water supplies (3 bulk and 105 reticulated). There is concern iodine may interact with fluoride. Public concern anticipated as experience with fluoridation. Won't reach those on private water supplies (e.g. tank water).
Iodine tablets	No regulatory requirements. Consumer choice preserved.	Population reach not assured. Costly. Risks of over consumption.

Adapted : Seal J (In Press).

3. Implementation

The implementation of the iodine fortification program involved establishing:

- a communication strategy;
- a program to monitor the iodine concentration in bread and milk; and
- a program to monitor the iodine status of the Tasmanian population.

A communication strategy was developed to ensure all key stakeholders were adequately informed. Specific target audiences were identified and key messages prepared for each group. Key components of the communication strategy were the MoUs between the TDHHS and bakers, and the salt supplier; the preparation of briefings, pamphlets and fact sheets for health professionals and media coverage by the three major Tasmanian newspapers. Although a telephone information line was set up to answer public concerns in relation to the program, very few calls were received. From this, it was concluded the general public had a relatively high level of acceptance for the program.

The objective of the Tasmanian iodine monitoring program was to determine the effect of fortification on the iodine status of the general population and in high-risk groups. A secondary objective was to identify any negative outcomes of the fortification program. Monitoring includes regular assessment of urinary iodine levels in school aged children and pregnant women, as well as the iodine content of bread from bakeries participating in the program. At the end of 2004, three years after implementation of the program, no evidence of any negative effects due to an increase in iodine.

4. Uptake by Industry

In 2003 a follow up study was undertaken to determine the participation of bakeries in the iodisation program (Turnbull, 2004). The study included 83 small to medium bakeries, 32 of which had signed the MoU. Telephone interviews were conducted in order to minimise costs and reduce participant burden. Of those bakeries contacted, 70% were using iodised salt (only 38% has signed the MoU). The major barrier to participation was the use of premixes manufactured out side of Tasmania. The survey concluded that the program has high acceptance among small to medium sized bakeries with little impact on business including time, cost or consumer acceptance.

5. Effect on Dietary Intake

The levels of iodine in bread baked with iodised salt were monitored as part of the iodine fortification program. This showed that the median (mid-point) level of iodine in bread was 35 μg/100 g with a range of 20 – 70 μg/100g. Thus, bread baking with iodised salt can provide significant amounts of additional iodine in the diet. Ongoing monitoring of milk iodine levels also confirmed that milk was still an important source of dietary iodine, having a median concentration of 210 μg/L, with a range from 100 – 440 μg/L.

6. Effect on Iodine Status

The TDHHS have an ongoing monitoring program to measure urinary iodine concentrations. Prior to the commencement of the iodine fortification program, surveys of Tasmanian school children aged 4 -14 years in 1998-99 and 2000-01 showed that the iodine status of the population was mildly iodine deficient (Hynes, 2004). After the introduction of the iodine fortification program in 2001, iodine status improved, as shown in Table 2. In 2003, urine samples were collected from 347 children, in 31 different classes from 29 different schools. The median urinary iodine level was 105 µg/L (98.5 µg/L - 111.5 µg/L), with 10% less than 50 µg/L. This suggests the population is now iodine replete.

Table 2: Urinary Iodine Concentration in Tasmanian School Children prior to, and following, Implementation of the Tasmanian (Interim) Iodine Supplementation Program

	Sample size	**Age (years)**	**Median (µg/L)[§]**	**%<50µg/L**
1998	241	4-14	75	13
2000	215	5-14	77	21
2003[‡]	343	8-11	105	10

[§]WHO criteria for optimal iodine nutrition: median>100 µg/L; <20% below 50 µg/L
[‡]Tasmanian (interim) Iodine Supplementation Program implemented October 2001

7. Conclusion

The interim Tasmanian fortification program demonstrates:

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

References:

Hynes, K.L., Blizzard, C.L., Venn, A.J., *et al*. (2004) Persistent iodine deficiency in a cohort of Tasmanian school children: associations with socio-economic status, geographic location and dietary factors. *Aust. N. Z. J. Public Health*, 28:476-81.

Seal, J. (In Press). The Makings of the Tasmanian (interim) Iodine Supplementation Program 2001-2004. In: Richards, P. ed. *Goitre Monitor: History of Iodine deficiency Disorders in Tasmania from Pre-British Settlement to the Present Day*. Australian Society for the History of Medicine, Launceston.

Turnbull, F., Lee, S., Seal, J., Johnson, E., Shaw, K. (2004) Tasmanian iodine supplementation program: participation by small-medium sized bakeries. *Proceedings of the Dietitians Association Of Australia 22nd Annual Conference.* Deakin

Attachment 7

Safety Assessment Report for P230 Consideration of Mandatory Fortification with Iodine

Contents

Executive 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 and the regulation of thyroid hormone production and secretion.

Ingested iodine, in the form of iodide, is readily absorbed from the gastrointestinal tract. Absorbed iodide enters the circulation where it is taken up primarily by the thyroid gland. The uptake of iodide by the thyroid gland is controlled by thyroid-stimulating hormone, which is highly sensitive to dietary iodine intake. At low intakes representing iodine deficiency, uptake of iodide into the thyroid gland is increased and at very high intakes, iodide uptake into the thyroid gland 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.

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 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;
- sensitivity reactions to free iodide, which are unrelated to thyroid gland function. Such reactions are typically associated with very large oral doses of iodide (>300 mg/day), which would be highly unlikely from dietary sources, even with fortification;
- iodine poisoning, resulting from acute intakes of large quantities (grams) of iodine. Cases of iodine poisoning are only rarely seen.

This review has largely focused on effects on the thyroid gland, which is regarded as the primary and most sensitive indicator of iodine toxicity.

Excess iodine can produce an enlargement of the gland (goitre) and/or affect the production of the thyroid hormones. A diminished production of the thyroid hormones is referred to as hypothyroidism and may be accompanied by goitre. An increased thyroid hormone synthesis and secretion by the thyroid gland 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 history of iodine deficiency may be prone to the development of iodine-induced hyperthyroidism if iodine exposure increases later in life.

Particular life stages may also be more vulnerable to excess iodine, for example the foetus and newborn infants are particularly susceptible to iodine-induced 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 some individuals being able to tolerate quite large intakes (up to 50 μg/kg/day). 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 or have 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 elevation in thyroid-stimulating hormone concentration while serum thyroid hormone concentrations are 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 considered an indicator of existing risk of induced 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.

An upper intake level (UL)[27] of 1100 μg iodine/day for adults has been established by the US Institute of Medicine. FSANZ has adopted this level as a UL for the purpose of risk assessment for the general healthy population. The National Health and Medical Research Council also subsequently adopted this in the new *Nutrient Reference Values for Australia and New Zealand*[28]. The UL has been adjusted for different age groups on a bodyweight basis.

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.

[27] 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.
[28] This document is available online at http://www.nhmrc.gov.au/publications/synopses/n35syn.htm

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 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 recognized 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 does generate 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 specialized 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 µg/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 gland is controlled by the thyroid-stimulating hormone, 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 gland 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 µg/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 synthesized only in the thyroid gland.

Thyroid-stimulating hormone 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 thyroid-stimulating hormone from the pituitary.

Deiodination 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 which is 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 gland. 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 gland 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 1.1 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.

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 thyroid-stimulating hormone.

Box 1.1: Terminology

Goitre refers to an enlargement of the thyroid gland 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 (referred to as endemic goitre) or the ingestion of large quantities of goitrogenic foods or drugs. 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 the mild impairment to hormone production.

Goitre can also be associated with both **hypo**thyroidism and **hyper**thyroidism.

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 thyroid-stimulating hormone 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 thyroid-stimulating hormone and the additional thyroid-stimulating hormone 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, or thyrotoxicosis, which is caused by ingestion of exogenous thyroid hormone.

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 (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: foetuses 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.

This 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.

Excessive intake of iodine by pregnant women is therefore particularly undesirable with there being many instances of iodine-induced goitres and/or hypothyroidism occurring in newborn infants of mothers who have taken iodine during pregnancy. Infant goitres may regress spontaneously after several months, but deaths due to compression of the trachea have occurred (Galina *et al.*, 1962).

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 thyroid-stimulating hormone concentrations, both within the normal range of values 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 euthyroid[29] 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.

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

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 to 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).

During the same period, 177 women in the prison gave birth to 181 full term infants without any enlargement of the thyroid being noted in the infants (Stockton and Thomas, 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. During this period an increasing number of patients with thyroid disorders had been observed. 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. Among those with mildly deficient iodine intake, those with more than adequate intake, and those with excessive intake, the cumulative incidence of clinical hypothyroidism was 0.2 percent, 0.5 percent, and 0.3 percent, respectively. For sub-clinical hypothyroidism, the cumulative incidence was 0.2 percent, 2.6 percent, and 2.9 percent, respectively; and for autoimmune thyroiditis the cumulative incidence was 0.2 percent, 1.0 percent, and 1.3 percent, respectively. The differences in cumulative incidence for clinical hypothyroidism observed among the three cohorts were non-significant, however the data do suggest that increasing iodine intakes from mildly deficient to more than adequate or excessive may increase the incidence and prevalence of sub-clinical hypothyroidism and autoimuune thyroiditis.

Very little data are available in relation to other life-stage groups. In the case of elderly adults, 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.

Few data are available on adverse effects of chronic exposure to high iodine intakes in children. 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 thyroid-stimulating hormone concentrations; although thyroid-stimulating hormone concentrations were significantly higher in the high iodine group. These chronic intake levels therefore did not induce clinical hypothyroidism. The prevalence of thyroid gland enlargement and goitre in the population were also evaluated. 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) 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) of 10 µg/kg/day and a LOAEL of 29 µg/kg/day for sub-clinical hypothyroidism in healthy human children (ATSDR, 2004). 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.

Much larger 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. Thyroid-stimulating hormone assays were not available, but it was suggested that the increase in serum thyroid-stimulating hormone was involved in the generation of goitre. No cases of clinical hypothyroidism were reported.

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, 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). Such effects have also not been observed in children following the introduction of iodine fortification programmes (Delange and Hetzel, 2005).

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 median urinary iodide (UI) concentration 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 UI concentrations >300 µg/L, with 11% having UI concentrations >500 µg/day. This contrasts to figures for children from coastal Hokkaido, where 59% had UI concentrations >500 µg/L, and 39% had UI concentrations >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.

UI concentrations ≥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.

Maternal exposures to excess iodine during pregnancy have been shown to produce goitre and hypothyroidism in the foetus and neonates. In general, clinical cases have involved maternal exposures to several hundred milligrams of iodine/day during pregnancy.

For example, 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).

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 to 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).

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).

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).

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 appears to be accepted as a common complication 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). Additionally, 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). The incidence of iodine-induced hyperthyroidism is said to revert to normal or even below normal after one to ten years of iodine supplementation (Delange and Hetzel, 2005).

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 the 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). Goitre predisposes to thyroid papillary cancer as diffuse hyperplasia may be followed by nodular hyperplasia, benign tumour formation and eventual follicular papillary cancer, the risk being related to the presence of goitre, not the functional state of the thyroid (SCF, 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; however, because not all studies have found an increased risk of cancer, the relationship between iodine intake and thyroid cancer still remains unclear (ATSDR, 2004). A recurrent observation in these studies is an apparent shift in histopathology toward a higher prevalence of papillary cancer after increased iodine intake in otherwise iodine-deficient populations. This shift towards a higher prevalence of certain types of thyroid cancer results in the prognosis being significantly improved due to the shift towards differentiated forms of thyroid cancer that are diagnosed at earlier stages (Delange and Lecomte, 2000). Two studies found a significant excess of thyroid gland cancer in populations from endemic goitre regions whose diets were supplemented to achieve approximate iodine intakes of 3.5 µg/kg bw/day (Harach and Williams, 1995; Harach *et al.,* 1985).

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 gland 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; Rosenburg *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 anaphylactoid[30] 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. 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 present in all three 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.

---

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

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

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 induced hypothyroidism (SCF, 2002). 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 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). Chronic iodine intakes of approximately 1000 µg/day however appear to be well tolerated by healthy adults.

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)[31].

[31] 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.

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

As there is no evidence of increased susceptibility in children, 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 infants 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).

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.

References:

Aboul-Khair, S.A., Buchanan, T.J., Crooks, J., *et al.* (1966). Structural and functional development of the human foetal thyroid. *Clin. Sci*. 31: 415 – 424.

ATSDR (2004). Toxicological profile for iodine. U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Atlanta, GA. http://www.atsdr.cdc.gov/

Azizi, F. & Daftarian, N. (2001). Side-effects of iodised oil administration in patients with simple goiter. *J. Endocrinol. Invest*. 24: 72 – 77.

Azizi, F., Hedayati, M., Rahmani, M., Sheikholeslam, R., Allahverdian, S. & Salarkia, N. (2005). Reappraisal of the risk of iodine-induced hyperthyroidism: an epidemiological population survey. *J. Endocrinol. Invest*. 28: 23 – 29.

Barker, D.J.P. & Phillips, D.I.W. (1984). Current incidence of thyrotoxicosis and past prevalence of goitre in 12 British towns. *Lancet* 2: 567 – 570.

Baumgartner, T.G. (1976). Potassium iodide and iododerma. *Am. J. Hosp. Pharm*. 33: 601 – 603.

Bender, D.A. & Bender, A.E. (1997). *Nutrition, a Reference Handbook*. Oxford University Press.

Book, S.A. & Goldman, M. (1975). Thyroidal radioiodine exposure of the foetus. *Health Phys*. 29: 874 – 877.

Boyages, S.C., Bloot, A.M., Maberly, G.F. *et al.* (1989). Thyroid autoimmunity in endemic goiter caused by excessive iodine intake. *Clin. Endocrinol*. 31: 452 – 465.

Cavalieri, R.R. (1980). Trace elements: iodine. In: *Modern Nutrition in Health and Disease, 6th Edition* (Ed: Goodhardt, R.S). Lea and Febriger. Philadelphia, U.S. pp 395 – 407.

Cavalieri, R.R. (1997). Iodine metabolism and thyroid physiology: current concepts. *Thyroid* 7: 177 – 181.

Chow, C.C., Phillips, D.I.W. Lazarus, J.H. *et al.* (1991). Effect of low dose iodide supplementation on thyroid function in potentially susceptible subjects: Are dietary iodide levels in Britain acceptable? *Clin. Endocrinol.* 34: 413 – 416.

Christiansen, C., Pichler, W.J. & Skotland, T. (2000). Delayed allergy-like reactions to X-ray contrast media: mechanistic considerations. *Eur. Radiol*. 10: 1965 – 1975.

Clark, M.N. (1981). A fatal case of iodine poisoning. *Clin. Toxicol*. 18: 807 – 811.

Coakley, F.V. & Panicek, D.M. (1997). Iodine allergy: an oyster without a pearl? *Am. J. Roentgenol*. 169: 951 – 952.

Connolly, R.J., Vidor, G.I. & Stewart, J.C. (1970). Increase in thyrotoxicosis in endemic goiter area after iodation of bread. *Lancet* 1: 500 – 502.

Connolly, R.J. (1971a). An increase in thyrotoxicosis in southern Tasmania after an increase in dietary iodine. *Med. J. Aust.* 1: 1268 – 1271.

Connolly, R.J. (1971b). The changing iodine environment of Tasmania. *Med. J. Aust*. 2: 1191 – 1193.

Cuddihy, R.G. (1966). Thyroidal iodine-131 uptake, turnover and blocking in adult and adolescents. *Health Phys*. 12: 1021 – 1025.

Curd, J.G., Milgrom, H., Stevenson, D.D. *et al.* (1979). Potassium iodide sensitivity in four patients with hypocomplementemic vasculitis. *Ann. Intern. Med*. 91: 853 – 857.

Daul, C.B., Morgan, J.E. & Lehrer, S.B. (1993). Hypersensitivity reactions to crustacea and molluscs. *Clin. Rev. Allergy* 11: 201 – 222.

DeLange, F.M. & Ermans, A-M. (1996). Iodine deficiency. In: *Werner and Ingbar's The Thyroid: A Fundamental and Clinical Text* (Eds: Braverman, L.E. & Utiger R.D). Lippincott-Raven, Philadelphia, PA, pp 296 – 316.

DeLange, F., de Benoist, B. & Alnwick, D., (1999). Risks of iodine-induced hyperthyroidism after correction of iodine deficiency by iodized salt. *Thyroid* 9: 545 – 556.

Delange, F. & Lecomte, P. (2000). Iodine supplementation: benefits outweigh risks. *Drug Safety* 22: 89 – 95.

Delange, F. & Hetzel, B. (2005). The iodine deficiency disorders. In: *The Thyroid and its Diseases*. [www.thyroidmanager.org/chapter20/Chapter20.pdf, accessed on 10 May 2006]

Dyck, R.F., Bear, R.A., Goldstein, M.B. *et al.* (1979). Iodine/iodide toxic reaction: Case report with emphasis on the nature of metabolic acidosis. *Can. Med. Assoc. J*. 120: 704 – 706.

Eastman, C.J. (1999). Where has all our iodine gone? *Med. J. Aust*. 171: 455-456.
European Scientific Committee on Food (ESCF) (2002). *Opinion of the Scientific Committee on Food on the Tolerable Upper Intake of Iodine.* SCF/CS/NUT/UPPLEV/26, European Commission, Brussels.

Evans, T.C., Kretzschmar, R.M., Hodges, R.E., *et al.* (1967). Radioiodine uptake studies of the human fetal thyroid. *J. Nucl. Med*. 8: 157 – 165.

Finkelstein, J. & Jacobi, M. (1937). Fatal iodine poisoning: A clinico-pathologic and experimental study. *Adv. Intern. Med*. 60: 1283 – 1296.

Fisher, D.A, Oddie, T.H. and Epperson, D. (1965). Effect on increased dietary iodide on thyroid accumulation and secretion in euthyroid Arkansas subjects*. J. Clin. Endocrinol*. 25: 1580 – 1590.

Fradkin, J.E. & Wolff, J. (1983). Iodide-induced thyrotoxicosis. *Medicine* 62: 1 – 20.

Freund, G., Thomas Jr, W.C., Bird, E.D., Kinman, R.N. & Black, A.P. (1966). Effect of iodinated water supplies on thyroid function. *J. Clin. Endocr*. 26: 619 – 624.

Galina, M.P., Avnet, M.L. & Einhorn, A. (1962). Iodides during pregnancy: An apparent cause of neonatal death. *N. Engl. J. Med.* 267: 1124 – 1127.

Gardner, D.F., Centor, R.M. & Utiger, R.D. (1988). Effects of low dose oral iodide supplementation on thyroid function in normal men. *Clin. Endocrinol.* 28: 283 – 288.

Georgitis, W.J., McDermott, M.T. & Kidd, G.S. (1993). An iodine load from water purification tablets alters thyroid function in humans. *Mil. Med*. 158: 794 – 797.

Harach, H.R. & Williams, E.D. (1995). Thyroid cancer and thyroiditis in the goitrous region of Salta, Argentina before and after iodine prophylaxis. *Clin. Endocrinol*. 43: 701 – 706.

Harach, H.R., Escalanate, D.A., Onativia, A., Outes, J.L., Day, E.S. & Williams, E.D. (1985). Thyroid carcinoma and thyroiditis in an endemic goitre region before and after iodine prophylaxis. *Acta Endocrinol*. 108: 55 – 60.

Hetzel, B. & Clugston, G. (1999). Iodine. In: *Modern Nutrition in Health and Disease, 9th edition* (Eds: Shils, M.E., Olson, J.A., Shike, M. & Ross, A.C), Williams & Wilkins, Baltimore, pp 253 – 264.

Horn, B & Kabins, S.A. (1972). Iodide fever. *Am. J. Med. Sci*. 264: 467 – 471.

Horn-Ross, P.L. Morris, J.S., Lee, M., *et al.* (2001). Iodine and thyroid cancer risk among women in a multiethnic population: the Bay Area Thyroid Cancer Study. *Cancer Epidemiol. Biomarkers Prev*. 10: 979 – 985.

Huang, S.W. (2005). Seafood and iodine: an analysis of a medical myth. *Allergy Asthma Proc*. 26: 468 – 469.

Iancu, T., Boyanower, Y. & Laurian, N. (1974). Congenital goiter due to maternal ingestion of iodide. *Am. J. Dis. Child* 128: 528 – 530.

Institute of Medicine (2001). *Dietary reference intakes: vitamin A, K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc*. A Report of the Panel on Micronutrients, Subcommittees on Upper Reference Levels of Nutrients and of Interpretation and Use of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. National Academy Press, Washington DC.

Khan, F., Einbinder, J.M., Seriff, N.S. *et al.* (1973). Supperative ulcerating iododerma – a rare manifestation of inorganic iodide hypersensitivity. *N. Engl. J. Med*. 289: 1018 – 1020.

Kint, A. & Van Herpe, L. (1977). Iododerma. *Dermatologica* 155: 171 – 173.

Kolonel, L.N., Hankin, J.H., Wilkens, L.R., *et al.* (1990). An epidemiologic study of thyroid cancer in Hawaii. *Cancer Causes Control* 1: 223 – 234.

Kubota, Y., Koga, T. & Nakayama, J. (2000). Iodine allergy induced by consumption of iodine-containing food. *Contact Dermatitis* 42: 286.

Kurtz, S.C. & Aber, R.C. (1982). Potassium iodide as a cause of prolonged fever. *Arch. Intern. Med*. 142: 1543 – 1544.

Laroche, D., Namour, F., Lefrancois, C., Aimone-Gastin, I., Romano, A., Sainte-Laudy, I., Laxenaire, M.-C. and Gueant, J.L. (1999). Anaphylactoid and anaphylactic reactions to iodinated contrast material. *Allergy* 54: 13 – 16.

Larsen, P.R., Davies, T.F. & Hay, I.D. (1998). The thyroid gland. In: *William's Textbook of Endocrinology* (Eds: Wilson, J.D., Foster, D.W. , Kronenberg, H.M. *et al.*), Philadelphia, PA, W.B. Saunders Company, pp 390-515.

Laurberg, P., Pedersen, K.M., Hreidarsson, A. *et al.* (1998). Iodine intake and the pattern of thyroid disorders: A comparative epidemiological study of thyroid abnormalities in the elderly in Iceland and in Jutland, Denmark. *J. Clin. Endocr. Metab.* 83: 765 – 769.

Li, W., Qu, C, Jia, G. *et al.* (1987). Endemic goiter in Central China caused by excessive iodine intake. *Lancet* 1: 257 – 258.

Liesenkötter, K.P., Gopel, W., Bogner, U. *et al.* (1996). Earliest prevention of endemic goitre by iodine supplementation during pregnancy. *Eur. J. Endocrinol.* 134: 443 – 448.

Lind, P., Langsteger, W., Molnar, M., Gallowitsch, H.J., Mikosch, P. & Gomez, I. (1998). Epidemiology of thyroid diseases in iodine sufficiency. *Thyroid* 8: 1179 – 1183.

Markou, K., Georgopoulos, N., Kyriazopoulou, V. & Vagenakis, A.G. (2001). Iodine-induced hypothyroidism. *Thyroid* 11: 501 – 510.

Moneret-Vautrin, D.A., Mata, E., Gerard, H. *et al.* (1989). Probably allergy to polyvidon, responsible for a reaction to iodinated contrast medium: a case of asthma after hysterolsalpingography. *Allerg. Immunol*. 21: 198 – 199.

Mostbeck, A., Galvan, G., Bauer, P *et al.* (1998). The incidence of hyperthyroidism in Austria from 1987 to 1995 before and after an increase in salt iodization in 1990. *Eur. J. Nucl. Med*. 25: 367 – 374.

Mu, L., Chengyi, Q., Qidong, Q. *et al.* (1987). Endemic goitre in central China caused by excessive iodine intake. *Lancet* 2: 257 – 259.

Nagataki, S. & Yokoyama, N. (1996). Other factors regulating thyroid function: autoregulation: effects of iodide. In: *Werner and Ingbar's The Thyroid: A Fundamental and Clinical Text* (Eds: Braverman, L.E. & Utiger R.D). Lippincott-Raven, Philadelphia, PA, pp 241-247.

Namba, H., Yamashita, S., Kimura, H. *et al.* (1993). Evidence of thyroid volume increase in normal subjects receiving excess iodide. *J. Clin. Endocrinol. Metab.* 76: 605 – 608.

NHMRC (2006) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*, National Health and Medical Research Council, Commonwealth of Australia, Canberra.

Nishioka, K., Seguchi, T., Yasuno, H. *et al.* (2000). The results of ingredient patch testing in contact dermatitis elicited by povidone-iodine preparations. *Contact Dermatitis* 42: 90 – 94.

NNT (2002). Mechanisms of toxicity of chemicals affecting the function of the thyroid gland. Berthelsew, P & Thorup, I (eds), Nordic Working Group on Food Toxicology and Risk Evaluation, Nordic Council of Ministers, Tema Nord.

O'Connell, R., Parkin, L., Manning, P., Bell, D., Herbison, P. & Holmes, J. (2005) A cluster of thyrotoxicosis associated with consumption of a soy milk product. *Aust. NZ J Public Health* 29: 511 – 512.

Okana, M. (1989). Irritant contact dermatitis caused by povidone-iodine. *J. Am. Acad. Dermatol*. 20: 860.

Oliner, L., Kohlenbrener, R.M., Fields, T. *et al.* (1957). Thyroid function studies in children: Normal values for thyroidal I^{131} uptake and PBI^{131} levels up to the age of 18. *J. Clin. Endocrinol. Metab*. 17: 61 – 75.

Park, Y.K. *et al.* (1981). Estimation of dietary iodine intake of Americans in recent years. *Journal of the American Dietetic Association* 79: 17 – 24.

Paul, T., Meyers, B., Witorsch, R.J., Pino, S., Chipkin, S., Ingbar, S.H. & Braverman, L.E. (1988). The effect of small increases in dietary iodine on thyroid function in euthyroid subjects. *Metabolism* 37: 121 – 124.

Pedersen, K.M., Laurberg, P., Iverson, E. *et al.* (1993). Amelioration of some pregnancy-associated variations in thyroid function by iodine supplementation. *J. Clin. Endocrinol. Metab.* 77: 1078 – 1083.

Phillips, D.I.W., Barker, D.J.P., Winter, P.D. & Osmond, C. (1983). Mortality from thyrotoxicosis in England and Wales and its association with the previous prevalence of endemic goitre. *J. Epidemiol. Community Health* 37: 305 – 309.

Rajatanavin, R., Safran, M., Stoller, W.A., Mordes, J.P. & Braverman, L.E. (1984). Five patients with iodine-induced hyperthyroidism. *Am. J. Med*. 77: 378 – 384.

Ramsden, D. Passant, F.H., Peabody, C.O. *et al.* (1967). Radioiodine uptakes in the thyroid: Studies of the blocking and subsequent recovery of the gland following the administration of stable iodine. *Health Phys*. 13: 633 – 646.

Riggs, D.S. (1952). Quantitative aspects of iodine metabolism in man. *Pharmacol. Rev*. 4: 284 – 370.

Robison, L.M., Sylvester, P.W., Birkenfeld, P. *et al.* (1998). Comparison of the effects of iodine and iodide on thyroid function in humans. J. Toxicol. Environ. Health 55: 93 – 106.

Rosenburg, F.R., Einbinder, J., Walzer, R.A. *et al.* (1972). Vegetating iododerma. *Arch. Dermatol*. 105: 900 – 905.

Saller, B. (1998). Kinetics of acute and chronic iodine excess. *Exp. Clin. Endocrinol. Diabetes* 106 (Suppl): S34 – S38.

Savoie, J.C., Massin, J.P., Thomopoulos, P. *et al.* (1975). Iodine-induced thyrotoxicosis in apparently normal thyroid glands. *J. Clin. Endocr. Metab*. 41: 685 – 691.

SCF (2002). Opinion of the Scientific Committee for Food on the Tolerable Upper Intake Level for Iodine. Health & Consumer Protection Directorate-General, European Commission.

Shelly, W.B. (1967). Generalized pustular psoriasis induced by potassium iodide. *JAMA* 201: 133 – 138.

Shilo, S & Hirsch, H.J. (1986). Iodine-induced thyrotoxicosis in a patient with a normal thyroid gland. *Postgrad. Med. J*. 62: 661 – 662.

Small, M.D., Bezman, A., Longarni, A.E., *et al.* (1961). Absorption of potassium iodide from gastro-intestinal tract. *Proc. Soc. Exp. Biol. Med*. 106: 450 – 452.

Soria, C., Allegue, F., Espana, A. *et al.* (1990). Vegetating iododerma with underlying systemic diseases: report of three cases. *J. Am. Acad. Dermatol*. 22: 418 – 422.

Stanbury, J.B., Ermans, A.B., Bourdoux, P. *et al.* (1998). Iodine-induced hyperthyroidism: Occurrence and epidemiology. *Thyroid* 8: 83 – 100.

Stather, J.B & Greenhalgh, J.R. (1983). The metabolism of iodine in children and adults. National Radiation Protection Board, Chilton Didcot, Oxfordshire, England. Report No. NRPB-R140.

Stewart, J.C. (1975). Epidemiology and pathogenesis of iodine-induced thyrotoxicosis in Northern Tasmania. *N.Z. Med. J*. 81: 25 – 26.

Stewart, J.C. & Vidor, G.I. (1976). Thyrotoxicosis induced by iodine contamination of food: a common unrecognized condition? *Br. Med. J.* 1: 372 – 375.

Stockton, L.K. & Thomas Jr, W.C. (1978). Absence of neonatal goiter during maternal use of iodinated water. *Clin. Res*. 26: 586A.

Stone, O.J. (1985). Proliferative iododerma: A possible mechanism. *Int. J. Dermatol*. 24: 565 – 566.

Suzuki, H., Higuchi, T., Sawa, K., Ohtaki, S. & Horiuchi, Y. (1965). 'Endemic coast goiter' in Hokkaido, Japan. *Acta Endocrinol (Copenh)* 50: 161 – 176.

Teng, W., Shan, Z., Teng, X., Guan, H., Li, Y., Teng, D., Jin, Y., Yu, X., Fan, C., Chong, W., Yang, F., Dai, H., Yu, Y., Li, J., Chen, Y., Zhao, D., Shi, X., Hu, F., Mao, J., Gu, X., Yang, R., Tong, Y., Wang, W., Gao, T. and Li, C. (2006). Effect of iodine intake on thyroid diseases in China. N. Engl. J. Med. 354: 2783 – 2793.

Thomas Jr, W.C., Malagodi, M.H., Oates, T.W. & McCourt, J.P. (1978). Effects of an iodinated water supply. *Trans. Am. Clin. Climatological Assoc*. 90: 153 – 162.

Tosti, A., Vincenzi, C. Bardazzi, F. *et al.* (1990). Allergic contact dermatitis due to povidone-iodine. *Contact Dermatitis* 23: 197 – 198.

Tresch, D.D., Sweet, D.L., Keelan, M.H.J. *et al.* (1974). Acute iodide intoxication with cardiac irritability. *Arch. Intern. Med*. 134: 760 – 762.

Van Dilla, M.A. & Fulwyler, M.J. (1963). Thyroid metabolism in children and adults using very small (nanocurie) doses of iodine^{125} and iodine^{131}. *Health Phys*. 9: 1325 – 1331.

Van Ketel, W.G. & van den Berg, W.H.H.W. (1990). Sensitization to povidone-iodine. *Dermatol. Clin*. 8: 107 – 109.

Vicens-Calvet, E., Potau, N., Carreras, E., *et al.* (1998). Diagnosis and treatment in utero of goiter with hypothyroidism caused by iodide overload. *J. Pediatr*. 133: 147 – 148.

Waran, K.D. & Munsick, R.A. (1995). Anaphylaxis from povidone-iodine. *Lancet* 345: 1506.

WHO (1989). Evaluation of Certain Food Additives and Contaminants (Thirty-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series. No. 776.

Wolff, J., Chaikoff, I.L., Goldberg, R.C. *et al.* (1949). The temporary nature of the inhibitory action of excess iodide on organic iodine synthesis in the normal thyroid. *Endocrinol*. 45: 504 – 513.

Zimmermann, M.B., Ito, Y., Hess, S.Y., Fujieda, K. & Molinari, L. (2005). High thyroid volume in children with excess dietary iodine intakes. *Am. J. Clin. Nutr*. 81: 840 – 844.

Attachment 8

Food Technology Report

Contents

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	$Ca(IO_3)_2.6H_2O$	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	$NaI.2H_20$	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 crystallized in an evapocrystallizer, 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 doesn't 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 sanitizers 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 of 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 oxidize the sulphydryl 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/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 pasteurized 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 (KIO_3) 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 included '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.

References:

Amr, A.S., and Jabay, O.A. (2004) Effect of salt iodization on the quality of pickled vegetables'. *J. Food Agric. Environ.*, 2(2):151-156.

Azanza, M.P.V., Cariaso, K., de la Cerna, M.C., de Ocampo, C., Galvez, F., Moises, M., Pujanes, K. (1998) Use of iodized salt in processed Philipine food products, *Asia Pacific J. Clin. Nutr.*, 7(2):123-127.

Bhatnagar, A., Maharda, N.S., Ambardar, V.S., Dham, D.N., Magdum M., Sankar, R. (1997) Iodine loss from iodised salt on heating. *Ind. J. Ped.*, 64(4):883-5.

Benmiloud, M., Chaouki, M.L., Gutekunst, R., Teichert, H.M., Wood, W.G. and Dunn, J.T. (1994) Oral iodized oil for correcting iodine deficiency: optimal dosing and outcome indicator selection. *J. Clin. Endocrin. Metab.*, 79, 20-24.

Buttfield, I.H., and Hetzel, B.S. (1967) Endemic goitre in Eastern New Guinea. With special reference to the use of iodized oil in prophylaxis and treatment. *Bull. WHO*, 36:243.

Delange, R.F. and Hetzel, B. (2004) The iodine deficiency disorders. http://www.thyroidmanager.org/Chapter20/20_frame.htm. Accessed on 5 July 2005

Doman, M., Korsak, D., Lekowska-Kochaniak, A., Popowski, J. (1999) The effect of potassium iodide on cabbage fermentation and growth of chosen microorganisms – short report. *Polish J. Food Nutr. Sci.*, 8/49(2): 201-208.

Eltom, M., Elnagar, B., Sulieman, E.A., Karlsson, F.A., van Thi, H.V., Bordoux, P., Gebre-Medhin, M. (1995) The use of sugar as a vehicle for iodine fortification in endemic iodine deficiency. *Int. J. Food Sci. Nutr.,* 46(3), 281-9.

Fennema, O.R. (1985) Food Chemistry, 2nd edn, Marcel Dekker Inc, New York.

Food and Agriculture Organization of the United Nations (FAO) (1996) Food fortification: technology and quality control, FAO Food and Nutrition Paper – 60, Rome.

Grace, N.D. and Waghorn, G.C. (2004) Impact of iodine supplementation of dairy cows on milk production and iodine concentration in milk. *N. Z. Vet. J.*, 53(1), 10-13.

Harris, M.J., Jooste, P.L., Charlton, K.E. (2003) The use of iodised salt in the manufacturing of processed foods in South Africa: bread and bread premixes, margarine, and flavourants of salty snacks. *Int. J. Food Sci. Nutr.*, 54, 13-19.

Kammerlehner, J. (1995) Iodine, an essential trace element – its occurrence in milk and dairy products – their enrichment, a contribution to minimizing dietary iodine deficiency. *DMZ Lebensmittelindustrie und Milchwirtschaft*, 116(12): 560-568.

Kaufmann, S. and Rambeck, W.A. (1997) Effect of feedstuff iodine content on the iodine level in milk, with particular reference to milk quality. *Zeitschrift fuer Ernaehrungswissenschaft*, 36(1): 83-84.

Kojima, N. and Brown, H.D. (1955) The effects of iodized salt in processed fruits and vegetables. *Food Tech*, 9:103-107.

Mannar, M.G.V. and Dunn, J.T. (1995) Salt iodization for the elimination of iodine deficiency, International Council for Control of Iodine Deficiency Disorders, UNICEF, New York, NY US, WHO, Genève CH.

Solomons, N.W. (1998) Slow-release iodine in local water supplies reverses iodine deficiency disorders: is it worth its salt? *Nutr. Reviews*, 56(9), 280-281.

State Government of Victoria, Australia (2004) Iodine explained. http://www.betterhealth.vic.gov.au/bhcv2/bhcarticles.nsf/pages/Iodine_explained. Accessed 4 July 2005.

Thomson, C.D., Colls, A.J., Conaglen, J.V., Macormack, M., Stiles, M. and Mann, J. (1997) Iodine status of New Zealand residents as assessed by urinary iodide excretion and thyroid hormones. *Br. J. Nutr.,* 78(6):901-912.

Untoro, J., Schultink, W., Gross, R., West, C.E. and Hautvast, J.G.A.J. (1998) Efficacy of different types of iodised oil. *Lancet*, 351:752-753.

West, C.E., de Koning, F.L.H.A. and Merx, R.J.H.M. (1995) Effect of Iodized salt on the colour and taste of food, UNICEF, New York.

Winger, R.J., Koenig, J., Je Lee, S., Wham, C., and House, D.A., (2005), Technological Issues with Iodine Fortification of Foods, Final Report for New Zealand Food Safety Authority. Ministry of Health, Wellington.

Attachment 9

Dietary Intake Methodology Report

Contents

EXECUTIVE SUMMARY

A dietary intake assessment was conducted to assess the potential impact the introduction of mandatory fortification of food with iodine in Australia and New Zealand would have on iodine intakes among the target groups of children aged up to 3 years, women of child-bearing age (assumed to be 16-44 years), and the population in general (Australia – 2 years and above; New Zealand – 15 years and above).

The aim was to determine a level of fortification that maximised iodine intakes for the target groups while minimising the proportion of the population with dietary iodine intakes below the Estimated Average Requirements (EAR) and above the Upper Level of Intake (UL).

Salt was identified as the food vehicle for iodine fortification of the food supply. Two broad food groups were selected and were evaluated for the effect that replacing non-iodised salt with iodised salt in commercial food manufacture would have on dietary iodine intakes. These food groups were cereal-based foods and processed foods, noting that a cereal based food or a processed food only increases in iodine content under the proposed mandatory iodine fortification program if it contains salt. Not all cereal based foods or processed foods contain salt or they contain negligible quantities (e.g. plain dried pasta, flour, rice grains etc.).

Dietary modelling was conducted for Australian and New Zealand populations to estimate:

1. current iodine intakes (***'Baseline'***) from food based on current naturally occurring iodine concentrations in foods and iodine concentrations in foods resulting from the uptake of voluntary fortification uses of iodine permitted in the *Australia New Zealand Food Standards Code* (the Code);

2. iodine intakes when non-iodised salt is replaced with iodised salt containing 30 milligrams (mg) iodine per kg of salt in cereal-based foods (**'*Scenario 1 - Cereal based foods*'**) and where the voluntary permission for iodine fortification of discretionary salt (salt used in cooking and/or at the table) is reduced from 25-65 mg iodine/kg salt to 20 mg iodine/kg salt; and

3. iodine intakes when non-iodised salt is replaced with iodised salt containing 15 milligrams (mg) iodine per kg of salt in processed foods (***'Scenario 2 - Processed foods'***) and where the voluntary permission for iodine fortification of discretionary salt is reduced from 25-65 mg iodine/kg salt to 20 mg iodine/kg salt.

These dietary modelling scenarios did not take into account iodine intakes from supplements containing iodine. The two scenarios presented were selected after a process of evaluation of a larger number of models as the two scenarios that best met the criteria given above, to maximise iodine intakes for the target groups whilst minimising undesirable levels of high iodine intakes. For example, one scenario considered in the early stages was a 40 mg iodine per kg salt fortification for cereal products. Although this enabled the target groups to achieve intakes closer to target levels this was not pursued further as the proportion of the general population exceeding the UL for iodine was undesirable.

Two different types of food consumption data were used in the assessment of dietary iodine intakes: (1) National Nutrition Survey (NNS) data; and (2) theoretical diets.

The NNS data that were used included the 1995 NNS from Australia that surveyed 13,858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4,636 people aged 15 years and above. Since there were no NNS data for Australians aged less than 2 years and New Zealanders aged less than 15 years available for dietary modelling, theoretical diets were used to assess dietary iodine intakes for the target groups, Australian children aged 1 year and New Zealand children aged 1-3 years.

The dietary modelling results indicated that mean iodine intakes increase under both of the fortification scenarios, with *'Scenario 2 – Processed foods'* showing a slightly higher increase. It should be noted that:

- New Zealand has lower baseline iodine intakes possibly due to the lower iodine concentration in milk in comparison to Australia. Milk is a major contributor to iodine intakes.
- For both *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*, estimated 95th percentile dietary iodine intakes exceed the UL for Australian children aged 1 year (120-140% UL) and New Zealand children aged 1-3 years (110-140% UL).
- Australian children aged 2-3 years have estimated dietary iodine intakes that exceed the UL, the magnitude of which varies, depending on whether children who reported consuming discretionary salt were assumed to have non-iodised or iodised salt. *'Scenario 2 – Processed foods'* showed a greater exceedance of the UL (10-20% of the population group) than for *'Scenario 1 – Cereal based foods'* (6-16% of the population group).
- Of all of the population groups assessed, Australian children aged 2-3 years had the largest proportion of the group exceeding the UL.
- For both *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*, there was a reduction in the proportion of the population with dietary iodine intakes below the EAR from *'Baseline'* for all of the population groups assessed.
- As age increased, there was a general tendency for there to be a greater proportion of the population with dietary iodine intakes that were less than the EAR.
- Of all of the population groups assessed, pregnant and lactating women had the highest proportions of the population group with dietary iodine intakes below the EAR for *'Baseline'*, '*Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*.
- Of the scenarios assessed, *'Scenario 2 – Processed foods'* had the lowest percentage of the population groups below the EAR but the greatest percentage of the population groups with dietary iodine intakes above the UL.

1. Dietary Modelling Conducted to Estimate Iodine Intakes

1.1 What is Dietary Modelling?

Dietary modelling is a tool used to estimate intakes of food chemicals from the diet as part of the FSANZ risk assessment process. To estimate dietary intake of food chemicals, records of what foods people have eaten are needed and reports of how much of the food chemical of interest is in each food. The accuracy of these intake estimates depends on the quality of the data used in the dietary models. Sometimes, all the data needed are not available or the accuracy is uncertain so assumptions have to be made, either about the foods eaten or about chemical levels, based on previous knowledge and experience.

The models are generally set up according to international conventions for food chemical intake estimates, however, each modelling process requires decisions to be made about how to set the model up and what assumptions to make; a different decision may result in a different answer. Therefore, FSANZ documents clearly all such decisions, model assumptions and data limitations to enable the results to be understood in the context of the data available and so that FSANZ risk managers can make informed decisions.

1.2 Population Groups Assessed

Iodine is used in the production of hormones essential in the brain development of the foetus and young child. This is reflected in a substantially elevated requirement for iodine during pregnancy and lactation. Children, especially up to 2-3 years, are still experiencing substantial developments to their brain and nervous system. This makes them a particularly vulnerable group to iodine deficiency. Consequently, the target groups for iodine fortification modelling were identified as:

1. children aged up to 3 years; and
2. women 16-44 years, who were taken to represent the target group of women of child-bearing age when estimating dietary iodine intakes.

Iodine intakes were also assessed for the general Australian population aged 2 years and above and the New Zealand population aged 15 years and above to assess potential public health and safety risks of high iodine intakes.

The dietary intake assessment was conducted separately for both the Australian and New Zealand populations and target sub-population groups.

1.3 Dietary Modelling Approach

The dietary intake assessment discussed in this attachment was conducted using FSANZ's dietary modelling computer program, DIAMOND.

Dietary Intake = food chemical concentration x food consumption

The iodine intake was estimated by combining usual patterns of food consumption, as derived from NNS data, with current concentrations of iodine in food and the proposed levels of use of iodine in salt (see Figure 1 for an overview of the dietary modelling approach). More details of each step in the process are given below.

1.4 Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13,858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4,636 people aged 15 years and above.

Both of these surveys used a 24-hour food recall methodology. A second 24-hour recall was also conducted on a subset of respondents in both surveys for a non-consecutive day.

Standard methodologies were used to estimate intake based on consumption data from the first 24 hour recall (day one), which were then adjusted to estimate 'usual intake' by using consumption information from the second 24 hour recall (day two) (see Appendix 1*: How were the estimated dietary intakes estimated?* for more information on the second day adjusted nutrient intake methodology).

It is recognised that these survey data have several limitations. For a complete list of limitations see Section 5*: Limitations*.

1.5 Additional Food Consumption Data or other Relevant Data

1.5.1 Discretionary Salt Consumption Data

The iodine fortification of salt is voluntary and not all salt available on the retail market is iodised. Salt is currently permitted to contain 25 - 65 mg iodine/kg salt. The consumption of discretionary salt used in cooking and/or at the table is a potentially significant source of iodine where people are consuming iodised salt.

Limited data on the consumption of discretionary salt were available from the 1995 Australian NNS. Data on the consumption of discretionary salt were not available for the 1997 New Zealand NNS. The Australian NNS asked two question "How often do you add salt to food during cooking?" and "How often do you add salt after food is cooked?". Possible responses were: "never, rarely, sometimes or usually?". In response to these questions, approximately 62% of Australians aged 2 years and above reported using discretionary salt. Further details on the proportion of Australian population groups who consume discretionary salt can be found in Table 1 below.

Table 1: Proportion of Australian Population Groups Who Consume Discretionary Salt, as Reported in the 1995 NNS

Australian population group	Proportion of Australian population groups consuming discretionary salt (%)
2-3 years	36
4-8 years	48
9-13 years	55
14-18 years	63
19-29 years	59
30-49 years	60
50-69 years	70
70 years and above	75
Females 16-44 years	55
2 years and above	62

Since the data from the NNSs on discretionary salt consumption were limited to the proportion consuming discretionary salt, an estimate of the amount of salt consumed was derived from grocery market share data for salt. The per capita salt consumption derivation is given below.

$$\text{Per capita salt consumption} = \frac{\text{Salt sales (grams/year)}}{\text{365 days/year x number of people in the population}}$$

The Australian data were derived from a number of sources (Retail World Pty Ltd, 2001; Flanagan, 2002; Flanagan, 2004; Flanagan, 2005; Flanagan, 2006), and were based on grocery sales of salt over a 12 month period. Using the grocery market share data it was determined that, for Australian consumers of discretionary salt, the consumption was 2.7 grams per person per day, based on 62% of the population consuming discretionary salt. This salt consumption figure was then matched to each respondent from the 1995 NNS who reported consuming discretionary salt.

The New Zealand data are per capita salt consumption for all New Zealanders aged over 2 years and were based on supermarket sales of salt (iodised and non-iodised) over a 12 month period. The calculation does not include salt sold through other outlets such as Asian supermarkets etc. Therefore the consumption of discretionary salt by New Zealanders is likely to be an underestimate. Using these data, it was determined that, across the New Zealand population, 1.0 gram of discretionary salt was consumed per person per day. This salt consumption figure was then matched to every respondent from the 1997 NNS.

1.5.2 Food Consumption Data for Australian Children Aged 1 Year and New Zealand Children Aged 1-3 Years

As there are no data available from the 1995 Australian NNS for children aged < 2 years, a theoretical diet was constructed to estimate dietary iodine intake for the target group of children aged 1 year. Similarly, as there are no data available from the 1997 New Zealand NNS for children aged < 15 years, a theoretical diet was used to estimate dietary iodine intake for the target group of New Zealand children aged 1-3 years.

A number of theoretical diets were used, some assuming consumption of Formulated Supplementary Foods for Young children (FSFYC) as a partial alternative to milk. Since theoretical diets are based on mean food consumption amounts only, individual records are not available to derive a distribution of food intakes and hence nutrient intakes. The proportion of these population groups with dietary iodine intakes below the EAR or above the UL could therefore not be calculated. As an alternative, the 95th percentile dietary iodine intake was estimated and then compared to the UL, using the internationally accepted formula (WHO, 1985) of:

$$95^{th} \text{ percentile intake} = \text{mean intake x 2.5}$$

Full details on how the theoretical diets were constructed can be found in Appendix 1 Section

1.2 For Australian children aged 1 year and New Zealand children aged 1-3 years.

Figure 1: Dietary Modelling Approach used for Assessing Iodine Intakes for Australia and New Zealand

1. Identification of two food groups for iodine fortification
Cereal based foods
Processed foods

2. Selection of the type of DIAMOND model
Nutrient Intake Model adjusted for second day nutrient intakes

3. Selection of population groups to assess
- *Children aged up to 3 years*
- *Women of child-bearing age (16-44 years)*
- *Australian population aged 2 years & above; New Zealand population aged 15 years & above*
- *Age and gender groups from Nutrient Reference Values*

4. Selection of three scenarios to model

4a. 'Baseline'
To assess current iodine intakes, including intake from discretionary salt use.

4b. 'Scenario 1 – Cereal based foods'
'Baseline' + mandatory fortification of salt used in the manufacture of commercially available 'cereal based foods', including intake from discretionary salt.

4c. 'Scenario 2 – Processed foods'
'Baseline' + mandatory fortification of salt used in the manufacture of commercially available 'processed foods', including intake from discretionary salt.

5. Selection of iodine concentration levels for fortified salt
30 mg or 40 mg iodine/kg salt used in manufacture of cereal-based foods.
15 mg iodine/kg salt used in manufacture of processed foods.
Discretionary salt fortified with 45 mg iodine/kg salt at Baseline, 20 mg iodine/kg salt in Scenarios 1 and 2.

6. Estimation of dietary iodine intakes for each Scenario and population group
Dietary Intake = food chemical concentration x food consumption amount from National Nutrition Surveys

7. Comparison of estimated dietary iodine intakes for each Scenario and population group with the Estimated Average Requirement (EAR) and Upper Level of Intake (UL)

1.6 Food Vehicle

Salt was identified as the food vehicle for iodine fortification of the food supply (see Section 7 in Draft Assessment Report). In evaluating potential food groups for fortification with iodine, the major contributors to salt intake from processed foods were determined. For the Australian population groups of children aged 2-3 years, women aged 16-44 years and the population aged 2 years and above, the major contributor (≥ 5%) to salt intake from processed foods was cereals and cereal products. Other major contributors included cereal-based products and dishes; meat, poultry and game products and dishes; milk, milk products and dishes; and savoury sauces and condiments. For New Zealand population groups of women aged 16-44 years and the population aged 15 years and above, bread (including rolls and specialty breads) was the major contributor to salt intake from processed foods. Sauces, bread-based dishes, pork, grains and pasta, sausages and processed meats, and pies and pasties were other major contributors to salt intake from processed foods for one or more of the target New Zealand population groups.

Further details on the food groups that are major contributors to salt intake from processed foods for Australian and New Zealand population groups can be found in Tables A2.1a and A2.1b of Appendix 2, respectively.

Since cereals and cereal products were the major contributor to salt intake from processed foods for Australia and that breads were the major contributor for New Zealand, two broad options for iodine fortification were investigated: (1) replacing non-iodised salt with iodised salt in commercially-prepared cereal based foods; and (2) replacing non-iodised salt with iodised salt in processed foods. A cereal based food or a processed food would only increase in iodine content under mandatory iodine fortification if it contains salt. Not all cereal based foods or processed foods contain salt or they contain negligible quantities (e.g. plain dried pasta, flour, rice grains etc.). Figure 2 outlines the cereal based foods and processed foods deemed to contain salt for dietary modelling purposes, based on information from food packages and food composition data.

Figure 2: Foods that Contain Salt for Dietary Modelling Purposes

Cereal based foods includes breads (plain, sweet and savoury), some breakfast cereals, pizza bases, doughnuts, cakes, sweet biscuits, crackers/savoury biscuits, slices, hotplate products (pikelets, scones, crumpets etc.) and pastry.

Processed foods includes the cereal based foods listed above and cheeses; sauces, gravies and stocks; flavoured rices, pastas and noodles; takeaway foods (e.g. hamburgers, pizzas etc.); pre-prepared meals or meal components (e.g. frozen oven fried potato wedges, refrigerated prepared quiche, frozen crumbed fish); pies; butter, margarines and spreads; canned foods; processed meats (e.g. salami, frankfurts etc.); sausages; soups; dressings and mayonnaise; chutneys, relishes and mustards; snack foods (e.g. potato crisps); confectionery.

1.7 Scenarios and Iodine Concentration Data

Three scenarios were modelled for the purpose of this Proposal:

1. ***'Baseline'*** to estimate current iodine intakes from food alone, based on current naturally occurring iodine concentrations in foods and iodine concentrations in foods resulting from permitted uses of iodine in the Code. The consumption of discretionary salt was also considered. The iodine concentration in iodised discretionary salt was assumed to be 45 mg iodine/kg salt for dietary modelling purposes and was based on industry-supplied data, noting that it is also the midpoint of the range of currently permitted iodine fortification of salt (25 – 65 mg iodine/kg salt).

2. **'*Scenario 1 - Cereal based foods*'** – non-iodised salt is replaced with iodised salt containing 30 milligrams (mg) iodine per kg of salt in cereal-based foods. The voluntary permission for iodine fortification of discretionary salt is reduced from 25-65 mg iodine/kg salt to 20 mg iodine/kg salt.

3. ***'Scenario 2 - Processed foods'*** – non-iodised salt is replaced with iodised salt containing 15 milligrams (mg) iodine per kg of salt in processed foods. The voluntary permission for iodine fortification of discretionary salt is reduced from 25-65 mg iodine/kg salt to 20 mg iodine/kg salt.

1.7.1 Rationale for Reducing Discretionary Salt Iodine Permission in the Scenario 1 and 2 Models

Baseline dietary modelling using the current voluntary permission for iodising salt resulted in large ranges of iodine intakes and subsequent proportions of population groups with dietary iodine intakes below the EAR and above the UL. For example, using iodised rather than non-iodised discretionary salt adds an extra 122 μg iodine per day for an Australian consumer and an extra 45 μg iodine per person per day for a New Zealander.

The high level of uncertainty about the current estimated iodine intakes meant it would be difficult to predict the impact of a mandatory iodine fortification program and hence difficult to make risk management decisions based on dietary modelling results. To reduce the uncertainty around potential iodine intakes under the two fortification scenarios (i.e. '*Scenario 1 - Cereal based foods*' and *'Scenario 2 - Processed foods'*), the voluntary permission for the iodine fortification of discretionary salt was reduced from 25-65 mg iodine/kg salt to 20 mg iodine/kg salt. This resulted in a decrease in the range of predicted iodine intakes. For the two scenarios, using iodised rather than non-iodised discretionary salt adds an extra 54 μg iodine per discretionary salt user per day for an Australia consumer and an extra 20 μg iodine per person per day for a New Zealander.

1.7.2 'Baseline' Model

This model represents current estimated iodine intakes for each population group, assessed in the current regulatory environment, i.e. before mandatory iodine fortification permissions are given in Australia and New Zealand.

This model only considers where voluntary iodine permissions outlined in Standard 1.3.2 of the Code have been taken up by industry, as evidenced by products available on the supermarket shelves or by analytical data. It does not include foods or food groups where voluntary fortification of iodine is permitted in the Code but has not been taken up by industry. It takes into account naturally occurring iodine in food. It does not take into account iodine intakes from the use of iodine supplements or multi-vitamin supplements containing iodine.

Baseline iodine concentrations for foods were derived from four major sources:

1. Total diet studies for Australia and New Zealand (Food Standards Australia New Zealand, 2005; Vannoort and Thomson, 2005c; Vannoort and Thomson, 2005d) provided information on around 90 and 120 foods respectively that are commonly consumed foods. As well as providing information on iodine levels in these foods, the results of the studies also identified major contributing food groups (such as dairy) for which more detailed information on iodine levels was necessary.

2. Analytical data for foods sampled in both countries from around 2000 to 2005. Many of these foods were dairy and seafood. Where the same foods were available in both countries (for example, foods manufactured in one country and sold in both, such as breakfast cereals), the same data were able to be used in the modelling for both countries.

3. Overseas analytical data were used when no relevant Australian or New Zealand data were identified and a food is known to be imported into both countries (for example, canned fish or European cheeses). Data from the UK (Food Standards Agency, 2002) and Denmark (Møller *et al*., 2006) were major information sources.

4. Recipe calculations were used to derive iodine levels in mixed foods (e.g. spaghetti bolognese) for which analytical data were not available.

Information from these four sources was matched against the 1995 Australian and 1997 New Zealand NNS food codes, assigning an iodine value to virtually all individual food codes.

1.7.3 'Scenario 1 – Cereal Based Foods'

This model was conducted to estimate potential dietary iodine intakes for each population group should mandatory iodine fortification of salt used in cereal based foods be introduced in Australia and New Zealand at 30 mg iodine per kg of salt.

This model includes *'Baseline'* iodine concentrations for all foods other than salt containing cereal based foods. It did not take into account iodine intakes from supplements containing iodine.

The iodine contributed by the replacement of non-iodised salt with iodised salt in the target foods was calculated. This was done by first compiling the salt content of each of the foods in the target food group(s). A database on the concentrations of salt in cereal based foods was prepared specifically for the assessment of this proposal and used the most applicable and up-to-date data available. Proportions of salt in foods were estimated based on analytical information from Australian and New Zealand food composition data.

A second calculation determined how much iodine the salt would contribute to the food. The iodine contribution from the salt was then added to the 'Baseline' iodine concentration of that food. The resulting iodine concentrations for each food were then used in the dietary modelling. For example, the 'Scenario 1- Cereal based foods' iodine concentration for white bread was calculated as outlined in Figure 3:

Figure 3: Method for Calculating Iodine Concentration in Salt Containing Foods for 'Scenario 1 – Cereal Based Foods' And 'Scenario 2 – Processed Foods' for Dietary Modelling Purposes

Iodine concentration in bread (non-iodised salt):	1.37 µg/100 g
Proportion of salt in bread:	1.36%
Concentration of iodine in salt:	30 mg/kg salt

Iodine concentration in bread (using iodised salt):
1.37 µg I/100 g bread + (0.00136 kg salt/100 g bread x 30,000 µg I/kg salt)
= 42.2 µg iodine /100 g bread

For dietary modelling purposes, these estimates do not take into account potential losses of iodine during production and storage.

1.7.4 'Scenario 2 – Processed Foods'

This model was conducted to estimate potential dietary iodine intakes for each population group should mandatory iodine fortification of salt used in processed foods be permitted in Australia and New Zealand at 15 mg iodine per kg of salt.

This model includes 'Baseline' iodine concentrations for all foods other than salt containing processed foods. A database on the concentrations of salt in processed foods was prepared specifically for the assessment of this proposal and used the most applicable and up-to-date data available. It does not take into account iodine intake from the use of iodine supplements or multi-vitamin supplements containing iodine.

The iodine contributed by the replacement of non-iodised salt with iodised salt in the target foods was calculated using the method listed in Figure 3 above.

1.8 How were the Estimated Dietary Iodine Intakes Calculated?

A detailed explanation of how the estimated dietary intakes were calculated using an adjustment for a second day of food consumption records can be found in Appendix 1.

2. Assumptions Used in the Dietary Modelling

The aim of the dietary intake assessment is to make as realistic an estimate of dietary iodine intake as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary intake assessment did not underestimate intake.

The assumptions made in the dietary modelling are listed below, broken down into several categories.

2.1 Consumer Behaviour

- Consumption of foods as recorded in the NNSs represent current food consumption amounts;
- the dietary patterns for females aged 16-44 years are representative of the dietary patterns for pregnant women and for lactating women;
- consumers always select products containing iodine at the concentrations specified;
- consumers do not alter their food consumption habits upon iodine fortified products becoming more available on the market. For example, consumers do not swap from non-iodised to iodised discretionary salt;
- for Australian consumers aged 2 years and above that were identified in the NNS as consuming discretionary salt, the daily consumption of discretionary salt was 2.7 grams per person per day;
- since data on the New Zealanders consuming discretionary salt were not available from the 1997 NZ NNS, it was assumed that all New Zealanders aged 15 years and above consumed 1.0 gram of discretionary salt per day, based on salt sales data;
- Australian children aged 1 year do not consume discretionary salt; and
- New Zealand children aged 1-3 years do not consume discretionary salt.

2.2 Concentration Data

- Where there were no Australian iodine concentration data for specific foods, it was assumed that New Zealand data were representative of these food groups, and vice versa for New Zealand;
- where a food was not included in the intake assessment, it was assumed to contain a zero concentration of iodine; and
- there is no contribution to iodine intake through the use of complementary medicines (Australia) or dietary supplements (New Zealand) for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* models.

2.3 Food Vehicles

- For *'Scenario 1 – Cereal based foods'*, salt was assumed to be used as an ingredient in breads (plain, sweet and savoury), some breakfast cereals (those currently containing salt), pizza bases, doughnuts, cakes, sweet biscuits, crackers/savoury biscuits, slices, hotplate products (pikelets, scones, crumpets etc) and pastry; and

- for *'Scenario 2 –Processed foods'* salt was assumed to be used as an ingredient in the cereal based foods listed above and cheeses; sauces, gravies and stocks; flavoured rices, pastas and noodles; takeaway foods (e.g. hamburgers, pizzas etc.); pre-prepared meals or meal components (e.g. frozen oven fried potato wedges, refrigerated prepared quiche, frozen crumbed fish); pies; butter, margarines and spreads; canned foods; processed meats (e.g. salami, frankfurts etc.); sausages; soups; dressings and mayonnaise; chutneys, relishes and mustards; snack foods (e.g. potato crisps); confectionery.

2.4 General

- All iodine present in food is absorbed by the body;
- there are no reductions in the iodine concentrations in iodised salt from cooking and storage; and
- for the purpose of this assessment, it is assumed that 1 millilitre is equal to 1 gram for all liquid and semi-liquid foods (e.g. orange juice).

3. Estimated Mean Dietary Iodine Intakes

The results section of this report is primarily focused on the target population groups, with results for the general population groups also presented for comparison and for use in risk assessments.

Dietary iodine intakes were estimated at *'Baseline'* to determine the amount of iodine the target population groups receive from the naturally-occurring iodine in foods and from the current levels of voluntary iodine fortification. These *'Baseline'* iodine intakes were then used to assess the impact that mandatory fortification from *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* could have on iodine intakes in the target groups.

Dietary iodine intakes were estimated for non-target groups aged between 4 and 18 years to assess the impact that mandatory fortification from *Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* may have on public health and safety, specifically on the proportion of the population group or sub group estimated to exceed the UL for iodine.

3.1 Results for Young Children

Mean dietary iodine intakes for Australian children aged 1 year and for New Zealand children aged 1-3 years were calculated using 'theoretical diets'. The range of dietary iodine intakes take into consideration a previously assessed application (A528) for changing permitted iodine levels in FSFYC or 'toddler milks'. The lower number in the results presented as a range represents a situation where no FSFYC or 'toddler milks' are consumed; the upper number in the range represents a situation where 1 serve (226 g) of FSFYC is consumed per day instead of cow's milk.

At *'Baseline'*, Australian children aged 1 year have higher mean dietary iodine intakes in comparison to New Zealand children aged 1-3 years. The differences between Australia and New Zealand could be due to (1) the lower milk iodine concentration in New Zealand in comparison to Australia; (2) the different age groups being assessed; and/or (3) the different methods of constructing the theoretical diets.

For both of the iodine fortification scenarios, the estimated mean dietary iodine intakes for Australian children aged 1 year and New Zealand children aged 1-3 years are similar. Both *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* result in higher mean dietary iodine intakes for Australian children aged 1 year and New Zealand children aged 1-3 years in comparison to the *'Baseline'*.

3.2 Results for all other Population Groups

For all other population groups, mean dietary iodine intakes were derived from the 1995 and 1997 NNSs. A range of dietary iodine intakes are presented; the lower number in the range represents a situation where non-iodised discretionary salt is consumed, and the upper number in the range represents where iodised discretionary salt is consumed.

For all other population groups assessed for Australia and New Zealand, there is an increase in estimated mean dietary iodine intakes from *'Baseline'* for both *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*, with Scenario 2 showing slightly higher increases. Refer to Figure 4 for an overview of mean dietary iodine intakes. The results indicate that the New Zealand population aged 15 years and above has a lower baseline mean iodine intake compared to Australians aged 2 years and above. For women aged 16-44 years, New Zealanders also have a lower baseline iodine intake in comparison to Australians. The lower mean iodine intakes in New Zealand could be due to the lower iodine contents of some key foods, such as milk, in comparison to Australia.

For a complete set of numerical results of iodine intakes for all population groups assessed, refer to Tables A2.2 and A2.3 in Appendix 2.

3.3 Estimated Increases in Iodine Intakes

The results show an increase in estimated dietary iodine intakes from baseline for both *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* foods for the target groups, and all other population groups assessed.

The incremental increase in iodine intake from 'Baseline' for the target groups of children 1-3 years and women of child bearing age (16-44 years) are shown in Tables 2a and 2b.

Table 2: Estimated Increases in Mean Iodine Intakes for Target Groups Should Mandatory Fortification of Salt in Either Cereal Based Foods or Processed Foods be Introduced

a. Based on theoretical diets

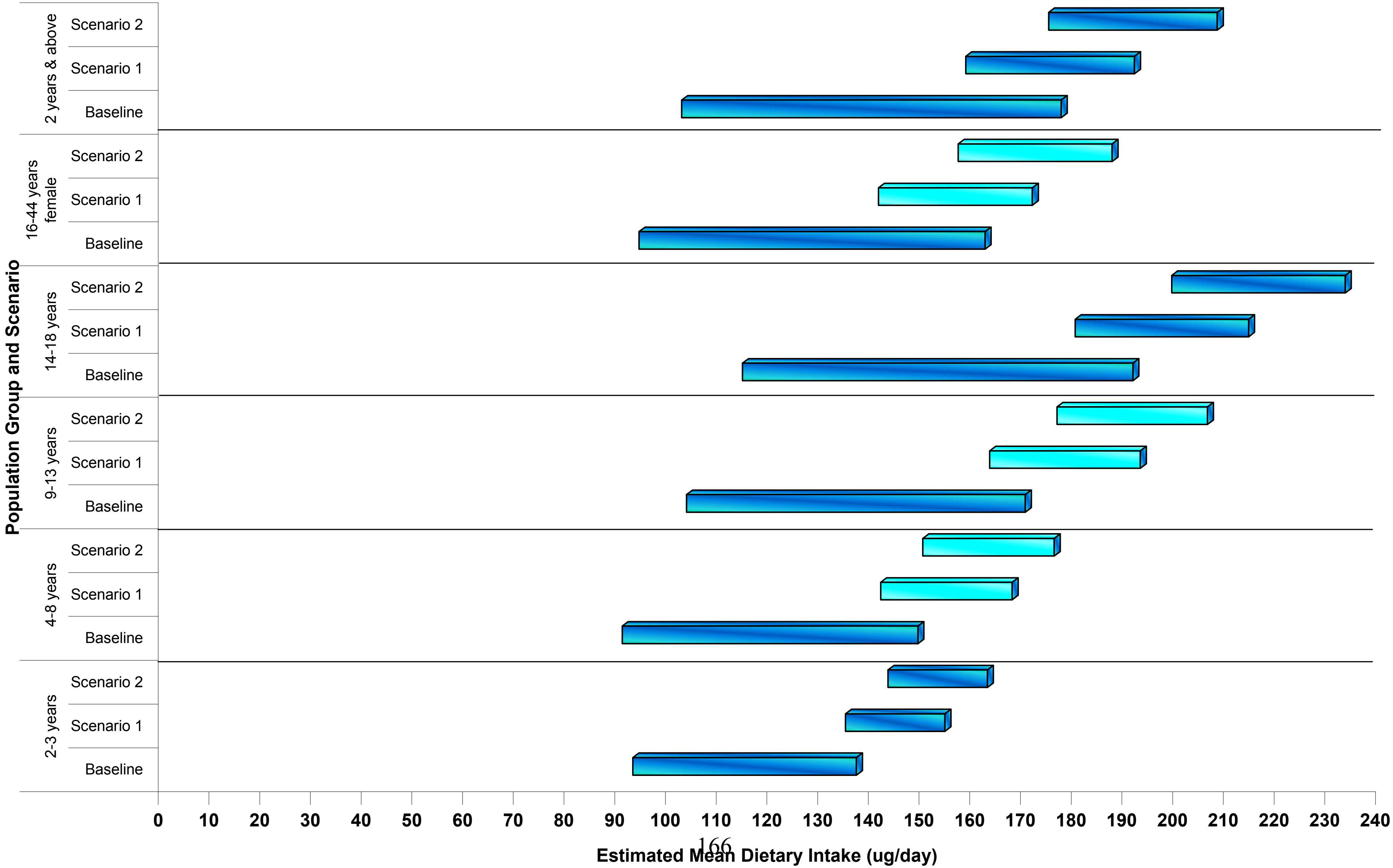
Country	**Population group**	**Model**	**Baseline mean dietary iodine intake (µg/day)**		**Increase in mean iodine intake from 'Baseline' (µg/day)**	
			Without FSFYC	With FSFYC	Without FSFYC	With FSFYC
Australia	Children 1 year	*'Scenario 1 – Cereal based foods': 30 mg I/kg salt*	79	96	+16	+16
		'Scenario 2 – Processed foods': 15 mg I/kg salt	79	96	+17	+17
New Zealand	Children 1-3 years	*'Scenario 1 – Cereal based foods': 30 mg I/kg salt*	48	72	+37	+37
		'Scenario 2 – Processed foods': 15 mg I/kg salt	48	72	+41	+41

b. Based on NNS data

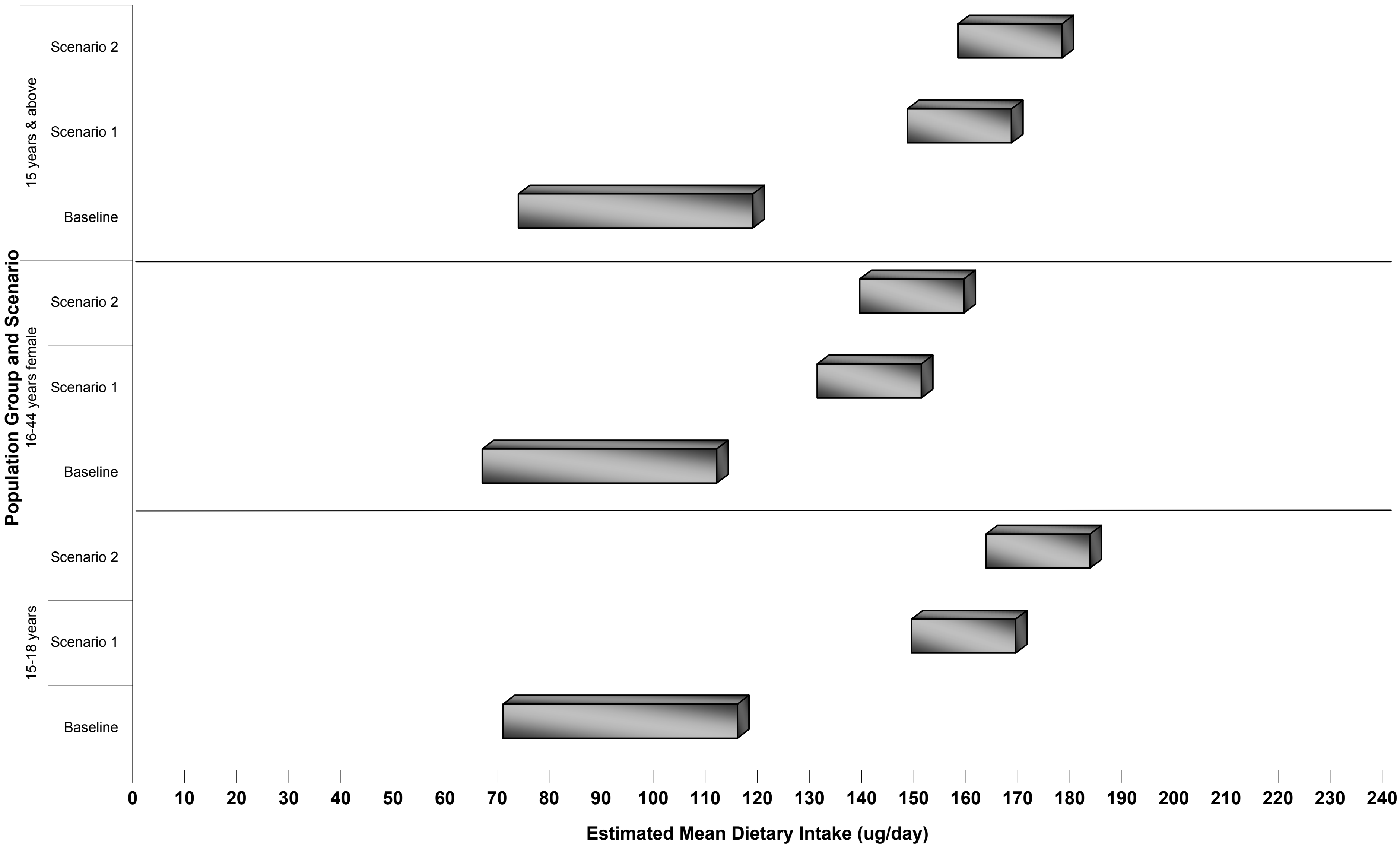
Country	**Population group**	**Model**	**Baseline mean dietary iodine intake (µg/day)**		**Increase in mean iodine intake from 'Baseline' (µg/day)**	
			Non-iodised discretionary salt	Iodised discretionary salt	Non-iodised discretionary salt	Iodised discretionary salt
Australia	Children 2-3 years	*'Scenario 1 – Cereal based foods': 30 mg I/kg salt*	93	137	+42	+17
		'Scenario 2 – Processed foods': 15 mg I/kg salt	93	137	+50	+26
	Women 16-44 years	*'Scenario 1 – Cereal based foods': 30 mg I/kg salt*	94	162	+47	+9
		'Scenario 2 – Processed foods': 15 mg I/kg salt	94	162	+63	+25
New Zealand	Women 16-44 years	*'Scenario 1 – Cereal based foods': 30 mg I/kg salt*	66	111	+64	+39
		'Scenario 2 – Processed foods': 15 mg I/kg salt	66	111	+72	+47

Figure 4: Estimated Mean Dietary Intakes of Iodine (µg/day) for Baseline, 'Scenario 1 – Cereal-Based Foods' and 'Scenario 2 – Processed Foods' Models.

a. Australia



b. New Zealand



3.4 Major Contributors to Iodine Intakes

The major foods contributing ≥5% to total iodine dietary intakes are shown in Figures 5-7. These are displayed for the total population assessments as well as for women aged 16-44 years and children aged up to 3 years. A full list of all the food groups and their contributions can be found in Tables A2.4 and A2.5 in Appendix 2. The calculations for major contributing foods were based on intakes derived from the first 24-hour recall data only.

3.4.1 Australian Children Aged 1 Year

When FSFYC are not included in the theoretical diet, the major contributor to iodine intake for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* is milk. The other major contributor is bread. When FSFYC are included in the diet, the major contributor to iodine intake is FSFYC, followed by milk for all scenarios considered. For *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*, bread is also a major contributor to iodine intakes. Discretionary salt use is not considered in these theoretical diets.

3.4.2 Australian Children Aged 2-3 Years

When the consumption of discretionary iodised salt is not included in the model, the major contributor to iodine intake for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* is milk, milk products and dishes. At *'Baseline'*, non-alcoholic beverages are also a major contributor. For *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*, cereal-based products and dishes (e.g. biscuits, cakes, pastries, pizzas, sandwiches etc.) and cereals and cereal products (grains, flours, breakfast cereals, pastas, noodles etc.) are major contributors. For *'Scenario 2 – Processed foods'*, meat, poultry and game products and dishes (e.g. plain meats, ham, sausages, processed meats etc.) is also major contributing food group.

3.4.3 New Zealand Children Aged 1-3 Years

When FSFYC are not included in the theoretical diet, the major contributors to iodine intake for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* are milk and yoghurt. At *'Baseline'*, eggs are also major contributors to iodine intakes. For *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods',* bread is a major contributor. When FSFYC are included, the major contributor to iodine intake is FSFYC for all scenarios considered. At *'Baseline'*, eggs and yoghurt are also major contributors and for *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*, bread is a major contributor to iodine intakes.

3.4.4 Women Aged 16-44 Years

For Australian women aged 16-44 years, the major contributors to iodine intakes for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* are milk, milk products and dishes, non-alcoholic beverages, water, cereal-based products and dishes, and cereals and cereal products. Meat, poultry and game products and dishes are also major contributors to iodine intakes for *'Scenario 2 – Processed foods'*.

For New Zealand women aged 16-44 years, the major contributors to iodine intakes for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* are milks, fish/seafood, and eggs and egg dishes. At *'Baseline'*, non-alcoholic beverages and grains and pasta are also major contributors. For *'Scenario 1 – Cereal based foods'*, bread (includes rolls and specialty breads) and bread based dishes are major contributors while for *'Scenario 2 – Processed foods'*, bread (includes rolls and specialty breads), grains and pasta, and sauces are major contributors.

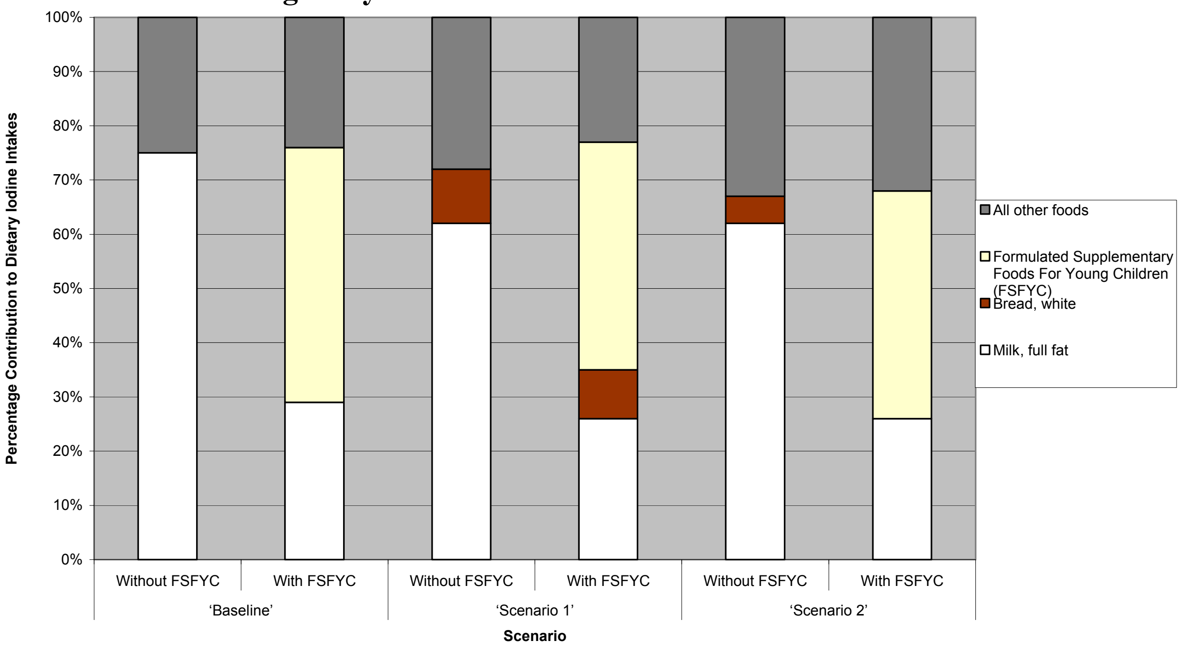
3.4.5 Australian Population Aged 2 Years and Above and The New Zealand Population Aged 15 Years and Above

For Australians aged 2 years and above, the major contributors to iodine intakes for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* are similar to those for the target groups, that is milk, milk products and dishes, non-alcoholic beverages, water, cereal-based products and dishes, and cereals and cereal products. Meat, poultry and game products and dishes are also major contributors to iodine intakes for *'Scenario 2 – Processed foods'*.

For New Zealanders aged 15 years and above, the major contributors to iodine intakes for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* are milks, fish/seafood, and eggs and egg dishes. For *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*, bread (includes rolls and specialty breads) is also a major contributor.

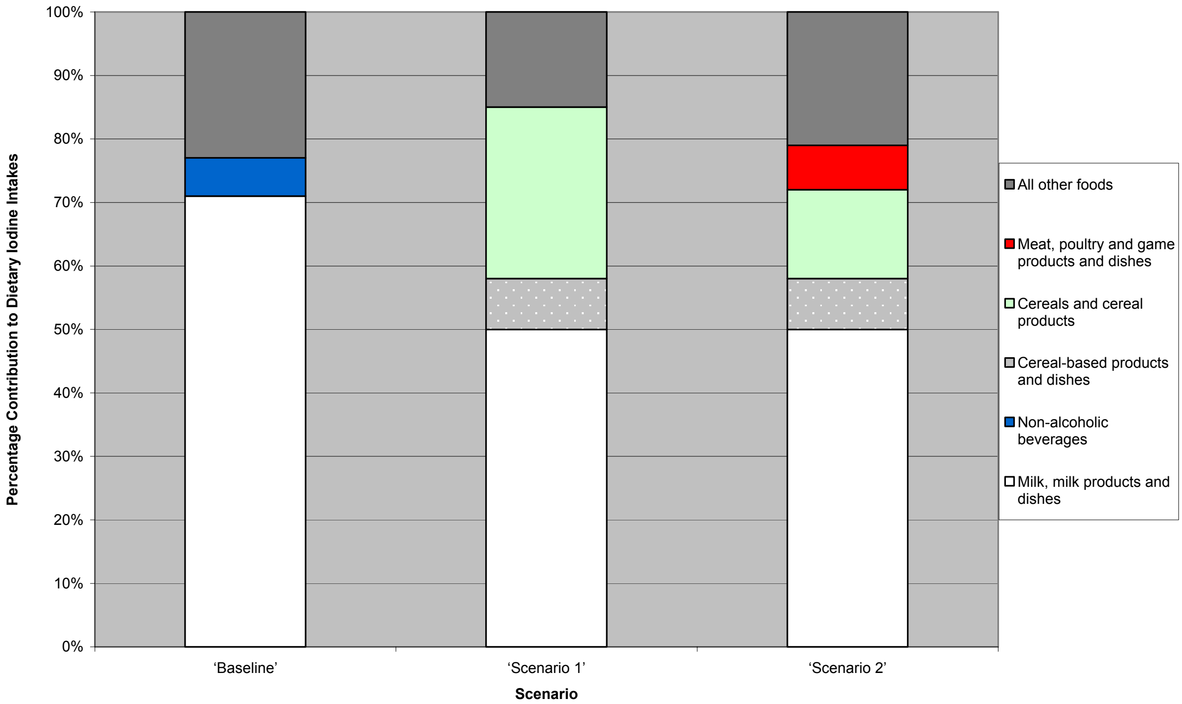
Figure 5: Major Contributors to Total Iodine Dietary Intakes for Australian and New Zealand Children Aged up to 3 Years

a. Australian children aged 1 year[32]

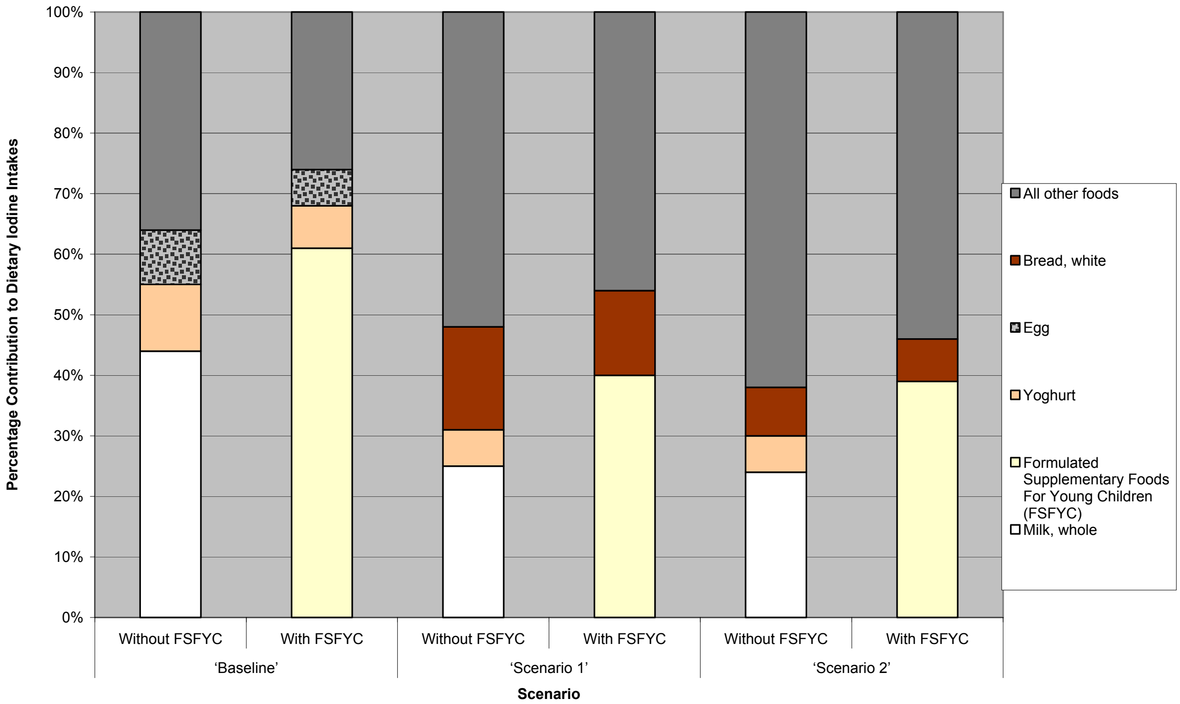


[32] The percent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

b. Australian Children Aged 2-3 Years[33]



c. New Zealand Children Aged 1-3 Years[2]

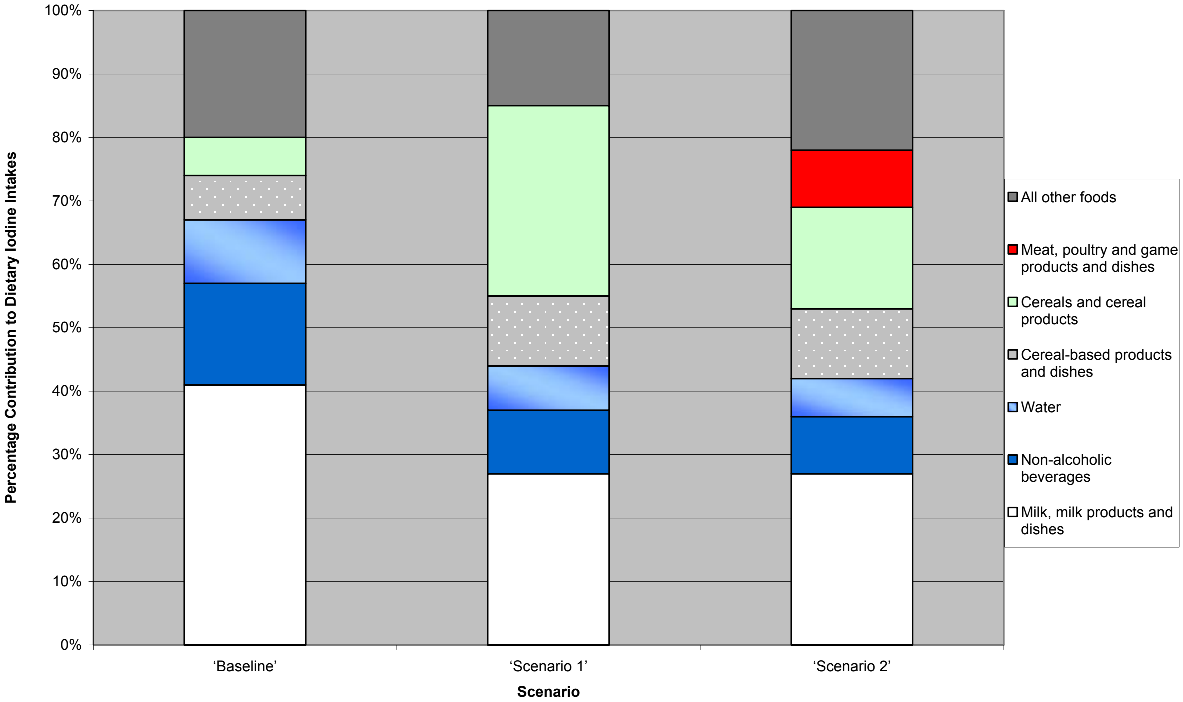


---

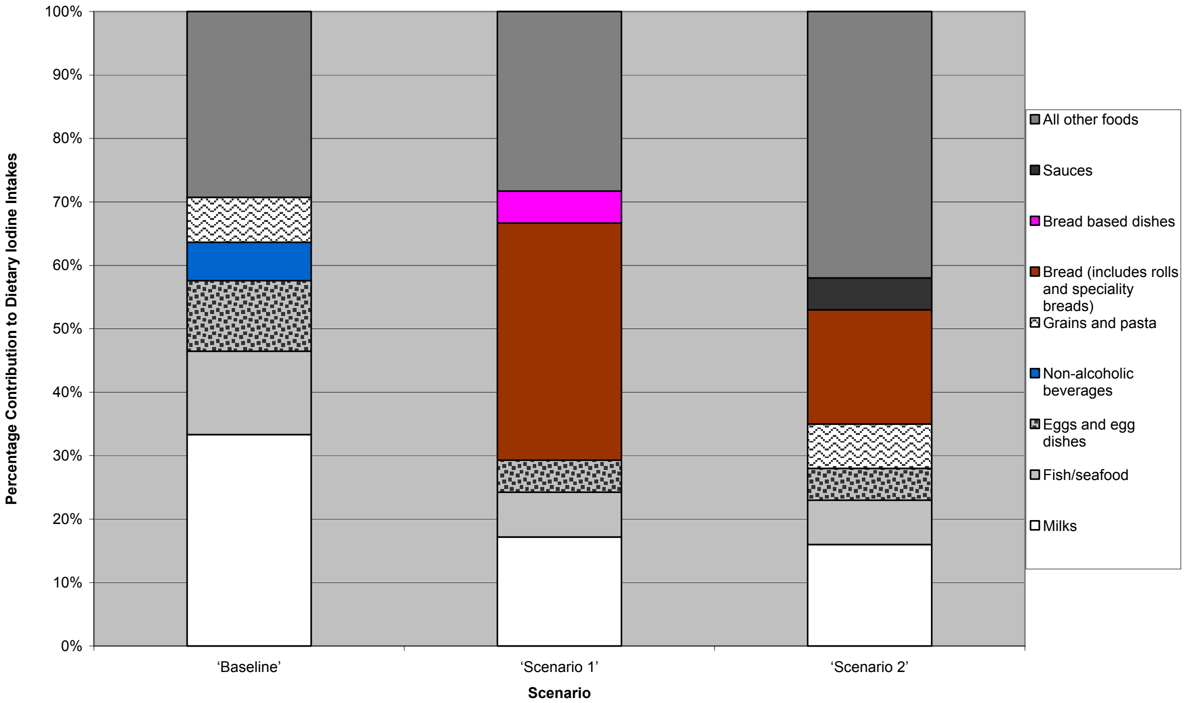
[33] The percent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

Figure 6: Major Contributors to Total Iodine Dietary Intakes for Australian and New Zealand Women Aged 16-44 Years[34]

a. Australia



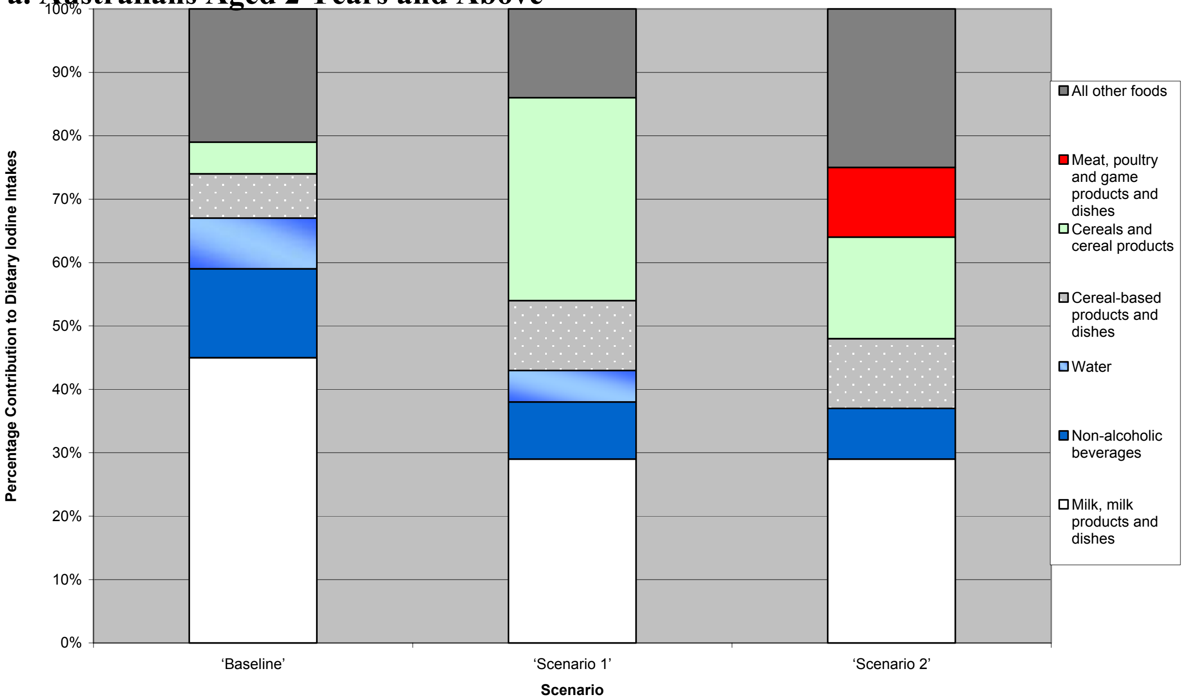
b. New Zealand



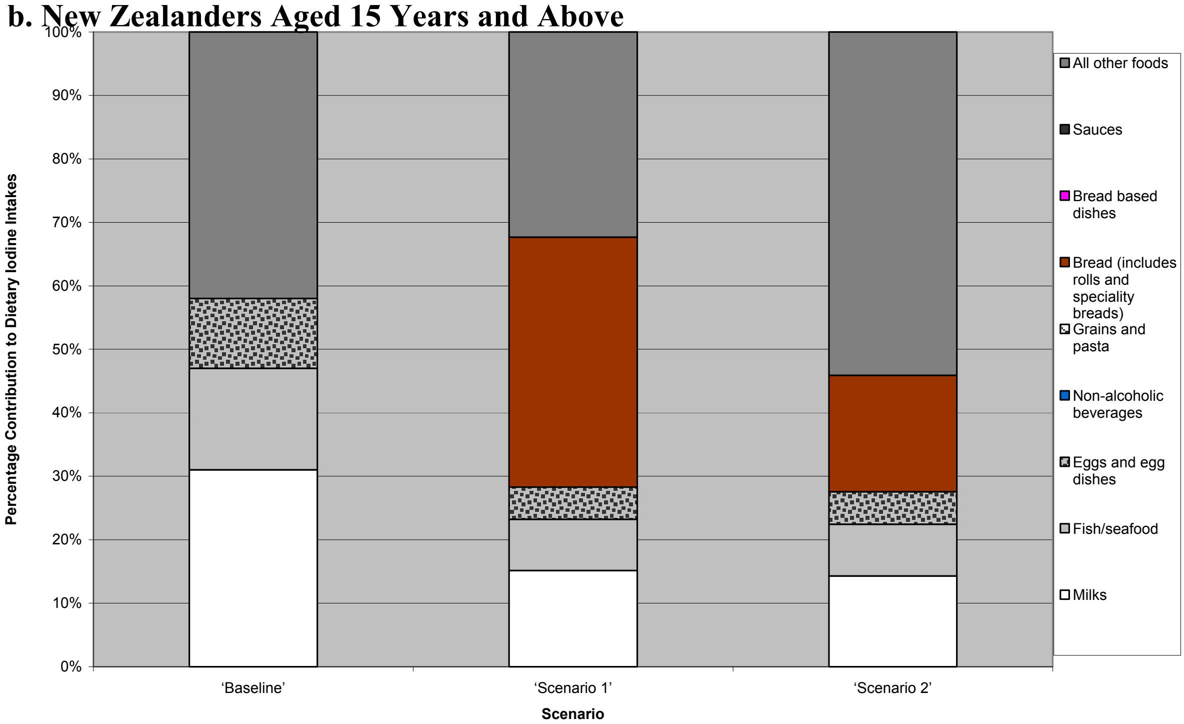
[34] The percent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

Figure 7: Major Contributors to Total Iodine Dietary Intakes for Australian and New Zealand Populations[35]

a. Australians Aged 2 Years and Above



b. New Zealanders Aged 15 Years and Above



[35] The percent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario. Only the major contributors for each scenario are shown separately.

4. Limitations of the Dietary Modelling

Dietary modelling based on 1995 or 1997 NNS food consumption data provides the best estimate of actual consumption of a food and the resulting estimated dietary intake of a nutrient for the population. However, it should be noted that the NNS data does have its limitations. These limitations relate to the age of the data and the changes in eating patterns that may have occurred since the data were collected. Generally, consumption of staple foods such as fruit, vegetables, meat, dairy products and cereal products, which make up the majority of most people's diet, is unlikely to have changed markedly since 1995/1997 (Cook *et al*., 2001). The uncertainty is associated with the consumption of foods that may have changed in consumption since 1995/1997, or that have been introduced to the market since 1995/1997.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Food Standards Code to allow more innovation in the food industry. As a consequence, a limitation of the dietary modelling is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997.

Additionally, since the data were collected for the NNSs, there has been an increase in the range of products that are fortified with nutrients. Therefore, the nutrient databases from the NNSs used for dietary modelling may not be entirely representative of the nutrient levels in some foods that are now on the market. FSANZ does update the food composition database through analytical programs, and scans of the market place. However, with the market place continually changing it is difficult to account for all fortified products. For the purposes of the dietary intake assessment for this Proposal, iodine concentrations have been assigned to foods to take this into account as far as possible and therefore should reflect current concentrations and foods fortified. Analytical values used may not fully reflect actual levels due to natural variation in iodine concentrations due to seasonal variation, different geographical locations, different varieties etc. and due to differences in sampling and analytical techniques.

A limitation of estimating dietary intake over a period time using food recalls is that people may over- or under-report food consumption, particularly for certain types of foods. Over- and under-reporting of food consumption has not been accounted for in this dietary intake assessment. However, adjusting intakes based on two days of food consumption data accounts for some variation both within individuals and between individuals.

Since the 1995 Australian NNS does not report on respondents aged below 2 years and the 1997 New Zealand NNS does not report on respondent aged below 15 years, theoretical diets were used to estimate dietary iodine intakes for children in the target group of up to 3 years. Theoretical diets for Australian children aged 1 year and New Zealand children aged 1-3 years were used in this assessment, and mean food consumption amounts may not be as accurate as the data derived for other population groups from the NNSs.

A limitation regarding data on discretionary salt consumption was that quantitative data were not available in the 1995 and 1997 NNSs. Some qualitative data from the 1995 NNS were available. Therefore, grocery market share data had to be used to determine approximate levels of discretionary salt consumption for both Australia and New Zealand. This was discussed earlier in the report in *1.5.1 Discretionary salt consumption data*.

While the results of national nutrition surveys can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In addition, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This prevents distortion of actual food consumption amounts that may result in an unrealistic intake estimate. Maori and Pacific Islanders were over-sampled in the 1997 New Zealand NNS so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary intake assessment because population weights were not used.

5. Comparison of the Estimated Dietary Intakes with the Upper Level of Intake (UL)

In order to determine if the proposed level of addition of iodine to salt for use in the manufacture of cereal based foods or processed foods will be of concern to public health and safety, the estimated dietary iodine intakes were compared with the Nutrient Reference Value (NRV) called an Upper Level of Intake (UL). The UL is "the highest average daily nutrient intake level likely to pose adverse health effects to almost all individuals in the general population" (National Health and Medical Research Council, 2006). The ULs used in this assessment, from the NRVs released this year for Australia and New Zealand (National Health and Medical Research Council 2006), are shown in Table 3 below.

Table 3: Upper Levels of Intake Used in the Dietary Modelling for Iodine Intake

Age Group	Upper Level of Intake (µg/day)
2-3 years	200
4-8 years	300
9-13 years	600
14-18 years	900
19-29 years	1,100
30-49 years	1,100
50-69 years	1,100
70 years and above	1,100
16-44 years – pregnant	1,100
16-44 years - lactating	1,100

Dietary iodine intakes for Australian children aged 1 year and for New Zealand children aged 1-3 years were estimated using a 'theoretical diet'. Consequently, the percentage of these population groups with dietary iodine intakes above the UL could not be determined. As an alternative, the 95th percentile dietary iodine intake was estimated and then compared to the UL. For more information on the comparison of mean and 95th percentile dietary iodine intakes with the UL, refer to Table 3.2 of Appendix 3.

At *'Baseline'*, Australian children aged 1 year had 95th percentile dietary iodine intakes which were equivalent to or greater than the UL (100% with no FSFYC-120% with FSFYC) while, for New Zealand children aged 1-3 years, 95th percentile intakes were below the UL (60% with no FSFYC-90% with FSFYC). For *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*, 95th percentile dietary iodine intakes exceeded the UL for both Australians aged 1 year (120-140%) and New Zealanders aged 1-3 years (110-140%).

For all other population groups, the estimated dietary intakes for iodine were determined for each individual respondent in the 1995 and 1997 NNSs and were compared to the relevant UL for their age group and gender. The proportion of each population group exceeding the UL is shown in Figure 11 for Australian and New Zealand target population groups and the non-target groups of children aged between 4 and 18 years. Full details of the proportions of each population group above the UL can be found in Table A3.3 in Appendix 3.

The percentage of each population group with dietary iodine intakes above the UL is presented as a range; the lower number in the range represents where non-iodised discretionary salt is consumed, and the upper number in the range represents where iodised discretionary salt is consumed. As mentioned previously, a number of other fortification scenarios were investigated. Results for one of these additional scenarios of fortifying cereal based foods using 40 mg iodine/kg salt rather than the proposed 30 mg iodine/kg salt is shown in Figure 8 for Australian children aged 2-3 years. The higher (undesirable) proportion of children predicted to exceed the UL for iodine indicates why this scenario was excluded from further consideration as a mandatory fortification measure.

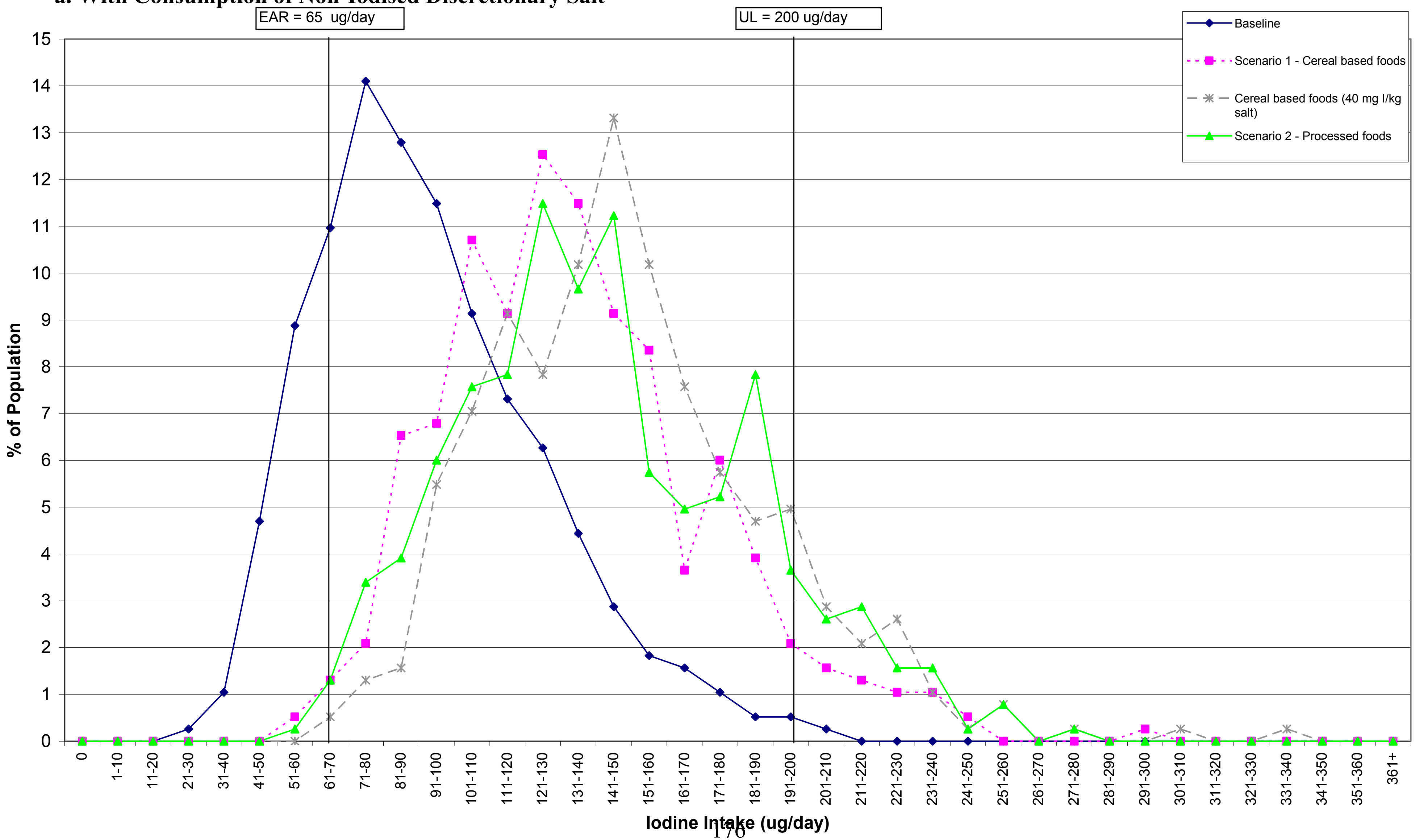
For Australians aged 2 years and above, <1% of the population have dietary iodine intakes that exceed the UL for *'Baseline'*, *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*. Australian children aged 2-3 years have the greatest percentage of the population that exceed the UL. Up to 24% of 2-3 year old children for *'Baseline'*, up to 16% for *'Scenario 1 – Cereal based foods'* and up to 20% for *'Scenario 2 – Processed foods'* have dietary iodine intakes that exceed the UL. The percentage of 4-8 year old children with iodine intakes above the UL is less than or equal to 2% of the population for all of the scenarios examined.

For the majority of the New Zealand population groups assessed, the percentage of the population with dietary iodine intakes that exceeded the UL for *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* was zero. For all New Zealanders aged 15 years and above for *'Scenario 2 – Processed foods'*, there was <1% of the population with dietary iodine intakes greater than the UL.

Figure 8 shows the dietary iodine intake distributions for *'Baseline', 'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* for Australian children aged 2-3 years, including a comparison with the UL. Figures 9 and 10 show distributions of dietary iodine intakes for women of child bearing age (16-44 years) for Australia and New Zealand respectively; however the UL is off the right hand scale of the distribution, and therefore can not be seen on the graph.

Figure 8: Distribution of Dietary Intakes of Iodine (µG/Day) for Australian Children Aged 2-3 Years for Baseline, 'Scenario 1 – Cereal Based Foods', and 'Scenario 2 – Processed Foods' Models with Non-Iodised and Iodised Discretionary Salt.

a. With Consumption of Non-Iodised Discretionary Salt



b. With Consumption of Iodised Discretionary Salt

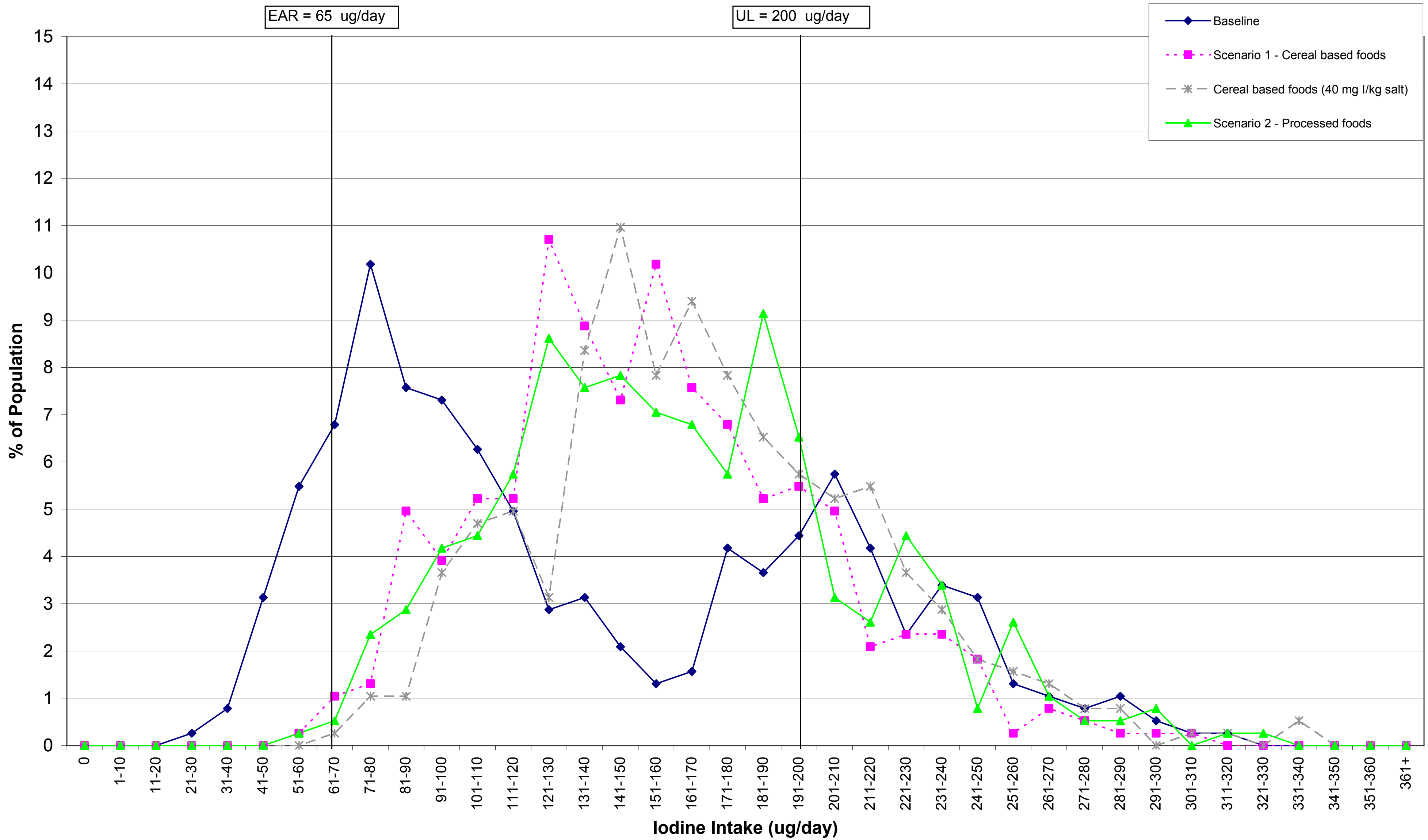
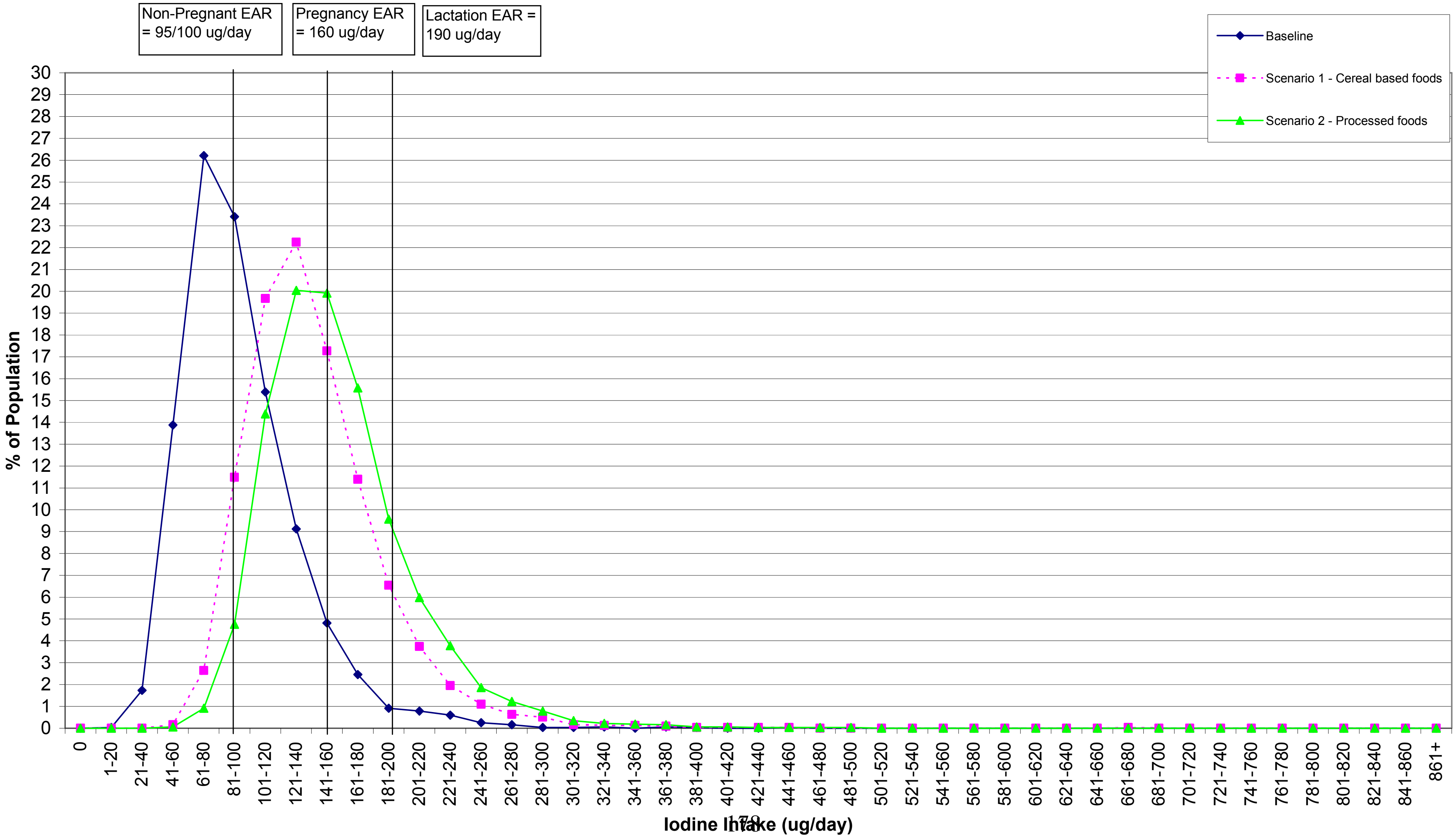


Figure 9: Distribution of Dietary Intakes of Iodine for Australian Women Aged 16-44 Years for Baseline, 'Scenario 1 – Cereal-Based Foods', and 'Scenario 2 – Processed Foods Models', with Non-Iodised and Iodised Discretionary Salt.

a. With consumption of non-iodised discretionary salt



b. With Iodised Discretionary Salt

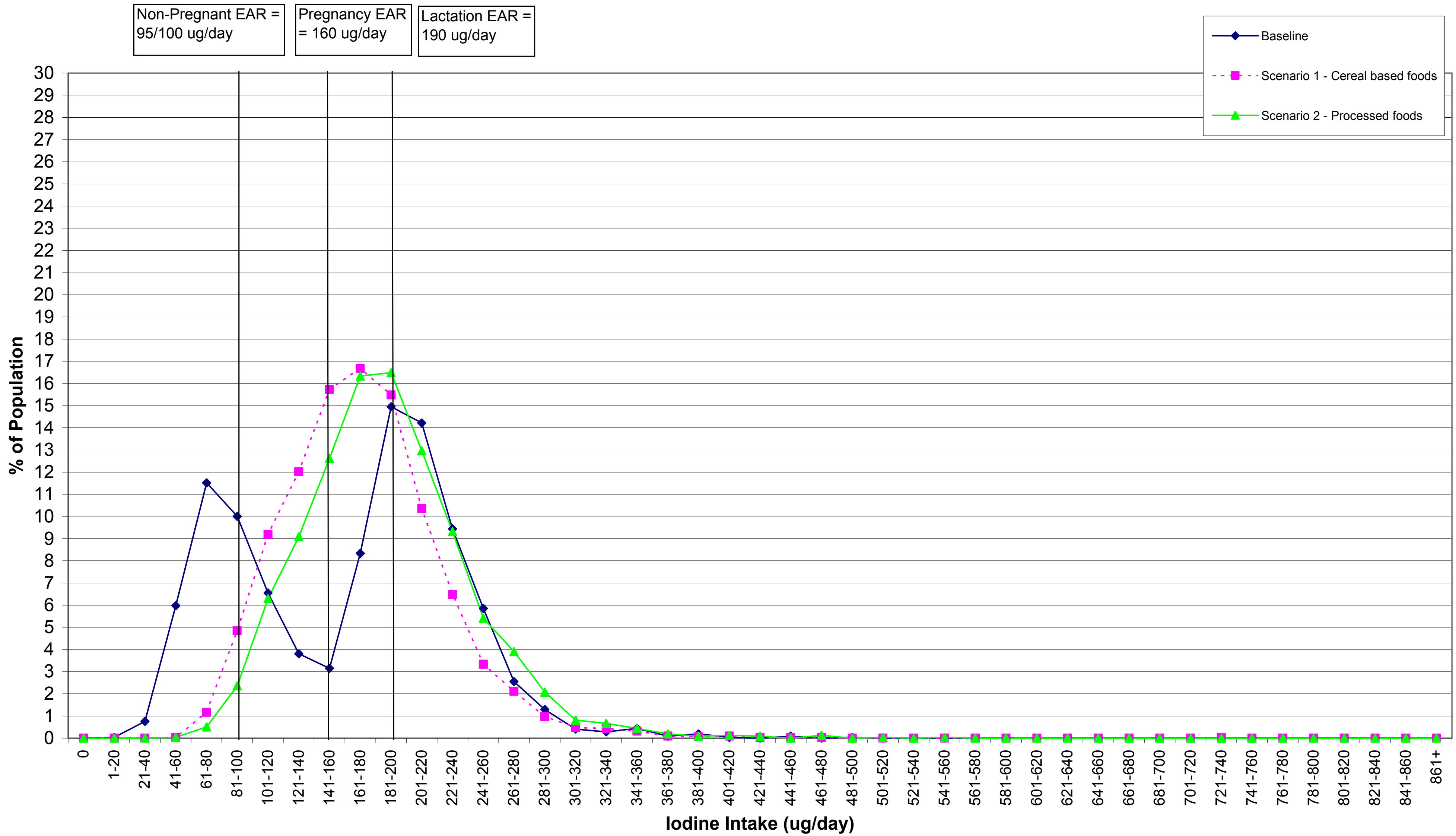
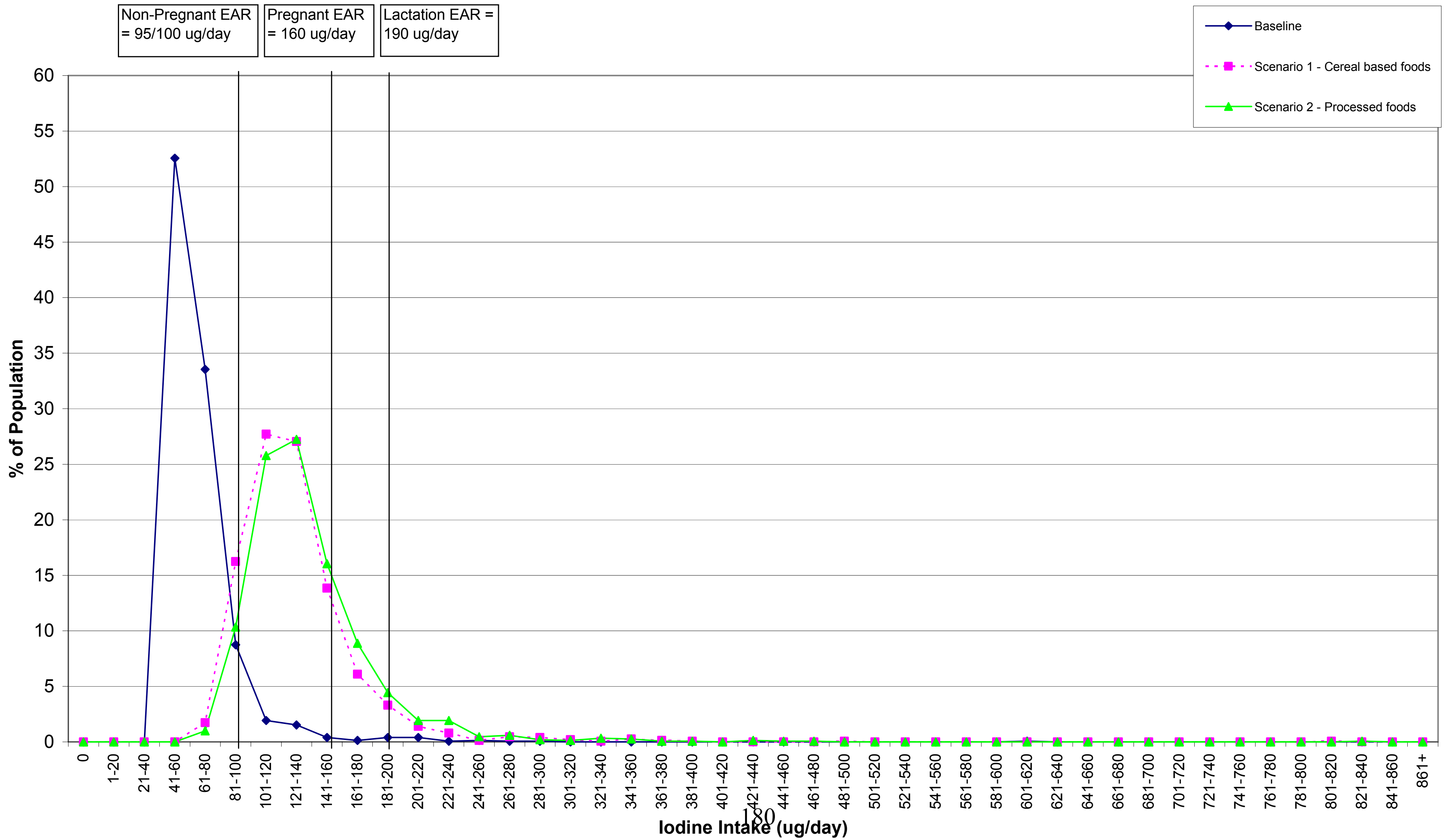


Figure 10: Distribution of Dietary Intakes Of Iodine for New Zealand Women Aged 16-44 Years For Baseline, 'Scenario 1 – Cereal-Based Foods', and 'Scenario 2 – Processed Foods' Models, with Non-Iodised and Iodised Discretionary Salt.

a. With Non-Iodised Discretionary Salt



b. With Iodised Discretionary Salt

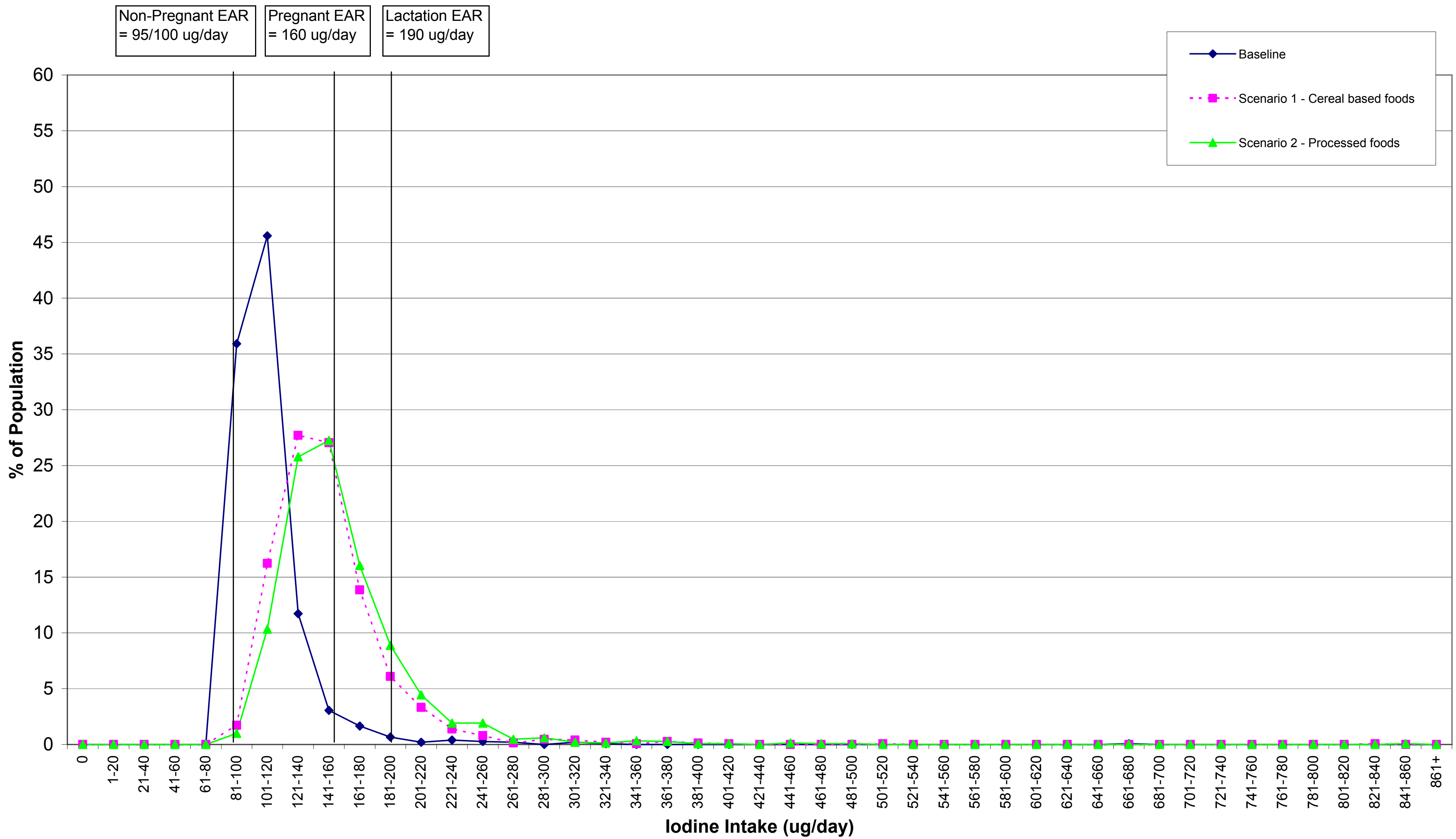
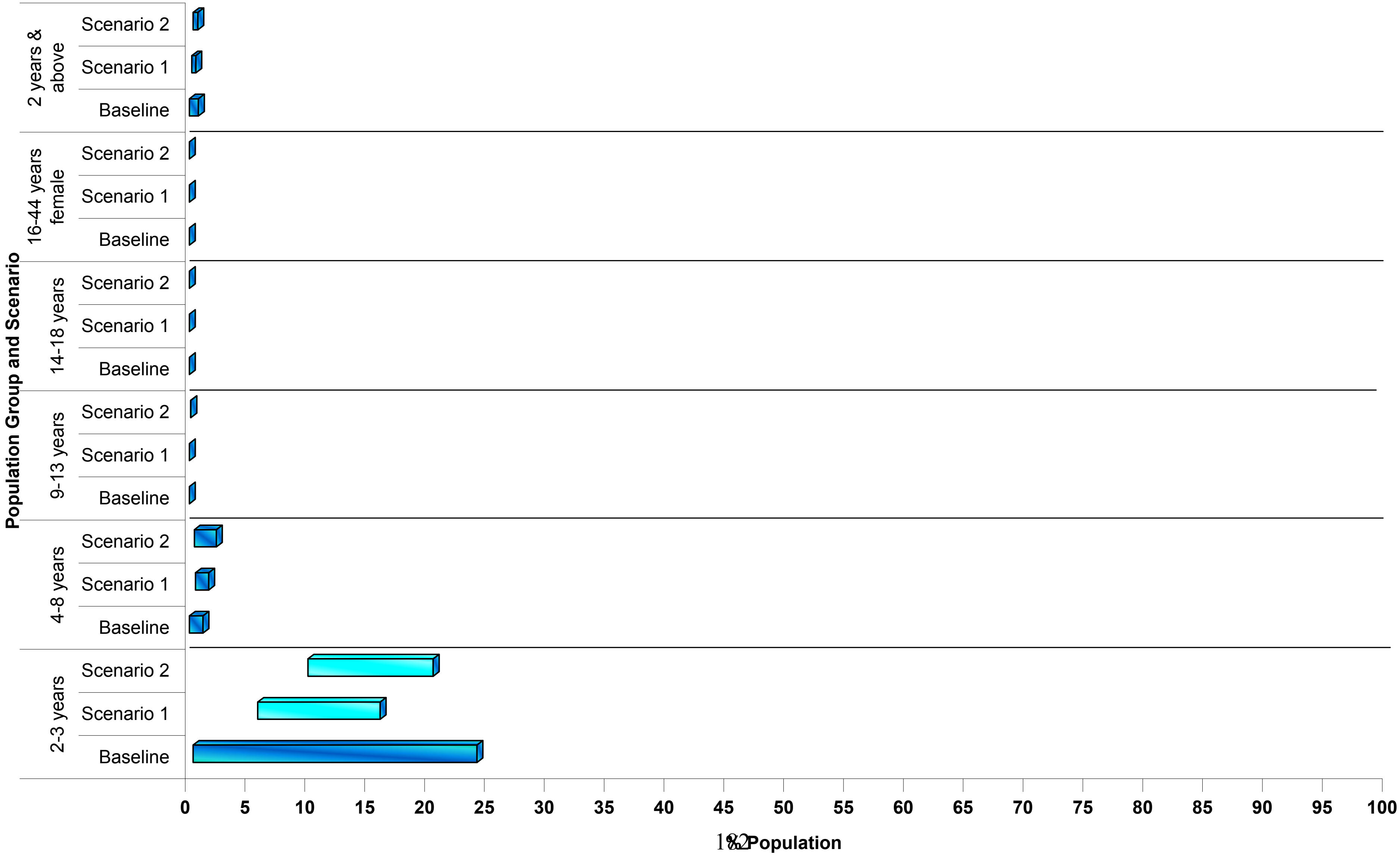
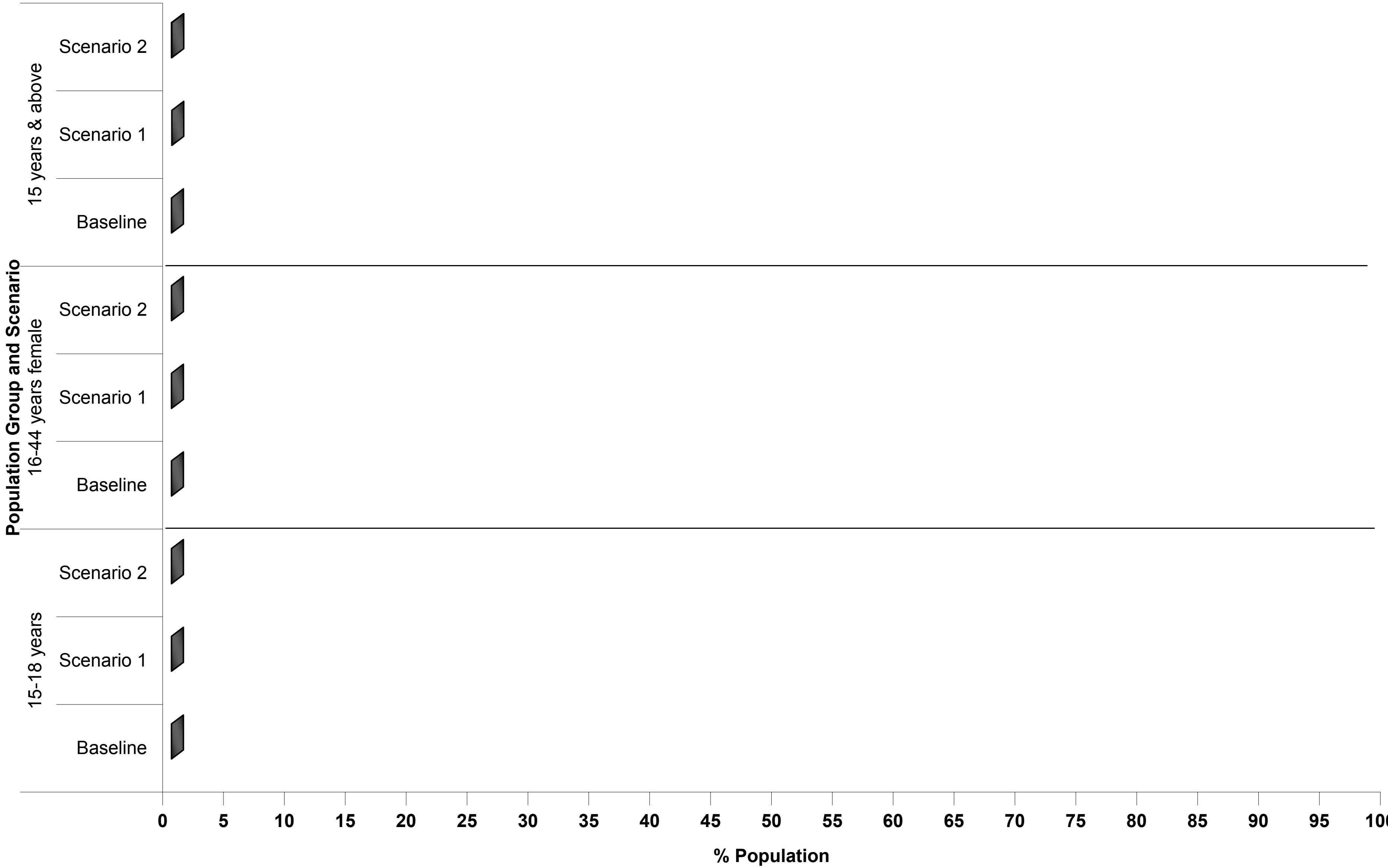


Figure 11: Estimated Percentage of Australian And New Zealand Population Groups with Dietary Iodine Intakes Above the Upper Level (UL) for Baseline, 'Scenario 1 – Cereal-Based Foods', and 'Scenario 2 – Processed Foods'.

a. Australia



b. New Zealand



6. Comparison of the Estimated Dietary Intakes with the Estimated Average Requirement (EAR)

In order to determine if the proposed level of addition of iodine to salt for use in the manufacture of cereal based foods or processed foods will be of benefit to the iodine intakes of Australian and New Zealand population groups, the estimated dietary iodine intakes were compared with the NRV called an Estimated Average Requirement (EAR). The EAR is "A daily nutrient level estimated to meet the requirements of half the healthy individuals in a particular life stage and gender group" (National Health and Medical Research Council 2006). The EARs used in this assessment, from the NRVs released this year for Australia and New Zealand (National Health and Medical Research Council 2006), are shown in Table 4 below.

Table 4: Estimated Average Requirements used in the Dietary Modelling for Iodine Intake

Age Group	Estimated Average Requirement (EAR) (µg/day)
2-3 years	65
4-8 years	65
9-13 years	75
14-18 years	95
19-29 years	100
30-49 years	100
50-69 years	100
70 years and above	100
16-44 years – pregnant	160
16-44 years - lactating	190

Dietary iodine intakes for Australian children aged 1 year and for New Zealand children aged 1-3 years were calculated using a 'theoretical diet'. Consequently, the percentage of these population groups with dietary iodine intakes below the EAR could not be determined.

For all other population groups, dietary iodine intakes were derived from the 1995 and 1997 NNSs. The estimated dietary intakes for iodine were determined for each individual and were compared to the relevant EAR for their age group and gender. The proportion of each population group with dietary iodine intakes below the EAR is shown in Figure 12 for Australian and New Zealand target population groups and the non-target groups of children aged between 4 and 18 years. Full details of the percentages of each population group with dietary iodine intakes below the EAR can be found in Table A3.1 in Appendix 3.

The percentage of each population group with dietary iodine intakes below the EAR is presented as a range; the lower number in the range represents where iodised discretionary salt is consumed, and the upper number in the range represents where non-iodised discretionary salt is consumed.

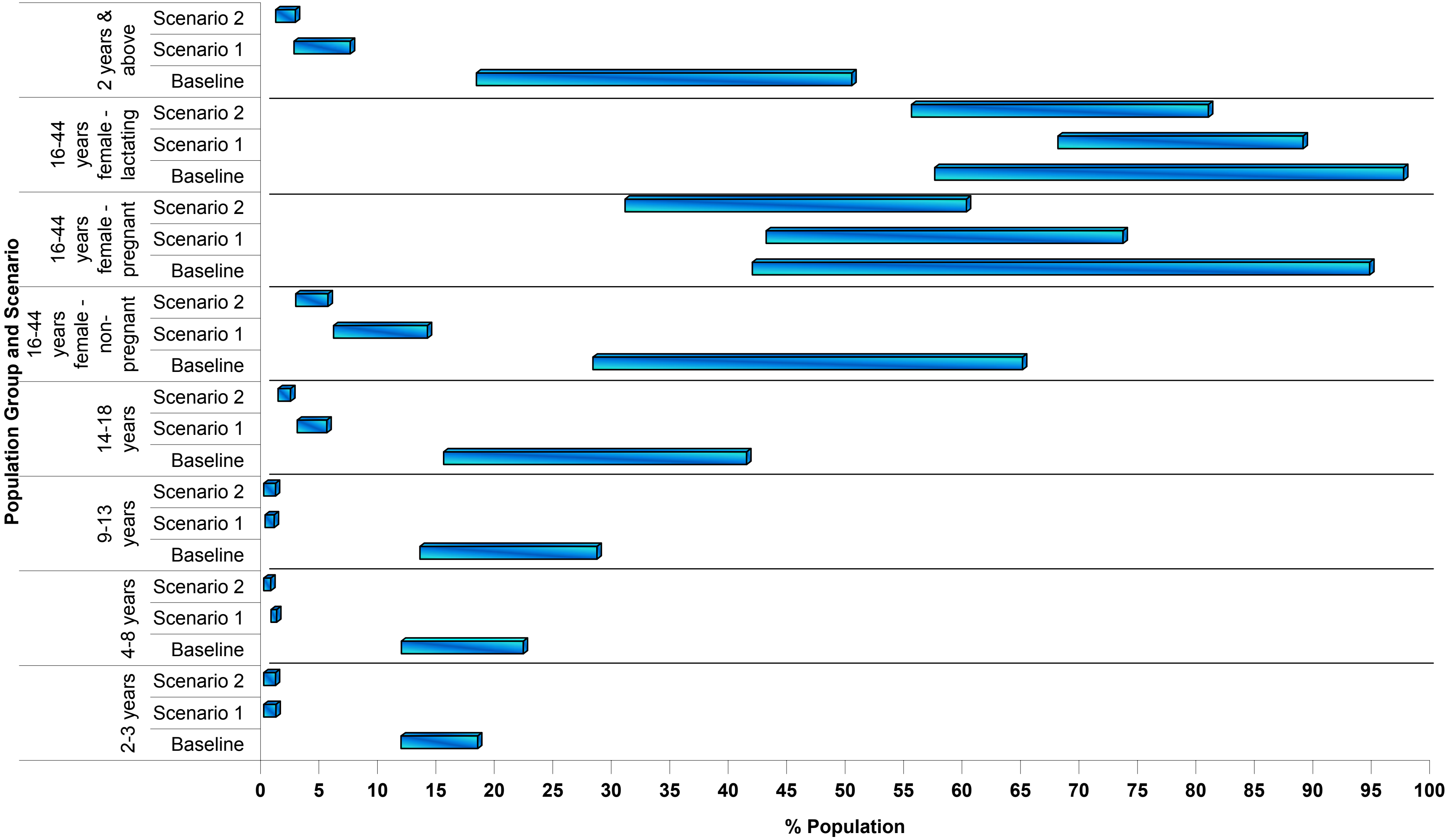
For all Australian and New Zealand population groups assessed, the percentage of the population with dietary iodine intakes below the EAR was lowest for *'Scenario 2 – Processed* foods', with *'Scenario 1 – Cereal based foods'* having a slightly higher percentage. *'Baseline'* had the highest percentage of respondents with dietary iodine intakes below the EAR.

The population group with the highest percentage of respondents with dietary iodine intakes below the EAR was lactating women, followed by pregnant women. These percentages remain high, even under the fortification scenarios being considered.

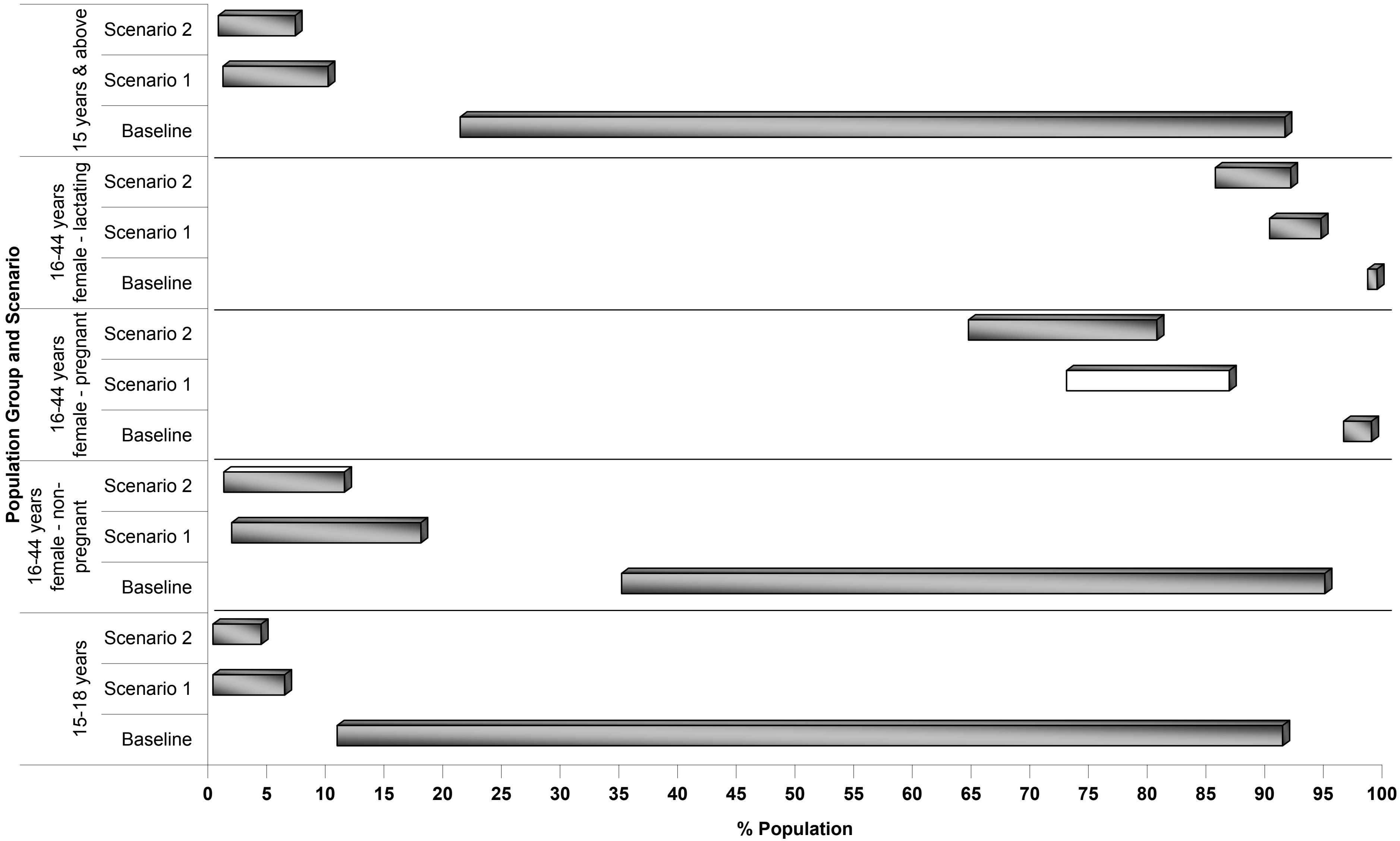
Figures 8-10 show the dietary iodine intake distributions, including a comparison to the EAR, for *'Baseline', 'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'* for Australian children aged 2-3 years and Australian and New Zealand women aged 16-44 years.

Figure 12: Estimated Percentage of Australian and New Zealand Population Groups with Dietary Iodine Intakes below the Estimated Average Requirement (EAR) for Baseline, 'Scenario 1 – Cereal-Based foods', and 'Scenario 2 – Processed foods'.

a. Australia



b. New Zealand



7. Assessing the Impact of a Mandatory Iodine Fortification Program on Populations with Adequate Iodine Intake

Data on the iodine concentration in urine collected for children aged 8-10 years old (see Section 2.1.1 of the Draft Assessment Report) indicates there may be some differences in iodine status by geographic location. One concern expressed in preliminary consultations undertaken by FSANZ is that a mandatory iodine program may increase the potential risk for people already consuming adequate iodine of exceeding the UL for iodine. Unfortunately, FSANZ is not in a position to assess this risk directly because no information is available on the factors that may be contributing to the reported differences in urinary iodine status.

In collating the iodine database for use in the modelling exercise for this risk assessment, FSANZ has investigated whether there were differences by geographic location in the iodine concentration data available for food and water. From the iodine analyses for food collected for the Australian Total Diet Study from different States and Territories, there were no obvious trends by location. For modelling purposes therefore, a national mean iodine concentration was derived from available analytical data for each food assigned an iodine value; a similar procedure was undertaken for the New Zealand assessment. There were a limited number of water samples for Australia with one or two samples available for each State or Territory. Of these, three samples had positive results (Western Australia one sample 3.8 µg/100 mL, one non-detect; Queensland 4.2 µg/100 mL and 4.3 µg/100 mL), with all other samples being non-detect results. As the small number of water samples were not representative of water available in each State or Territory, a nationally derived mean of 1.1 µg/100 mL for iodine concentration in water was used for the modelling presented elsewhere, assuming that non-detect results were half the LOD (i.e. 0.5 µg/100 mL).

To assess what difference the iodine level assigned to water makes to estimated iodine intakes, further modelling was undertaken for the two age groups who appear to be at risk of exceeding the UL for iodine, namely, children aged 2-3 years and children aged 4-8 years (sensitivity analysis). This was undertaken for Australia only as individual dietary records were only available for Australian children. Results are presented below for estimated iodine intakes assuming a zero concentration for iodine in water, the mean level of 1.1 µg/100 mL and an upper level of 4 µg/100 mL. It should be noted that the higher iodine intakes are indicative of potential intakes for children living in an area where the water is rich in iodine and cannot be related to location by State or Territory due to the non-representative nature of the water samples.

Results given in Table 5 indicate that the increase in iodine intake may be up to 17 µg per child per day compared to estimates using the mean iodine water concentration. Living in an area with high iodine water appears to make very little difference to the risk of iodine intakes exceeding the UL for 4-8 year olds, but results in a small increase in risk of exceeding the UL for 2-3 year olds (13% >UL if water has the high iodine content compared to 6% > UL previously estimated), with the maximum predicted iodine intake increasing from 299 µg iodine/day to 319 µg iodine/day (7% increase).

Table 5: Estimated Dietary Iodine Intakes for 2-3 year old Australian Children and the Percentage of this Population Group with Dietary Iodine Intakes Below the EAR and Above the UL, When Considering Low, Nationally Representative and High Iodine Concentrations in Water

Scenario	Iodine Concentration in Water (ug/100 g)	Dietary Iodine Intake (ug/day)*		% Respondents < EAR	% Respondents > UL	Maximum Iodine Intake (ug/day)
		Mean	Median			
Baseline model	0	86	80	27	0	199
	1.1 (Nationally representative)	93	88	18	<1	208
	4	110	104	9	2	228
Fortification in cereal based foods (30 mg I/kg salt)	0	128	125	2	4	289
	1.1 (Nationally representative)	135	130	1	6	299
	4	151	145	<1	13	319

* Assuming water is consumed as tap water and is used in recipes, jelly, cordials etc (for these age groups the iodine content of tea and coffee has not been adjusted as few consume these items)

REFERENCES

ACT Community Care. (2000) From Milk to More...Introducing foods to your baby. Publishing Services, Canberra.

Australian Bureau of Statistics. (1998) National Nutrition Survey Confidentialised Unit Record File 1995. Australian Bureau of Statistics, Canberra.

Cook, T., Rutishauser, I. and Allsopp, R. (2001) *The Bridging Study: comparing results from the 1983, 1985 and 1995 Australian national nutrition surveys*. Australian Food and Nutrition Monitoring Unit, Commonwealth Department of Health and Aged Care, Commonwealth of Australia, Canberra.

FAO (2004) *Human Energy Requirements: Report of a Joint FAO/WHO/UNU Expert Consultation, Rome, 17-24 October 2001. FAO Food and Nutrition Technical Report Series No 1*. FAO, Rome. ftp://ftp.fao.org/docrep/fao/007/y5686e/y5686e00.pdf. Accessed on

Flanagan, B. (2002) Retail World's Australasian Grocery Guide 2002. 12th ed, Retail Media, North Parramatta.

Flanagan, B. (2004) Retail World's Australasian Grocery Guide 2004. 14th ed, Retail Media, North Parramatta.

Flanagan, B. (2005) Retail World's Australasian Grocery Guide 2005. 15th ed, Retail Media, North Parramatta.

Flanagan, B. (2006) Retail World's Australasian Grocery Guide 2006. 16th ed, Retail Media, North Parramatta.

Food Standards Agency. (2002) McCance and Widdowson's The Composition of Foods, 6th Summary Edition. Royal Society of Chemistry, Cambridge.

Food Standards Australia New Zealand (2005) *The 22nd Australian Total Diet Study.* FSANZ, Canberra.

Hitchcock, N.E., Gracey, M., Gilmour, A.I. and Owler, E.N. (1986) Nutrition and growth in infancy and early childhood: a longitudinal study from birth to five years. *Monographs in Paediatrics* 19:1-92.

Møller, A., Saxholt, E., Christensen, A.T., Hartkopp, H.B. and Hess Ygil, K. (2006) Danish Food Composition Databank, revision 6.0. 2005. Institute of Food Safety and Nutrition, Danish Institute for Food and Veterinary Research.

National Health and Medical Research Council. (2001) Dietary Guidelines for Children and Adolescents In Australia Incorporating Infant Feeding Guidelines For Health Workers (Draft). (Unpublished Work) .

National Health and Medical Research Council (2006) *Nutrient Reference Values for Australia and New Zealand Including Recommended Dietary Intakes*. http://www.nhmrc.gov.au/publications/_files/n35.pdf. Accessed on 9 June 6 A.D.

Retail World Pty Ltd. (2001) Australian Grocery Industry Marketing Guide 2001. Retail World Pty Ltd, North Parramatta.

Rutishauser, I. (2000) Getting it right:- how to use the data from the 1995 National Nutrition Survey. Commonwealth of Australia, Canberra.

Vannoort, R.W. and Thomson, B.M. (2005d) *2003/04 New Zealand Total Diet Survey*. New Zealand Food Safety Authority, Wellington. www.nzfsa.govt.nz.

Vannoort, R.W. and Thomson, B.M. (2005c) *2003/04 New Zealand Total Diet Survey*. New Zealand Food Safety Authority, Wellington. www.nzfsa.govt.nz.

Vannoort, R.W. and Thomson, B.M. (2005b) *2003/04 New Zealand Total Diet Survey*. New Zealand Food Safety Authority, Wellington. www.nzfsa.govt.nz.

Vannoort, R.W. and Thomson, B.M. (2005a) *2003/04 New Zealand Total Diet Survey*. New Zealand Food Safety Authority, Wellington. www.nzfsa.govt.nz.

WHO. (1983) Measuring Change In Nutritional Status. WHO, Geneva.

WHO (1985) *Guidelines For The Study of Dietary Intakes of Chemical Contaminants*. WHO Offset Publication. 87, World Health Organisation, Geneva.

Appendix 1 - How Were the Estimated Dietary Iodine Intakes Calculated?

1.1 For all Population Groups except Australian Children Aged 1 year and New Zealand children aged 1-3 years

Iodine intakes were calculated for each individual in the NNSs using their individual food consumption records from the dietary survey. The DIAMOND program multiplies the specified concentration of iodine for an individual food by the amount of the food that an individual consumed in order to estimate the intake of iodine from each food. Once this has been completed for all of the foods specified to contain iodine, the total amount of iodine consumed from all foods is summed for each individual. Adjusted nutrient intakes are first calculated (see below) and population statistics (such as mean intakes) are then derived from the individuals' ranked intakes.

Adjusted nutrient intakes, which better reflect 'usual' daily nutrient intakes, were calculated because NRVs such as the EAR and UL are based on usual or long term intakes and it is therefore more appropriate to compare adjusted or 'usual' nutrient intakes with NRVs.

1.1.1 Calculating Adjusted Intakes

To calculate usual daily nutrient intakes, more than one day of food consumption data is required. Information for a second (non-consecutive) day of food consumption was collected from approximately 10% of Australian NNS respondents and 15% of New Zealand NNS respondents. In order to calculate an estimate of more usual nutrient intakes using both days of food consumption data, an adjustment is made to each respondent's iodine intake based on the first day of food consumption data from the NNS. The adjustment takes into account several pieces of data, including each person's day one nutrient intake, the mean nutrient intake from the group on day one, the standard deviation from the day one sample and the between person standard deviation from the day two sample. This calculation is described in Figure A1.1 below. For more information on the methodology of adjusting for second day intakes, see the Technical Paper on the National Nutrition Survey: Confidentialised Unit Record File (Australian Bureau of Statistics, 1998).

Figure A1.1: Calculating adjusted nutrient intakes

Adjusted value = $x + (x_1 - x) * (S_b/S_{obs})$

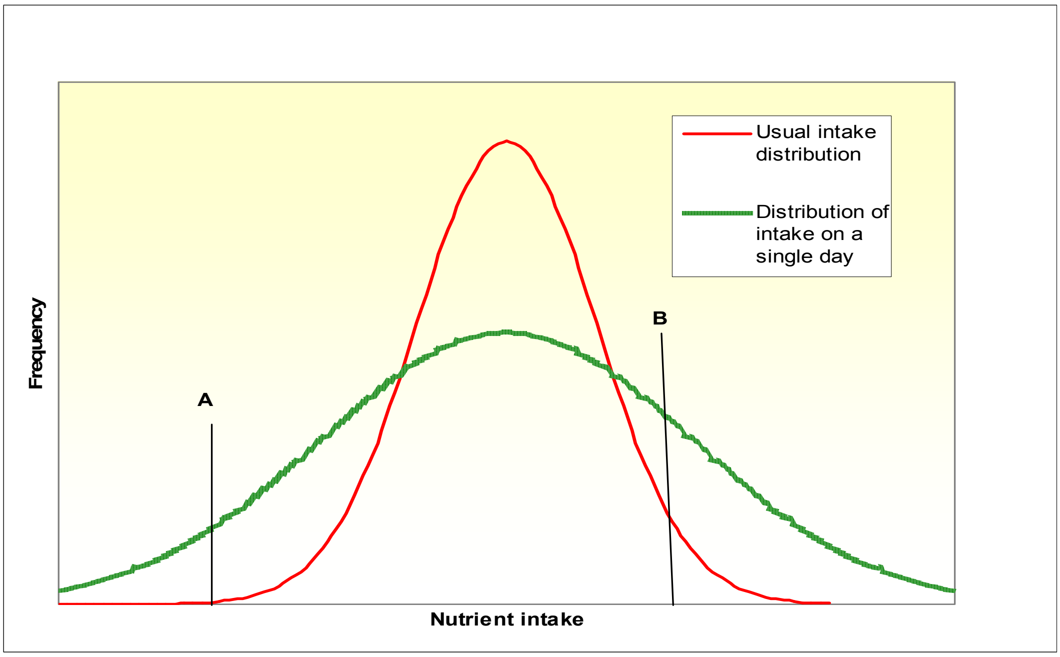
Where: x is the group mean for the Day 1 sample
x_1 is the individual's day 1 intake
S_b is the between person standard deviation; and
S_{obs} is the group standard deviation for the Day 1 sample

Source: (Australian Bureau of Statistics, 1998)

1.1.2 Comparison of One Day and Usual Intake Distributions

The range of intakes from respondents is broader based on a single day of food consumption data than the range of usual intakes (Figure A1.2) as the latter removes the variation in day to day intakes within each person and the variation between each person.

Figure A1.2: Comparison of One Day and Usual Intake Distributions



Using adjusted intakes provides better information for risk characterisation purposes. Use of adjusted (or usual) nutrient intakes will have little or no impact on estimated mean nutrient intakes, but would result in an estimated 95th percentile intake that is lower than the 95th percentile intake from a single day only, or a 5th percentile intake that is higher than the 5th percentile intake based on day one intakes only.

<u>Comparison of Intakes with NRVs</u>

Comparison of intakes, based on a single day of food consumption data, with NRVs such as EAR would result in a larger proportion of the population having intakes below a specified level (e.g. Figure A1.2, point A), which may overestimate the level of deficiency or inadequate intakes. A broader distribution from a single day of data also means a greater proportion of a population would exceed an upper cut off level, such as an upper level (e.g. Figure A1.2, point B), which overestimates the level of risk to this group of the population.

Note that where the proportion of each population group is expressed as being below the EAR or exceeding the UL, each individual's total adjusted intake (µg/day) was compared to the EAR or UL for their corresponding age and gender and a percentage was calculated.

1.2 For Australian Children Aged 1 Year and New Zealand Children Aged 1-3 Years

1.2.1 Australian Children Aged 1 Year

As there are no data available from the 1995 Australian NNS for children aged < 2 years, a theoretical diet was constructed to estimate dietary iodine intakes for children aged 1 year. A theoretical diet with mean food consumption figures for a 1 year old Australian was constructed.

The recommended energy intake for a twelve-month-old boy (FAO, 2004) at the 50th percentile weight (WHO, 1983) was used as the basis for the theoretical diet. Boys' weights were used because boys tend to be heavier than girls at the same age and therefore have higher energy and food requirements. It was assumed that 35 per cent of energy intake was derived from milk and 65 per cent from solids (Hitchcock *et al*., 1986). The patterns of consumption of a two-year-old child from the 1995 NNS were scaled down and used to determine the solid portion of the 1 year old's diet. Certain foods such as nuts (excluding peanut butter), coffee and alcohol were removed from the diet since nuts can be a choking risk (National Health and Medical Research Council, 2001) and coffee and alcohol are unsuitable foods for infants (ACT Community Care, 2000).

A number of theoretical diets were considered for young children with and without the consumption of one serve of FSFYC, assuming FSFYC replaced cow's milk. A range of dietary iodine intakes are presented; the lower number in the range represents where no FSFYC or 'toddler milks' are consumed; the upper number in the range represents where 1 serve (226 g) of FSFYC is consumed per day.

Due to a theoretical diet being used to calculate the dietary iodine intakes for Australian children aged 1 year, the proportion of the population group with dietary iodine intakes below the EAR or above the UL could not be calculated. As an alternative, the 95th percentile dietary iodine intake was estimated and then compared to the UL.

The 95th percentile dietary intakes were calculated using the internationally accepted formula (WHO, 1985) of:

$$95^{th} \text{ percentile intake} = \text{mean intake} \times 2.5$$

1.2.2 New Zealand Children Aged 1-3 Years

As there are no data available from the 1997 New Zealand NNS for children aged < 15 years, a theoretical diet was used to estimate dietary iodine intake for New Zealand children aged 1-3 years. The Simulated Diet for 1-3 year old toddlers that was used in the analysis of the 2003/04 New Zealand Total Diet Survey (NZ TDS) was used to estimate the mean dietary iodine intake in this assessment (Vannoort and Thomson, 2005b). The Simulated Diet was a 14-day diet constructed to represent average consumers and was derived from regional studies, rather than national studies of food and nutrient consumption (Vannoort and Thomson, 2005a).

Derived from the theoretical diet, a range of dietary iodine intakes are presented; the lower number in the range represents where no Formulated Supplementary Foods for Young Children (FSFYC) or 'toddler milks' are consumed; the upper number in the range represents where 1 serve (226 g) of FSFYC is consumed per day.

Due to a theoretical diet being used to calculate the dietary iodine intakes for New Zealand children aged 1-3 years, the proportion of the population group with dietary iodine intakes below the EAR or above the UL could not be calculated. As an alternative, the 95th percentile dietary iodine intake was estimated and then compared to the UL.

The 95th percentile dietary intakes were calculated using the internationally accepted formula (WHO, 1985) of:

95th percentile intake = mean intake x 2.5

1.3 How Were the Percent Contributors Calculated?

Percentage contributions of each food group to total estimated iodine intakes are calculated by summing the intakes for a food group from each individual in the population group who consumed a food from that group and dividing this by the sum of the intakes of all individuals from all food groups containing iodine, and multiplying this by 100. These calculations were done using the day 1 24-hour recall data.

Appendix 2 – Complete Information on Dietary Intake Assessment Results

Table A2.1: Contribution of Foods to Salt Intakes from Processed Foods at *'Baseline'* for Australian and New Zealand Target Population Groups

a. Australia

Food Category	**% Contribution to Salt Intake From Processed foods**		
	2-3 yrs	**16-44 yrs**	**2 years & above**
	All	**Female**	**All**
Cereals and cereal products	35	31	32
Cereal-based products and dishes	17	18	17
Meat, poultry and game products and dishes	17	18	21
Milk products and dishes	8	6	5
Savoury sauces and condiments	5	9	8
All other foods	18	18	17

Note:

1. **Cereals and cereal products** includes grains, cereal flours and starch powders, breads and rolls, breakfast cereals, English-style muffins, crumpets, tortillas, pastas, noodles and rice.
2. **Cereal-based products and dishes** 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.
3. **Meat, poultry and game products and dishes** includes plain beef, lamb, pork, veal, poultry, game meats, offal, ham, bacon, sausages, frankfurts, processed meats, and mixed dishes made from these meats.
4. **Milk products and dishes** includes milks (plain and flavoured), evaporated milk, condensed milk, milk powders, yoghurts (plain, flavoured and fruit), creams, cheeses, ice creams and ice confections (dairy and soy-based), frozen yoghurts, custards and other dairy-based desserts and soy-based beverages.
5. **Savoury sauces and condiments** includes gravies, savoury sauces (including dry mixes, simmer sauces, pasta sauces etc.), pickles, chutneys, relishes, salad dressings, mayonnaises, and stuffings.

b. New Zealand

Food Category	**% Contribution to Salt Intake From Processed foods**	
	16-44 yrs	**15 years & above**
	Female	**All**
Bread (includes rolls and speciality breads)	33	33
Sauces	9	8
Bread based dishes	6	6
Pork		6
Grains and Pasta	6	
Sausages and processed meats	5	6
Pies and pasties	5	5
All other foods	35	35

Note:

1. **Bread based dishes** includes pizzas, sandwiches, filled rolls and hamburgers, taco and tortilla-based dishes, dim sims, spring rolls, wontons and stuffings
2. **Pork** includes plain pork, pork stir-fries, stews and casseroles, ham and bacon.
3. **Grains and pasta** includes plain cooked rice, pasta, and noodles, filled pastas, savoury rice-based dishes, pasta-based dishes (e.g. lasagne, macaroni cheese), instant noodles, noodle-based dishes (e.g. chow mein), flours, bran and germ

Table A2.2: Estimated Mean Iodine Intakes for Australian and New Zealand Target Population Groups for *Baseline*, *'Scenario 1 – Cereal-based foods'*, *'Scenario 2 – Processed foods'* and *'Cereal-based foods (40 mg I/kg salt)'*.

a. Australia

Population Group	Estimated mean dietary iodine intake (µg/day)			
	Baseline	***'Scenario 1 – Cereal based foods'***	***'Scenario 2 – Processed foods'***	***'Cereal based foods (40 mg I/kg salt)'***
2-3 years	93 – 137	135 – 154	143 – 163	149 – 169
4-8 years	91 – 149	142 – 167	150 – 176	
9-13 years	103 – 170	163 – 193	176 – 206	
14-18 years	114 – 191	180 – 214	199 – 233	
16-44 years female	94 – 162	141 – 171	157 – 187	
19-29 years	113 – 184	175 – 206	198 – 229	
30-49 years	104 – 177	161 – 194	180 – 212	
50-69 years	98 – 183	151 – 188	166 – 204	
70 years & above	90 – 181	140 – 181	152 – 192	
2 years & above	102 – 177	158 – 192	175 – 208	

Note: in this table, the lower number in the range is the mean dietary iodine intake when all discretionary salt is not iodised; the upper number in the range is the mean dietary iodine intake when all discretionary salt is iodised. The concentration of iodine in discretionary iodised salt is 45 mg iodine/kg salt at *'Baseline'* and 20 mg iodine/kg salt for *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*.

b. New Zealand

Population Group	Estimated mean dietary iodine intake (µg/day)		
	Baseline	***'Scenario 1 – Cereal based foods'***	***'Scenario 2 – Processed foods'***
15-18 years	69 – 114	148 – 168	162 – 182
16-44 years female	66 – 111	130 – 150	138 – 158
19-29 years	67 – 117	146 – 166	160 – 180
30-49 years	75 – 120	152 – 172	162 – 182
50-69 years	72 – 117	145 – 165	153 – 173
70 years & above	67 – 112	136 – 156	140 – 160
15 years & above	72 – 117	147 – 167	157 – 177

Note: in this table, the lower number in the range is the mean dietary iodine intake when all discretionary salt is not iodised; the upper number in the range is the mean dietary iodine intake when all discretionary salt is iodised. The concentration of iodine in discretionary iodised salt is 45 mg iodine/kg salt at *'Baseline'* and 20 mg iodine/kg salt for *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*.

Table A2.3: Estimated Mean and 95th Percentile Dietary Iodine Intakes, in µg/day, for Australian Children Aged 1 Year and New Zealand Children Aged 1-3 Years for *Baseline*, *'Scenario 1 – Cereal-based foods'*, and *'Scenario 2 – Processed foods'*.

a. Australian children aged 1 year

Scenario	Estimated dietary iodine intake (µg/day)	
	Mean	**95th percentile**
'Baseline'	79 – 96	198 – 240
'Scenario 1 – Cereal based foods'	96 – 113	239 – 281
'Scenario 2 – Processed foods'	96 – 113	240 – 282

Note: in this table, the lower number in the range is the mean dietary iodine intake when no Formulated Supplementary Foods For Young Children (FSFYC) are included in the diet; the upper number in the range is the mean dietary iodine intake when 1 serve/day of FSFYC is included in the diet.

b. New Zealand children aged 1-3 years

Scenario	Estimated dietary iodine intake (µg/day)	
	Mean	**95th percentile**
'Baseline'	48 – 72	119 – 180
'Scenario 1 – Cereal based foods'	84 – 109	210 – 272
'Scenario 2 – Processed foods'	89 – 113	221 – 283

Note: in this table, the lower number in the range is the mean dietary iodine intake when no Formulated Supplementary Foods For Young Children (FSFYC) are included in the diet; the upper number in the range is the mean dietary iodine intake when 1 serve/day of FSFYC is included in the diet.

Table A2.4: Major Contributors (≥5%), Excluding Discretionary Salt, to Estimated Iodine Intakes for Australian and New Zealand Toddlers

a. Australians aged 1 year

Food Group Name	**Major contributors to Iodine Intakes (% iodine intake)**					
	'Baseline'		***'Scenario 1 – Cereal based foods'***		***'Scenario 2 – Processed foods'***	
	Without FSFYC	**With FSFYC**	**Without FSFYC**	**With FSFYC**	**Without FSFYC**	**With FSFYC**
Milk, full fat	**75**	29	**62**	26	**62**	26
Bread, white			10	9	5	
Formulated Supplementary Foods For Young Children (FSFYC)	0	**47**	0	**42**	0	**42**
All other foods	25	24	28	23	33	32

Note: The numbers in **bold** indicate the major contributor to iodine intake for the population group for that scenario; the percent contribution is listed only if it is ≥ 5%

b. New Zealanders aged 1-3 years

Food Group Name	**Major contributors to Iodine Intakes (% iodine intake)**					
	'Baseline'		***'Scenario 1 – Cereal based foods'***		***'Scenario 2 – Processed foods'***	
	Without FSFYC	**With FSFYC**	**Without FSFYC**	**With FSFYC**	**Without FSFYC**	**With FSFYC**
Milk, whole	**44**		**25**		**24**	
Formulated Supplementary Foods For Young Children (FSFYC)	0	**61**	0	**40**	0	**39**
Yoghurt	11	7	6		6	
Egg	9	6				
Bread, white			17	14	8	7
All other foods	36	26	52	46	62	54

Note: The numbers in **bold** indicate the major contributor to iodine intake for the population group for that scenario; the percent contribution is listed only if it is ≥ 5%

Table A2.5: Major Contributors (≥5%), Excluding Discretionary Salt, to Estimated Iodine Intakes for Australian and New Zealand Target Population Groups

a. Australia

Food Group Name	**Major contributors to Iodine Intakes (% iodine intake)**								
	2-3 years			**Females 16-44 years**			**2 years and above**		
	'Baseline'	***'Scenario 1 – Cereal based foods'***	***'Scenario 2 – Processed foods'***	***'Baseline'***	***'Scenario 1 – Cereal based foods'***	***'Scenario 2 – Processed foods'***	***'Baseline'***	***'Scenario 1 – Cereal based foods'***	***'Scenario 2 – Processed foods'***
Milk, milk products and dishes	**71**	**50**	**50**	**41**	27	**27**	**45**	29	**29**
Non-alcoholic beverages	6			16	10	9	14	9	8
Water				10	7	6	8	5	
Cereal-based products and dishes		8	8	7	11	11	7	11	11
Cereals and cereal products		27	14	6	**30**	16	5	**32**	16
Meat, poultry and game products and dishes			7			9			11
All other foods	23	15	21	20	15	22	21	14	25

Note: The numbers in **bold** indicate the major contributor to iodine intake for the population group for that scenario; the percent contribution is listed only if it is ≥ 5%

1. **Milk, milk products and dishes** includes milks (plain and flavoured), evaporated milk, condensed milk, milk powders, yoghurts (plain, flavoured and fruit), creams, cheeses, ice creams and ice confections (dairy and soy-based), frozen yoghurts, custards and other dairy-based desserts and soy-based beverages.
2. **Non-alcoholic beverages** includes teas, coffees, fruit and vegetable juices and drinks, cordials, soft drinks and mineral waters, electrolyte drinks, sports drinks, bottled water and tap water.
3. **Cereal-based products and dishes** 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.
4. **Cereals and cereal products** includes grains, cereal flours and starch powders, breads and rolls, breakfast cereals, English-style muffins, crumpets, tortillas, pastas, noodles and rice.
5. **Meat, poultry and game products and dishes** includes plain beef, lamb, pork, veal, poultry, game meats, offal, ham, bacon, sausages, frankfurts, processed meats, and mixed dishes made from these meats.

b. New Zealand

Food Group Name	Major contributors to Iodine Intakes (% iodine intake)					
	Females 16-44 years			15 years and above		
	'Baseline'	*'Scenario 1 – Cereal based foods'*	*'Scenario 2 – Processed foods'*	*'Baseline'*	*'Scenario 1 – Cereal based foods'*	*'Scenario 2 – Processed foods'*
Milks	**33**	17	16	**31**	15	14
Fish/seafood	13	7	7	16	8	8
Eggs and egg dishes	11	5	5	11	5	5
Non-alcoholic beverages	6					
Grains and pasta	7		7			
Bread (includes rolls and speciality breads)		**37**	**18**		**39**	**18**
Bread based dishes		5				
Sauces			5			
All other foods	29	28	42	42	32	53

Note: The numbers in **bold** indicate the major contributor to iodine intake for the population group for that scenario; the percent contribution is listed only if it is ≥ 5%

1. **Milk** includes cow's and goat's milks, evaporated milk, powdered milk, milkshakes, flavoured milk and soy beverages
2. **Fish/seafood** includes battered and crumbed fish, canned fish, plain cooked fish, smoked fish, shellfish, crustacean (plain cooked, battered, crumbed, canned, smoked and dishes made from fish/seafood)
3. **Non-alcoholic beverages** includes teas, coffees, hot chocolate drinks, fruit juices, cordials, fruit drinks, soft drinks, waters (tap, mineral) and sports drinks
4. **Grains and pasta** includes plain cooked rice, pasta, and noodles, filled pastas, savoury rice-based dishes, pasta-based dishes (e.g. lasagne, macaroni cheese), instant noodles, noodle-based dishes (e.g. chow mein), flours, bran and germ
5. **Bread** includes white, wholemeal, multigrain, rye, fruit bread, flat breads, topped breads (e.g. cheese topped), bagels, English-style muffins, crumpets and buns
6. **Bread based dishes** includes pizzas, sandwiches, filled rolls and hamburgers, taco and tortilla-based dishes, dim sims, spring rolls, wontons and stuffings
7. **Sauces** includes gravies and savoury sauces (e.g. simmer sauces), salad dressings, mayonnaise, pickles, chutneys, yeast and vegetable extracts

Appendix 3 – Complete information on risk characterisation

Table A3.1: Estimated Percentage of Australian and New Zealand Population Groups with Dietary Iodine Intakes below the Estimated Average Requirement (EAR) for *Baseline*, *'Scenario 1 – Cereal-based foods'*, *Scenario 2 – Processed foods'* and *'Cereal based foods (40 mg I/kg salt)'*.

a. Australia

Population Group	EAR (µg/day)	Estimated percentage of the population with dietary iodine intakes < EAR (%)			
		Baseline	***'Scenario 1 – Cereal-based foods'***	***'Scenario 2 – Processed foods'***	***'Cereal-based foods (40 mg I/kg salt)'***
2-3 years	65	12 – 18	1 – 1	0 – 1	0 – 0
4-8 years	65	12 – 22	< 1 – 1	0 – < 1	
9-13 years	75	13 – 29	< 1 – < 1	0 – 1	
14-18 years	95	15 – 41	3 – 5	1 – 2	
16-44 years female – non-pregnant	95/100 *	28 – 65	6 – 14	3 – 6	
16-44 years female – pregnant	160	42 – 95	43 – 74	31 – 60	
16-44 years female – lactating	190	57 – 98	68 – 89	55 – 81	
19-29 years	100	20 – 47	4 – 9	2 – 3	
30-49 years	100	22 – 54	3 – 8	1 – 3	
50-69 years	100	17 – 61	2 – 9	<1 – 3	
70 years & above	100	17 – 72	3 – 12	<1 – 5	
2 years & above	*	18 – 50	3 – 7	1 – 3	

Note: in this table, the lower number in the range is the percentage of the population group below the EAR when all discretionary salt is iodised; the upper number in the range is the percentage of the population group below the EAR when discretionary salt is not iodised. The concentration of iodine in discretionary iodised salt is 45 mg iodine/kg salt at *'Baseline'* and 20 mg iodine/kg salt for *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*.
* the appropriate EAR for each age group was used for each individual respondent.

b. New Zealand

Population Group	EAR (µg/day)	Estimated percentage of the population with dietary iodine intakes < EAR (%)		
		Baseline	*'Scenario 1 – Cereal-based foods'*	*'Scenario 2 – Processed foods'*
15-18 years	95	11 – 91	0 – 6	0 – 4
16-44 years female – non-pregnant	95/100*	35 – 95	2 – 18	< 1 – 11
16-44 years female – pregnant	160	96 – 99	73 – 87	64 – 80
16-44 years female – lactating	190	98 – 99	90 – 94	85 – 92
19-29 years	100	23 – 91	1 – 13	1 – 7
30-49 years	100	21 – 90	< 1 – 10	< 1 – 7
50-69 years	100	20 – 92	1 – 9	< 1 – 7
70 years & above	100	25 – 96	< 1 – 8	< 1 – 8
15 years & above	*	21 – 91	<1 – 10	< 1 – 7

Note: in this table, the lower number in the range is the percentage of the population group below the EAR when all discretionary salt is iodised; the upper number in the range is the percentage of the population group below the EAR when discretionary salt is not iodised. The concentration of iodine in discretionary iodised salt is 45 mg iodine/kg salt at *'Baseline'* and 20 mg iodine/kg salt for *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*.
* the appropriate EAR for each age group was used for each individual respondent.

Table A3.2: Estimated Mean and 95th Percentile Dietary Iodine Intakes, as a Percentage of the UL, for Australian Children Aged 1 Year and New Zealand Children Aged 1-3 Years for *Baseline*, *'Scenario 1 – Cereal-based foods'*, and *'Scenario 2 – Processed foods'*.

a. Australian children aged 1 year

Scenario	UL (µg/day)	Estimated dietary iodine intake (%UL)	
		Mean	**95th percentile**
'Baseline'	200	40 – 50	100 – 120
'Scenario 1 – Cereal based foods'	200	50 – 55	120 – 140
'Scenario 2 – Processed foods'	200	50 – 55	120 – 140

Note: in this table, the lower number in the range is the percentage of the UL when no Formulated Supplementary Foods For Young Children (FSFYC) are included in the diet; the upper number in the range is the percentage of the UL when 1 serve/day of FSFYC is included in the diet.

b. New Zealand children aged 1-3 years

Scenario	UL (µg/day)	Estimated dietary iodine intake (%UL)	
		Mean	**95th percentile**
'Baseline'	200	25 – 35	60 – 90
'Scenario 1 – Cereal based foods'	200	40 – 55	110 – 140
'Scenario 2 – Processed foods'	200	45 – 55	110 – 140

Note: in this table, the lower number in the range is the percentage of the UL when no Formulated Supplementary Foods For Young Children (FSFYC) are included in the diet; the upper number in the range is the percentage of the UL when 1 serve/day of FSFYC is included in the diet.

Table A3.3: Estimated Percentage of Australian and New Zealand Population Groups with Dietary Iodine Intakes above the Upper Level (UL) for *Baseline*, *'Scenario 1 – Cereal-Based Foods'*, *'Scenario 2 – Processed foods'*, and *'Cereal-based Foods (40 mg I/kg salt)'*.

a. Australia

Population Group	UL (µg/day)	Estimated percentage of the population with dietary iodine intakes > UL (%)			
		Baseline	*'Scenario 1 – Cereal based foods'*	*'Scenario 2 – Processed foods'*	*'Cereal based foods (40 mg I/kg salt)'*
2-3 years	200	< 1 – 24	6 – 16	10 – 20	10 - 25
4-8 years	300	0 – 1	< 1 – 1	< 1 – 2	
9-13 years	600	0 – 0	0 – 0	< 1 – < 1	
14-18 years	900	0 – 0	0 – 0	0 – 0	
16-44 years female	900/1,110*	0 – 0	0 – 0	0 – 0	
2 years & above	*	0 – < 1	< 1 – < 1	< 1 – < 1	

Note: in this table, the lower number in the range is the percentage of the population group above the UL when all discretionary salt is not iodised; the upper number in the range is the percentage of the population group above the UL when all discretionary salt is iodised. The concentration of iodine in discretionary iodised salt is 45 mg iodine/kg salt at *'Baseline'* and 20 mg iodine/kg salt for *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*.
* the appropriate UL for each age group was used for each individual respondent.

b. New Zealand

Population Group	UL (µg/day)	Estimated percentage of the population with dietary iodine intakes > UL (%)		
		Baseline	*'Scenario 1 – Cereal based foods'*	*'Scenario 2 – Processed foods'*
15-18 years	900	0 – 0	0 – 0	0 – 0
16-44 years female	900/1,110*	0 – 0	0 – 0	0 – 0
15 years & above	*	0 – 0	0 – 0	0 – < 1

Note: in this table, the lower number in the range is the percentage of the population group above the UL when all discretionary salt is not iodised; the upper number in the range is the percentage of the population group above the UL when all discretionary salt is iodised. The concentration of iodine in discretionary iodised salt is 45 mg iodine/kg salt at *'Baseline'* and 20 mg iodine/kg salt for *'Scenario 1 – Cereal based foods'* and *'Scenario 2 – Processed foods'*.
* the appropriate UL for each age group was used for each individual respondent.

Attachment 10

Assessment of Health Risk from Increased Iodine 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.

A Tolerable Upper Intake Level (UL) of 1100 µg iodine/day for adults has been established for iodine (Institute of Medicine, 2001; NHMRC, 2006). The UL 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 adjusted for different age groups on a bodyweight basis.

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 (ATSDR, 2004). The health risk for these individuals needs to be considered separately from the general population.

1. Implications of Exceeding the UL

Following introduction of mandatory iodine fortification at a level of 30 mg/kg salt in some cereal-based foods, it is estimated that a small percentage of young children may exceed the UL. 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 depends on 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 gland, 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 gland 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) have not been shown 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. 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.

The available data indicate there is considerable variation in iodine status among the different Australian States, whereas for New Zealand iodine deficiency appears to be geographically evenly distributed. It was not possible to factor this geographic variation in iodine intake into the dietary intake assessment for Australia; therefore the results of the intake assessment represent only average Australian intakes. This means the intakes of States which are classed as mildly deficient are likely to be overestimated, whereas the intakes of those States regarded as not deficient (Queensland and Western Australia) are likely to be underestimated. As a consequence, a greater proportion of young children exceeding the UL are expected to reside in the States that are not iodine deficient.

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.

Given the reduced margin of safety, it would be prudent to monitor the iodine intake and status of young children, following the introduction of mandatory iodine fortification.

2. Iodine-Induced Hyperthyroidism

Iodine-induce hyperthyroidism typically occurs in individuals with an underlying autonomously functioning thyroid gland 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 to 10 years of iodine supplementation (Delange and Hetzel, 2005).

In terms of the risk to the Australian and New Zealand population, the evidence indicates that widespread mild to 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 Australian and New Zealand context it is likely to be a rare event, this will be particularly the case in the Australian States that are not iodine deficient.

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.

While the risk to vulnerable groups is considered small, it may be prudent to alert health professionals to the potential for increased incidence of iodine-induced hyperthyroidism in certain vulnerable groups.

References:

ATSDR (2004). Toxicological profile for iodine. U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Atlanta, GA. http://www.atsdr.cdc.gov/

Delange, F. and Lecomte, P. (2000). Iodine supplementation: benefits outweigh risks. *Drug Safety* 22: 89 – 95.

Delange, F. and Hetzel, B. (2005). The iodine deficiency disorders. In: *The Thyroid and its Diseases*. [www.thyroidmanager.org/chapter20/Chapter20.pdf, accessed on 10 May 2006]

Hetzel, B. & Clugston, G. (1999). Iodine. In: *Modern Nutrition in Health and Disease, 9th edition* (Eds: Shils, M.E., Olson, J.A., Shike, M. & Ross, A.C), Williams & Wilkins, Baltimore, pp 253 – 264.

Institute of Medicine (2001). *Dietary reference intakes: vitamin A, K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc*. A Report of the Panel on Micronutrients, Subcommittees on Upper Reference Levels of Nutrients and of Interpretation and Use of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. National Academy Press, Washington DC.

NHMRC (2006) *Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*, National Health and Medical Research Council, Commonwealth of Australia, Canberra.

Park, Y.K., Harland, B.F., Vanderven, J.E., Shank, F.R., Prosky, L.(1981). Estimation of dietary iodine intake of Americans in recent years. *J. Am. Diet. Assoc.* 79: 17 – 24.

SCF (2002). Opinion of the Scientific Committee for Food on the Tolerable Upper Intake Level for Iodine. Health & Consumer Protection Directorate-General, European Commission.

Stanbury, J.B., Ermans, A.B., Bourdoux, P. *et al* .(1998). Iodine-induced hyperthyroidism: Occurrence and epidemiology. *Thyroid* 8: 83 – 100.

Stewart, J.C. (1975). Epidemiology and pathogenesis of iodine-induced thyrotoxicosis in Northern Tasmania. *N.Z. Med. J.* 81: 25 – 26.

Suzuki, H., Higuchi, T., Sawa, K., Ohtaki, S. & Horiuchi, Y. (1965). 'Endemic coast goiter' in Hokkaido, Japan. *Acta Endocrinol (Copenh)* 50: 161 – 176.

Topliss, D.J & Eastman, C.J. (2004) Diagnosis and management of hyperthyroidism and hypothyroidism. *Med. J. Aust*. 180: 186 – 193.

WHO (1989). Evaluation of Certain Food Additives and Contaminants (Thirty-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series. No. 776.

Zimmermann, M.B., Ito, Y., Hess, S.Y., Fujieda, K. & Molinari, L. (2005). High thyroid volume in children with excess dietary iodine intakes. *Am. J. Clin. Nutr*. 81: 840 – 844.

Attachment 11

Cost benefit Analysis

SEE SEPARATE DOCUMENT

Attachment 12

SUMMARY OF SUBMISSIONS
ON THE INITIAL ASSESSMENT REPORT

Executive Summary

Background

In February 2005 FSANZ received 38 submissions in response to the Initial Assessment Report of Proposal P230 – Consideration of Mandatory Fortification with Iodine. There were four options proposed at Initial Assessment to improve the iodine status of Australian and New Zealand populations, and in doing so reduce the risk of iodine deficiency disorders for vulnerable population groups such as the developing foetus and young children. These options are:

Option 1 – Maintaining the *status quo*;
Option 2 – Extension of permissions for voluntary iodine fortification;
Option 3 – Promotion of voluntary options to increase industry uptake; and
Option 4 – Mandatory iodine fortification.

Submitter representation and preferred regulatory options

Submitter Classification	No	Preferred Option						
		1	2	3	2&3	4	Opposes MF	Not Specified
Consumer	4						1	3
Industry	17		2	2	9	2		2
Health Professionals	10					10		
Government	7				1	5		1
Total	**38**	**0**	**2**	**2**	**10**	**17**	**1**	**6**

General Comments

All health professional submissions and the majority of government submissions supported mandatory iodine fortification. With the exception of the two salt industry submissions, industry submitters supported voluntary fortification, extending iodine permissions, the promotion of voluntary options or a combination of both options. While no submitters supported maintaining the *Status Quo,* six did not state a specific option and one submitter stated they were opposed to mandatory fortification.

Key Issues Identified From Submissions

1. Lack of data

Some submitters considered there was insufficient research on the extent of iodine deficiency in Australia, and that the Draft Assessment should be finalised after the results from the Australian National Iodine Nutrition Survey are published.

New Zealand submitters considered there was clear evidence of iodine deficiency in New Zealand to warrant action on this health issue. In the absence of data, it was suggested that non-regulatory measures should be considered. It was also noted that data from the National Nutrition Surveys for both Australia and New Zealand is outdated, and that more work needs to be done on sodium excretion in at-risk groups.

2. Lack of iodine in the food supply

Many public health professionals noted that it is difficult to choose a diet naturally rich in iodine due to the insufficient levels of iodine in the food supply, particularly in New Zealand. Many commented that while milk and diary products remain a major source of iodine in the diet, levels of iodine in these products has decreased significantly since the removal of iodophors as sanitisers in the dairy industry. Some commented that Australia could face serious health problems if there is a re-emergence of iodine deficiency, and many health professionals agree that iodine should be added to the food supply. One government authority considered that the Initial Assessment Report understated the public health importance of iodine deficiency and did not adequately reflect the size and significance of the problem.

3. Regulatory options

3.1 Status Quo

No submitters supported maintaining the s*tatus quo*. Many commented that maintaining the *Status Quo* does not solve the present public health problem.

3.2 Voluntary fortification

Industry submitters considered that voluntary iodine fortification retains consumer choice and allows for industry innovation. Some industry groups expressed willingness to participate in initiatives, such as a Code of Practice or a Memorandum of Understanding (MoU), to promote an increased uptake of voluntary permissions. However, others viewed MoUs as a form of *de facto* mandatory fortification. Other submitter groups commented that experience shows voluntary fortification options rarely work, and considered voluntary iodine fortification an inadequate response to an important public health issue and therefore fortification should not be left to industry discretion.

3.3 Mandatory fortification

Mandatory fortification was strongly supported by health professionals and government submitters. Many considered that mandatory fortification is the only viable option, and that it allows the level of fortification to be closely prescribed and monitored. Reasons provided for rejecting mandatory fortification included that it removes consumer choice, would present potential barriers to trade, and that it fails to meet the Ministerial Council's Policy Guideline on Fortification.

4. Health promotion/education strategies

Many submitters commented on the need for health promotion and education strategies as part of a fortification program, to educate consumers and health professionals on the importance of iodine in the diet and the health benefits and potential risks of iodine fortification. They considered that an education program alone would not be effective in improving the iodine status of the population due to the lack of iodine in the food supply. It was noted that these programs should not contradict nutrition messages to reduce salt consumption.

5. Risk of iodine-induced hyperthyroidism

Some submitters commented on the increased risk of iodine-induced hyperthyroidism (IIH) with fortification. Many noted the need to incrementally increase the amount of iodine in the food supply to minimise the effect of IIH. Others commented that the re-introduction of optimal iodine intakes would now be timely to minimise future risks of transient IIH caused when people are exposed to low iodine environments for many years. It was also considered that the frequent mention of IIH in the Initial Assessment Report was misleading, and that at worst an additional 4.5 cases of hyperthyroidism per 100,000 population per year could be expected. Overall the benefits of correcting iodine deficiency were considered to outweigh the risks.

6. Costs

Financial costs relating to mandatory iodine fortification of salt were identified as minor capital outlay at salt manufacturing plants, production related costs (e.g. cost of iodine and analytical testing) adding around 5% to the cost of salt to the food industry, labelling changes, product testing and monitoring costs. Public health professionals considered the costs incurred with mandatory fortification to be small in comparison to the health benefits gained. One submitter noted that a World Bank report estimated that for each US$1 spent on iodine deficiency disorders, there is s return of US$28.

7. Appropriate food vehicles

General comments on the selection of appropriate food vehicles included that it should be based on their ability to effectively deliver and sustain an increased iodine status in the target population, and not affect the properties of the food. Some submitters considered that it would be difficult for one food vehicle to reach all population groups equally, and that rather than a single food, a range of staple food products should be considered. It was also noted that iodine fortification should not legitimise unhealthy foods and that the food vehicle(s) chosen should be consistent with national nutrition guidelines. Conversely, industry considered they are best placed to identify foods consumed by target groups and to develop appropriately fortified products.

7.1 Flour

The fortification of flour was noted to be problematic by one industry submitter, due to the vast variety of flour types and the wide variety of food products that contain flour as an ingredient. It was also noted that if flour is selected as the food vehicle, then consumer acceptance and shelf life studies would need to be undertaken.

7.2 Bread

Many submitters in support of mandatory fortification considered bread a suitable food vehicle for iodine, either as the direct vehicle or use of iodised salt in bread. It was noted that bread is consumed regularly and would provide a reasonably consistent level of iodine. Some noted that if bread was the food vehicle, alternative options may need to be made available for those who do not eat bread. It was also considered that the use of iodised salt in bread would not contradict the promotion of the dietary guideline on reduced salt consumption.

7.3 Salt

Salt was considered an appropriate food vehicle by many submitters, and a number supported universal salt iodisation. It was noted that it is technically feasible to use iodised salt in food manufacturing, and that this is appropriate as a wide range of food products contain salt. Iodised table salt alone was not considered sufficient to ensure adequate population iodine intakes, though there was support for all table salt to be iodised. A submitter commented that substituting iodised salt in food processing would not promote increased salt consumption or consumption of foods high in salt.

7.4 Oil

There was limited support for adding iodine to oils. It was noted that iodine may oxidise if added to oil and that trials across food categories would be needed to confirm suitability. Another submitter considered that margarines could be another suitable food vehicle as salt is added when manufactured.

7.5 Milk

Some submitters considered milk as a possible food vehicle for iodine. Dairy industry submitters were opposed the mandatory fortification of dairy products with iodine, citing reasons of potential development of off flavours and that they were unaware of any country that uses milk or other dairy products as food vehicles for iodine fortification.

8. Monitoring

Many submitters considered that adequate monitoring and evaluation systems need to be in place before commencing iodine fortification. Aspects identified to be monitored included iodine status using urinary iodine and sodium, dietary intake of iodine, and incidence of iodine deficiency disorders, IIH and other adverse outcomes. Some commented that monitoring should be the responsibility of the jurisdictions, and industry did not consider that they should be expected to fund a monitoring program. One submitter noted that the impacts of voluntary fortification would be harder to monitor compared to mandatory fortification, since voluntary uptake would be determined for commercial reasons rather than health considerations.

9. Current salt permissions

Some submitters commented that the current iodine salt permission needs to be reviewed as the concentration of 25-65 mg/kg allows for too much variation and is not in keeping with recommendations from the World Health Organisation and the International Council for the Control of Iodine Deficiency Disorders. They proposed that the level should be 20-40 mg iodine/kg salt.

10. Consumer choice

Submitters not in favour of mandatory fortification consider that mandatory fortification compromises consumer choice, and believe that consumers have the right to choose whether they consume fortified foods. They consider that voluntary fortification provides consumers with choice, and that voluntary permissions should be extended to more food categories.

11. Trade issues

Some industry submitters highlighted potential trade barriers for both imports and exports of some food products, including the export of fortified foods to countries where the addition of iodine is prohibited. In addition, it was requested that non-iodised salt still be allowed to be manufactured for industrial applications.

12. Claims

Some industry submitters consider a health claim for iodine should be developed, to enable manufacturers to include information about the nutrient on the product label. Other submitters considered iodine fortification and any associated claims would not be attractive to consumers.

13. Vulnerable groups

It was noted by some submitters that even with mandatory fortification, additional measures may still be needed to ensure that population groups with increased requirements have adequate intakes. It was suggested that pregnant and breastfeeding women in Australia and New Zealand should receive daily iodine supplements.

14. Fortification policy guideline

Some submitters considered that the Specific Order Policy Principles of the Ministerial Council's Policy Guideline on Fortification have not been met.

15. Current iodine fortification strategies

Some submitters commented on the iodine fortification program implemented in Tasmania, where iodised salt is added to bread. Some noted the increase in the iodine status of the Tasmanian population as positive, though cautioned the sustainability of the program given its voluntary nature. One submitter commented that the use of iodised bread may simply mask the problem and not address the underlying need of ensuring optimal iodine nutrition for the most vulnerable.

16. Other issues raised

Other issues raised in submissions included:

- Fortified foods are not the same as foods that contain minerals in their natural forms.
- Concern that potassium iodate is the form that will be used in fortification.
- The need to remove anti-thyroid factors (e.g. isoflavones) from the diet before medicating everyone with iodine.
- Fluoride has a negative impact on iodine metabolism and thyroid hormones.
- Water supplies should not be fluoridated and the effect of iodine can only be properly assessed in the absence of fluoridation.
- The impact of this application on iodine levels of fruits and vegetables (used as a processing aid) needs to be incorporated into the dietary modelling to assess mandatory or voluntary iodine fortification strategies.
- Food standards should decrease health inequalities and not markedly increase the cost of healthy food.

SUMMARY OF SUBMISSIONS

FSANZ received 38 submissions in response to the Initial Assessment Report for Proposal P230 – Iodine Fortification, during the consultation period from 15 December 2004 to 23 February 2005. A summary of submitter comments is provided in the table below.

The four regulatory options presented in the Initial Assessment Report were:

Option 1 – Maintaining the *status quo*
Option 2 – Extension of permissions for voluntary iodine fortification
Option 3 – Promotion of voluntary options to increase industry uptake
Option 4 – Mandatory iodine fortification

No.	Submitter	Submission Comments
Consumers		
1.	Australian Consumers' Association (ACA) (Ms Clare Hughes)	**Will defer decision on a preferred option until after the release of the National Iodine Nutrition Survey (NINS)** • Draft Assessment should be finalised after the NINS survey is published. • There is insufficient research on the extent of iodine deficiency in Australia. *Health Promotion* • Health promotion campaigns encouraging people to seek iodine rich foods will not be effective, given the current levels of iodine in the food supply. • Health promotion campaigns should educate consumers on the benefits of consuming iodine but should not contradict nutrition messages to reduce salt consumption. *Mandatory versus Voluntary* • If the food supply has insufficient levels of iodine, mandatory fortification is more appropriate than voluntary fortification. • Manufacturers currently do not use iodised salt in their produce but are not prohibited from doing so. This raises the question as to why voluntary uptake is so poor and whether extending voluntary permissions would be effective. *Appropriate Food Vehicles* • Bread is an appropriate food vehicle. For those who don't consume sufficient bread, the use of iodised table salt should be encouraged. • ACA does not support the use of iodised salt for other commercial purposes, whether it is voluntary or mandatory. • Iodine should not be added to fat, energy foods, sugar or salt, as this may legitimise unhealthy foods. *Levels of Fortification* • ACA agrees with the concept of incrementally increasing the amounts of iodine into the food supply.

No.	Submitter	Submission Comments
		Consistency with Guidelines • If the decision is made to extend iodisation beyond salt or bread, ACA believes the additional foods should be consistent with nutritional guidelines. *Claims* • ACA believes that it is unlikely that iodine fortification and any associated health claims will be attractive to manufacturers. *Monitoring* • ACA will not support further iodine fortification unless an adequate monitoring and evaluation program is in place.
2.	Private (Ms Valerie James)	**Does not state a preference for any of the four regulatory options** • Believes anti-thyroid factors should first be removed from the diet before medicating everyone with iodine. • States that Crop and Food Research reported that the presence of soy isoflavones placed consumers who were hypothyroid at risk of further thyroid inadequacy. • Stated that ANZFA, when assessing the risks of phytoestrogens in infant formulas, reported that phytoestrogens have the potential to suppress thyroid function in some adults and infants. • Would like to see the removal of soy isoflavones from common foods before instigating a 'knee-jerk reaction' to add iodine to foods.
3.	Private (Mr Graham Bennett)	**Opposes mandatory fortification** • Is opposed to mandatory fortification of any food (salt in particular) believing it is a clear infringement of rights to make choices about one's own healthcare. *This form of mass medication is a clear infringement of my right to make choices for my own healthcare.* • Believes the public should be educated on the relative merits and potential harms of using fortified foods. Believes that fortified foods are not the same as foods that contain minerals in their natural form. *Iodine Forms* • Is concerned that potassium iodate is the form used in fortification. Would like to know were potassium iodate will be sourced from and what research will be undertaken to allow potassium iodate to be chosen in lieu of iodide, which at least has a history of safe medicinal use. *Labelling* • Labelling should be clear and specific whether iodine fortification is mandatory or voluntary. *Education* • Nutritional education needs to be improved to link symptomology with nutritional needs and advise accordingly. • Would prefer to choose a natural source of iodine.

<table>
<tr><th>No.</th><th>Submitter</th><th>Submission Comments</th></tr>
<tr><td>4.</td><td>Soy Information Service

(Valerie & Richard James)</td><td>Does not state a preference for any of the four regulatory options
Is aware that childhood goitre is endemic in New Zealand and in response the NZ MoH is considering adding iodine to the general diet.
The Aspell Report (1994) shows that soy products are goitrogenic. Whilst noting that additional iodine can offset such inhibition, the best strategy is to remove isoflavones from soy before human consumption.
Notes that soy is in numerous food items consumed daily by everyone.</td></tr>
<tr><td colspan="3">Industry</td></tr>
<tr><td>5.</td><td>Australian Food & Grocery Council (AFGC)

(Mr Tony Downer)</td><td>Supports Option 2 in combination with Option 3 - Extension and promotion of voluntary permissions.
It is premature to consider regulatory actions until the NINS is available to report on prevalence rates in Australia.
In the absence of data, other non-regulatory means should be considered.
As an interim step, AFGC recommends broadening permissions for voluntary fortification and increasing industry awareness of the need to utilise existing permissions.
AFGC believes that the lack of up-to- date data on current intake of iodine by the population of Australia hampers any risk assessment, whereas NZ has routinely monitored national iodine status. The most recent NZ data shows that 28% of children should be classified as iodine deficient.
AFGC rejects mandatory fortification as an option.
Appropriate Food Vehicles
Industry is best placed to identify foods consumed by target groups and to develop appropriately fortified products that communicate the benefit to the target group.
As consumer needs and dietary habits change over time, the market can adjust the fortified product mix to reflect those changes.
Existing permissions to fortify should be reviewed in light of current usage, with a view to widening the permissions in line with the target groups' dietary habits.
Promotion of Existing Voluntary Permissions
Industry incentives should be considered for the voluntary fortification of certain foods known to be consumed by the target groups.
AFGC proposes a concerted sustained national campaign to promote the voluntary use of iodised salt in food processing across Australia and New Zealand.
Monitoring
In the longer term, AFGC recommends supporting the evidence base by developing a trans-national program of monitoring Iodine Deficiency Disorders (IDD) status of the population and monitoring the food supply as part of the rolling National Nutrition Surveys.</td></tr>
<tr><td>6.</td><td>Campbell Arnott's – Asia Pacific, Australia</td><td>Supports Option 2 & 3 - Extension and promotion of voluntary permissions.
Option 1 (status quo) does not solve the present public health problem.
Option 2 shown to be effective in Tasmania.</td></tr>
</table>

No.	Submitter	Submission Comments
	(Dr Michael Depalo)	• Supports selection of additional food categories based on their ability to effectively deliver and sustain an increased iodine status in the target population. • Would be willing to participate in initiatives, such as a Code of Practice or a Memorandum of Understanding (MoU), to promote an increased uptake of voluntary permissions. *Appropriate Food Vehicles* • Food manufacturers would consider using iodised salt if costs were similar to using non-iodised salt. Suitable products that could use iodised salt would need to be identified. However, most foods would not be able to claim the presence of iodine. • Arnott's do not support mandatory iodisation of all salt in Australia as consumer choice would be compromised and it would affect exports, for example Japan does not permit the addition of iodine compounds. • There is a need for all parties involved (food manufacturers, communication experts, nutritionists and government) to determine the most effective and safe levels of iodine without compromising organoleptic qualities. *Monitoring* • On-going monitoring and surveillance is required to assess the present iodine status of Australians and future effects of fortification.
7.	Beer Wine and Spirits Council of New Zealand (Nicki Stewart)	**Supports Option 2 and Option 3 -** Extension of voluntary permissions and to a lesser extent promotion voluntary options • Initiatives, such as a Code of Practice or a MoU, could be developed with industry to promote an increase in iodine status in the target population. • If a public health benefit can be demonstrated, permissions should be given to allow iodine to be added to foods such as oil and sugar. However, these permissions should be voluntary and not mandatory. *Appropriate Food Vehicles* • The food categories selected would have to be able to effectively deliver and sustain an increase in iodine status without affecting the foods themselves. • Iodised salt is not used in the production of beer because of the possible reaction with other constituents to produce iodinated compounds which could affect flavours. • Salt is not widely used within the New Zealand Beer Industry and would result in an increase of iodine intake between 2 and 6 µg for the average beer drinker per day which is relatively low considering the RDI is 110-130 µg/day. • Brewers use significant quantities of liquid sugar as an adjunct and for priming which would be of concern if it became mandatory to add iodised sugar to food.
8.	BRI Australia Ltd (Ms Trish Griffiths)	**Supports option 2** – Extension of voluntary permissions • It is premature to consider mandatory iodine fortification of the food supply without firm data establishing the true extent of iodine deficiency.

No.	Submitter	Submission Comments
		• Consideration should be given to the fact that a previous permission to fortify bread in Tasmania (gazetted in 1964) was withdrawn in 1976 on the basis of increased incidence of iodine-induced hyperthyroidism (IIH). This risk following fortification should not be underestimated. *Claims* • Pre-approved health claims should be developed to enable manufacturers to include information about the nutrient on the product label. *Monitoring* • Monitoring and evaluation strategies need to be in place prior to any fortification measure being instigated. • Existing fortification initiatives, such as folate and thiamine, have not been well monitored. • The cost of public health initiatives like fortification should be borne by government rather than industry.
9.	Cheetham Salt Limited (Wallis Rickard)	**Supports Option 4** - Mandatory fortification**.** *Appropriate Food Vehicles* • Supports moves to improve public health by enhancing the iodine intake of the general population to appropriate levels. • Agrees with World Health organisation (WHO), United Nations International Emergency Fund (UNICEF) and the International Council for Control of Iodine Deficiency disorders (ICCIDD) that iodised retail salt is the best food vehicle. • Supports a staged and monitored approach where initially all retail salt would be iodised. Other foods could then be mandated to use iodised salt as appropriate, over a given period of time, and with continued monitoring of population iodine sufficiency. • Recommends against Option 2 to extend additional permissions to other food categories. *Education* • Their consumer research shows that the majority of consumers are unaware that iodine is an important nutrient and would like to see targeted promotional campaigns e.g. pregnant women. Continuing education is vital as new consumers enter the population. • Recommend the inclusion on salt containers of health messages indicating that iodine is a necessary nutrient and important in the daily diet. *Costs* • Our manufacturing plants would require only a minor capital outlay to meet demands if mandatory fortification was instigated. • Production related cost (cost of iodine, and analytical testing) would add around 5% to cost of salt to the food industry *Monitoring* • Realises that the adoption of such a policy would have some difficulties and supports a staged and monitored approach.

No.	Submitter	Submission Comments
10.	Coles Myer Ltd (CML) (Gillian Parton)	**Supports Option 2 in combination with Option 3** - Extension and promotion of voluntary permissions. • More information is needed to adequately demonstrate a significant population need, as presently there are only limited population studies of current iodine status. • Supports a collaborative and voluntary effort by regulators and industry in the first instance. • A MoU could easily be drawn up by FSANZ with industry involvement. • Recommends that a maximum iodine limit that can be found in food be legislated. • Notes that household consumption of salt is not included in FSANZ's assessment of dietary iodine intakes. • If the NINS shows that the iodine situation is significantly worse than previously determined then mandatory fortification may be the only option to achieve the necessary results. *Appropriate Food Vehicles* • Iodisation of water is not considered to be a viable option – difficult and impractical for those at-risk of excess iodine consumption. • If salt is selected as the most appropriate vehicle, potential issues arise from the high variability of salt intakes consumed by the most vulnerable sub-groups and concerns regarding the suitability for infants. • If bread is selected, more data is needed on the percentage of the population for whom bread is not a staple. Special consideration also needs to be given to the types of bread that should be fortified. • Essentially supports the WHO recommendation to use salt as the key strategy to eliminate IDD and FSANZ's suggestion that bread be another suitable primary vehicle for fortification. • No strategy should focus solely on salt as the single means of increasing iodine intakes. • Milk and flour may be beneficial vehicles provided there are no obvious changes to taste, shelf life and functionality. • Some food production processes may affect iodine stability and so may require further investigation. • CML is in a good position to drive some dietary change requiring suppliers of its household products to use iodised salt where possible. *Non-food Fortification Options* • Worth exploring further is the potential to substitute chlorinated water with iodine solutions (as a biocide), in cleaning manufacturing equipment. This can significantly reduce bacterial levels and does not produce any carcinogenic compounds associated with chlorine. *Potential Issues with Option 3* • In assessing the likely effectiveness of Option 3, it is necessary that iodised salt is readily available and at a similar price. Manufacturers will then need confirmation that replacing non-iodised salt with iodised salt is technologically feasible and cost effective. *Costs*

		• Additional cost would come from product design, product testing and additional information on labels. *Health Claims* • A consumer friendly iodine claim would be important. *Education* • A public health education program must also be implemented to educate consumers as to the health benefits and potential risks of iodine fortification. • If the proposed changes to legislation covering health and nutrition claims are gazetted, CML may be able to educate consumers, by promoting iodine fortified products and their benefits by various means. *Vulnerable Groups* • Promotion to at-risk populations may not necessarily be successful unless supplements for lower socio-economic groups are subsidised. • Supplements should only be available by prescription to avoid the possibility of misuse. *Monitoring* • Both the federal and state health departments and the medical profession have important roles to play in monitoring iodine status and adverse outcomes.
11.	Dairy Australia (Dr Anita Lawrence)	**Supports Option 2 -** Extension of voluntary permissions to include milk and other dairy foods. • Consideration for mandatory fortification of the food supply with iodine would appear to be premature at present as evidence presented in Proposal P230 is primarily based on smaller studies of subgroups of the population. • It would seem prudent to wait for the result of the NINS before mandatory fortification of iodine is considered. *Iodine Content of Dairy Foods* • In Australia in the 1960's the uncontrolled use of iodophors in milk production led to an increase in the iodine content of dairy foods and consequently in the Australian diet. Controls introduced in the 1970s saw changes to industry practices and as a result the iodine content of milk fell to normal levels. • In the 1980s the Australian Dairy Cooperation (now Dairy Australia) coordinated a comprehensive analysis of the nutritional composition of Australian dairy foods (NUTEST Project ADC 1999). At this time the iodine content of milk was 5 ug/100 g. This is the level likely to be naturally present without contamination from iodophors. • Dairy foods are a significant source of dietary iodine. *Appropriate Food Vehicles* • The dairy industry would welcome the opportunity for future innovation as offered by an extension of permissions for voluntary iodine fortification. • Mandatory fortification of salt with iodine would have an impact on the dairy industry in relation to cheese. The dairy industry does not want cheese to be labelled as 'iodised cheese' but the inclusion of 'iodised salt' in the ingredients listing would be accepted.

		• The dairy industry would be opposed to a mandatory iodine fortification program that included milk or other dairy products. The dairy industry does not think dairy products would be appropriate vehicle for widespread inclusion of iodine in the Australian Diet. • However, the dairy industry would welcome the opportunity for further innovation as offered by an extension of permissions for voluntary iodine fortification. *Estimated Average Requirements* • Determining the level of nutritional inadequacy against United States Estimated Average Requirement *(*EAR) values may not be relevant to the Australia and New Zealand situation. *Trade Barriers* • Mandatory use of iodised salt in manufactured goods may create barriers to trade to countries, such as Japan, where the addition of iodine is prohibited.
12.	Fonterra Cooperative Group Ltd (Joan Wright)	**Supports the combination of Options 2 and 3 –** Extension and promotion of voluntary permissions • Mandatory fortification should only be considered after alternative methods have been exhausted. • At this stage there is insufficient evidence of a 'significant population health need'. • It would be more appropriate to wait for the results of the NINS currently being conducted in Australia before considering mandatory fortification. • The current regulatory environment unreasonably restricts the ability to fortify and make claims on nutrients in milk. • Health campaigns should complement the activities of manufacturers. *Iodine Content of Dairy Foods* • In the 1960s, the use of iodophors in milk production was unregulated in New Zealand. • In the 1970s health officials requested that controls be placed on iodophor use. Other sanitisers have gradually replaced iodophors because they are less expensive and more effective. *Appropriate Food Vehicles* • To increase the iodine status of the population, several food groups rather than a single ingredient should be given permission to fortify on a voluntary basis so that consumer choice can be maintained. • Dairy products are not suitable vehicles for fortification due to the potential development of off flavours. • Fonterra is unaware of any country that uses milk or other dairy products as a vehicle for iodine fortification. • There is insufficient information on salt intakes to make iodine fortification of salt mandatory. • Fonterra is opposed to the inclusion of reference to 'iodine' within the product name but the declaration of 'iodised salt' in the ingredient list is accepted.

		Vulnerable Groups • They do not support a supplementation program to at-risk populations as a potential solution to increasing the iodine status of the population.
13.	Food Technology Association of Victoria Inc (David Gill)	**Supports Option 3** - Promotion of voluntary options • Further research is required to determine if iodine deficiency is a generalised phenomenon across Australia or is just restricted to particular areas. • There should be some consideration that the mandatory use of iodised salt could become a trade barrier to certain countries (i.e. Japan where iodised salt is not permitted due to sufficient iodine consumption through daily /traditional diets). *Appropriate Food Vehicles* • The use of iodised salt is probably the best route to achieve increases in the level of iodine in the population. *Monitoring* • Although it is not envisaged that Option 3 would result in excess iodine consumption, and the resulting medical problems/disorders, there should be a plan to monitor groups who may consume high levels of iodine.
14.	George Weston Foods Ltd (GWF) (Fiona Fleming)	**Support Option 2** - Extension of voluntary permissions **in combination with** increased health promotion and education strategies • Strongly believes that it is inappropriate for National Governments to shift the contingent liability for a public health measure onto the food industry for the solution. • GWF do **not** support a MoU encouraging industry uptake of voluntary permissions as they see it as a form of *de facto* mandatory fortification. • Mandatory fortification would restrict consumer choice, increase production costs and increase risk of IIH. • Data from the National Nutrition Survey is outdated. However, trends in Australia are showing that bread consumption is increasing. *Appropriate Food Vehicles* • GWF would consider the addition of iodine to a range of products after consideration of the target market. • Iodised salt should be one of the options for increasing the iodine level of foods. • Concerns about encouraging increased salt consumption could be addressed by increasing the level of iodine added to salt. • FSANZ should also consider potassium iodate as this will not impact on salt intakes. • GWF lists the disadvantages of using bread as a vehicle, including the cost of using iodised salt, labelling changes, cost of testing and other logistical effects. • If flour was considered for iodine addition then consumer acceptance and shelf life studies would need to be undertaken.

		Claims • FSANZ should develop a health claim for iodine. Without this, it will be difficult for industry to communicate the benefits of consuming fortified products in a consistent manner. *Costs* • GWF estimate that mandatory fortification of their food products would cost their business in excess of $400,000. This would significantly add to their business costs. *Monitoring* • Industry will have their own monitoring program in place for monitoring iodine levels in products. • The government should be responsible for continuous monitoring of the iodine status of the population, with a focus on those at-risk. GWF are not happy with the previous monitoring to examine the effectiveness of mandatory thiamine fortification of bread flour. • GWF are concerned that industry will not receive the support required from government to ensure an iodine fortification program is effective. Industry **must not** be expected to fund any monitoring program. • Ongoing monitoring and surveillance of iodine fortification is essential to minimise the risk of over exposure of iodine in at risk groups. GWF identified at-risk groups to be pregnant and breastfeeding women, older people with nodular goitres and children with cystic fibrosis.
15.	Goodman Fielders (GF) (Ms Kirsten Grinter)	**Supports Option 2 in combination with Option 3 -** Extension and promotion of voluntary permissions • GF believe existing permissions should be reviewed with a view to extending permissions to more food categories to retain consumer choice. • The benefits of a voluntary fortification program should be communicated through government and industry promotions. • Manufacturers wish to communicate the benefits of iodine via a health claim. • GF rejects mandatory iodine fortification as a viable approach, believing that it fails to meet the Ministerial Policy Guideline. • Assessment is needed to demonstrate that this would be the most effective public health strategy, that added amounts reach the target population and do not cause detrimental excesses. • The main disadvantage of mandatory fortification is the removal of consumer choice. • GF has been involved in the voluntary iodine addition program in Tasmania since its inception. *Appropriate Food Vehicles* • The addition of iodised salt should remain voluntary. • Substituting iodised salt in food processing would not promote increased salt consumption or consumption of foods high in salt. • Mandating the fortification of bread takes away consumer choice. • Iodine may oxidise if added to oil, thus spoiling the whole product. Trials across food categories would be needed to confirm suitability.

		Costs • In New Zealand, flour has nothing added to it and so millers would incur significant costs installing micro feeders. This cost would have to be passed onto the consumer. • The cost of moving to iodised salt (if mandated) would be ~ $18 extra per tonne and labelling changes would be required (small impact labelling changes are ~$1500 per change). There would need to be a significant lead in time. • Analytic costs for iodine testing of the various stages of production would be an ongoing cost. *Monitoring* • An ongoing monitoring program in Australia and New Zealand will be required to evaluate the effectiveness of both the regulatory and non-regulatory measures. • A trans-national program would be required to monitor IDD (though measurement of urinary iodine status of the vulnerable population) and IIH complications.
16.	New Zealand Association of Bakers Inc (NZAB) (Ms Marcia Dunnett)	**Supports Option 2 in combination with Option 3 -** Extension and promotion of voluntary permissions • Strongly opposes Option 4 –mandatory fortifications because it will limit consumer choice and result in a negative commercial impact on industry as consumers seek alternative food sources. • Mandatory fortification would also create problems for exporters and there is a risk of some sub-groups receiving excess iodine leading to IIH. • The decision to add iodine to the food supply should be voluntary and not imposed on a specific sector of the food chain thus artificially distorting the marketplace. *Consumer Choice* • NZAB commissioned a study examining people's views on mandatory fortification and provided a copy with their submission. • Results of the consumer research showed almost universal rejection of mandatory fortification of food which everyone eats for the sake of only a small number of people. The overall view was that mandatory fortification of food fails on the basics, contravenes personal rights and is a poor answer to public health issues. • Voluntary fortification would still provide consumers with a choice and on foods and supplements. This could then be monitored and the situation looked at as appropriate. *Appropriate Food Vehicles* • Fortification of salt is considered to be an appropriate vehicle because of its use by households already and can be placed in a wide range of food products. • NZAB are concerned that a single product (i.e. bread) be used as a vehicle for fortification because of the potential commercial impact on the bread baking industry, costs associated with re-labelling not borne by competing products, consumer resistance to fortification and disadvantaging people who do not eat bread as a staple.

No.	Submitter	Submission Comments
17.	The New Zealand Food & Grocery Council (FGC) (Ms Brenda Cutress)	**Supports Options 2 and 3 -** Extension and promotion of voluntary permissions • Options 2 and 3 retain consumer choice and allows for industry innovation. • In addition to the four regulatory options outlined in Proposal P230, FGC believes greater emphasis should be given to public health promotion as no campaigns have recently been undertaken to address the low iodine status of the population. • FGC does not support Option 1 (*Status Quo*), as widespread iodine deficiency is re-emerging. • FGC does not support Option 4 (Mandatory Fortification) because it will result in a lack of consumer choice, resistance by consumers, restrictions on the import of some products and difficulties with respect to export markets. Labelling costs would be high unless there is a provision for long lead in times. • FGC acknowledges the difficulty of finding a suitable food vehicle that will achieve the desired outcome. • Notes that the use of iodophors was stopped as a sanitiser in the dairy industry with the result that dairy products are no longer a major source of iodine. *Appropriate Food Vehicles* • With voluntary fortification consumer choice is retained and gives industry the choice of selecting the vehicle for fortification and allows industry to be more responsive to changing dietary requirements. • A WHO report has shown that there is a 20% reduction in iodine from the point of production to reaching the consumer and a further 20% loss in cooking. • Noted that in Thailand iodised fish sauce, instant noodles and chicken eggs are available and sugar was used as a vehicle for iodine supplementation in the Sudan. *Monitoring* • Whatever option is adopted the continued monitoring of the iodine status of the population will be necessary in order to assess the effectiveness of the measures that are adopted.
18.	Red Seal Natural Health Ltd. (N Scholes)	**Mostly favours Option 3 -** Promotion of voluntary options • Fluoride has a negative impact on iodine metabolism and thyroid hormones. Water supplies should **not** be fluoridated and the effect of iodine can only be properly assessed in the absence of fluoridation. • The value of mandatory fortification is that the level of fortification can be closely prescribed and monitored. However, the inevitable cost of imposing such a closely controlled scheme on producers and the monitoring of such a scheme outweigh the advantages. • Acknowledges the need for iodine fortification and/or supplementation for the New Zealand public, but also wants to allow customers the right to have a choice. • Concerned that not much is mentioned of the negative role that fluoride can have on iodine metabolism and thyroid hormones.

No.	Submitter	Submission Comments
		Appropriate Food Vehicles • Any fortification should begin at a low level. All regular table salt should be iodised. • An incremental strategy for increasing the amount of iodine in the food supply should be adopted. • Manufacturer of commercial food should use iodised salt. • Iodine supplementation in animal feed should be encouraged. *Health Promotion/Education* • The benefits of iodine fortification/supplementation should be presented to the public especially pregnant women and mothers of young children.
19.	Salt Institute, Alexander, VA, USA (Global Trade Association for the Salt Industry). (Mr Richard Hanneman,)	**Supports option 4 –** Mandatory fortification with a staged approach. • 'We stand ready to iodise all food grade salt as needed and assure FSANZ that neither adjusting the scope of distribution of iodised salt nor fortification level represents a difficult challenge from a technical or marketing perspective.' *Appropriate Food Vehicles* • Believes expanding the usage of iodised salt is appropriate and the best means of improving iodine sufficiency Australian and New Zealand populations. • Salt is consumed in relatively consistent quantities and within a relatively predictable range. • Recommends that all retail salt be iodised in the near term and that salt sold to food processors be iodised using some phase-in time frame that will permit education and buy-in. • It is entirely feasible, technically, to use iodised salt in food manufacturing. • Option 3 (promotion of voluntary options) might be a useful strategy and warrants further consideration. MoUs might be a useful means of education and phasing in the USI requirement and should be evaluated for this purpose. *Vulnerable Groups* • Recommends a targeted, non-regulatory promotion campaign aimed, at minimum, the most important group, which is expectant mothers. *Monitoring* • A phasing– in approach in the adoption of USI will not only provide a control for any adverse health effects at high levels leading to hyperthyroidism, it will also allow FSANZ to carefully monitor the population impacts.
20.	Sanitarium Health Food Company (Ms Trish Guy and Ms Alison Tickle)	**No specific option selected at this stage** • Mandatory fortification may allow for a consistent incremental increase in iodine levels. However, increased permissions for voluntary fortification combined with clear guidelines for making claims regarding iodine may assist in increasing industry uptake. • Does not support Option 1 as iodine levels in the Australian & New Zealand population are below recommended.

No.	Submitter	Submission Comments
		• Sanitarium would support guidelines being devised identifying the types of foods and the levels of iodine that can be safely added. • Sanitarium has used potassium iodide in the past to fortify So Good soymilk and found no adverse effects on shelf-life or taste. *Costs* • Mandatory fortification must be balanced against the potential increased costs to consumers both financially and through reduced consumer food choices. • Sanitarium state that the additional costs from using iodised salt include the following; testing the impact on taste, shelf-life and appearance; implementing a monitoring program; working with suppliers to ensure a consistent level of iodine and label changes. *Claims* • Unless manufacturers are able to promote the added iodine, it is unlikely they would voluntarily change from using non-iodised salt to iodised salt. *Appropriate Food Vehicles* • Grain based foods, dairy and non-dairy alternatives, bread, yeast extracts and juices are all food suitable for extending voluntary permissions.
21.	Sealord Group Ltd (Mr David Jones)	**Does not state a preference for any of the four regulatory options** • This Proposal must allow non-iodised salt to be manufactured for industrial applications. • Sealord uses breadcrumbs to coat fish portions for export to the Japanese market. This important market does not permit the addition of iodine. We also manufactures fish blocks with added salt for this and other markets.
Public Health Professionals		
22.	Agencies for Nutrition Action, New Zealand Ms Nicola Chilcott	**Supports Option 4 –** Mandatory fortification. *Appropriate Food Vehicles* • Recognises that more work is needed to establish the most appropriate food vehicle for fortification. • Not in favour of fortifying sugar and cooking oils, as this is inconsistent with New Zealand (NZ) Food & Nutrition Guidelines. *Education* • Any action to increase iodine intake needs to be accompanied by a comprehensive communication plan to inform consumers and health professionals.
23.	Auckland Regional Public Health Service, New Zealand (Ms Christine Cook)	**Supports Option 4 –** Mandatory fortification *Iodine Deficiency* • There is clear evidence of iodine deficiency (supported by data from Thomson and Skeaff, the 1997/98 NZ Total Diet Survey) and fortification should not be left to industry discretion. • Not possible to meet iodine requirements through diet alone.

No.	Submitter	Submission Comments
		Appropriate Food Vehicles • Manufacturers would replace non-iodised salt with iodised salt if product quality could be maintained. • Difficult for one food vehicle to reach all population groups equally. • If bread were the vehicle, population groups who traditionally eat little bread would be disadvantaged (e.g. Korean and Chinese families). It is noted that these communities are high salt users but traditionally don't use iodised salt. • The NZ Child Nutrition Survey found that 29% of children ate bread less than once a day. • Foods suitable for extending permissions for voluntary iodine fortification are bread and flour (using iodised salt as the vehicle). Unless iodine is added to gluten – free bread, people with gluten intolerance would be vulnerable to deficiency. • Although minimal use of salt is encouraged, it has the benefit of being recognised as the carrier for iodine by a substantial section of the community. • In contrast, sugar should not be the vehicle because it lacks nutritional value as well as historical knowledge as a source of supplemental iodine. *Vulnerable Groups* • Even with mandatory fortification, additional measures may still be needed to ensure that population groups with increased requirements (e.g. pregnant women) have adequate intakes. *Monitoring* • Ministry of Health (MoH) should be responsible for routine monitoring of iodine status and adverse outcomes. • Urinary iodine monitoring and random sampling of foods to ascertain whether iodine is present in the stated amounts should be conducted, and should be the responsibility of MoH and FSANZ respectively.
24.	Dietitians Association of Australia (DAA) (Ms Sue Cassidy)	**Supports Option 4 –** Mandatory fortification at this stage. • Is in favour of mandatory iodine fortification because of the high proportion of the population at risk of inadequate dietary iodine intakes. • The impact of this application on iodine levels of fruits and vegetables (used as a processing aid) needs to be incorporated into the dietary modelling to assess mandatory or voluntary iodine fortification strategies. • DAA cites Australian Dietary Guidelines, Heart Foundation Tick Program, National Stroke Foundation and the new Nutrient Reference Values (NRV) as activities to reduce current salt consumption. The new NRV of 1600 mg/day is significantly less than the current RDI value of 2300 mg/day. *Education* • Believes consumer education programs alone would not necessarily help replete the iodine status of the whole population as the general food supply appears to provide inadequate levels of iodine. • Food selection habits and variations within the population in the amounts of high-iodine foods consumed, will make it difficult to determine if such an approach would be effective on a national scale.

No.	Submitter	Submission Comments
		Appropriate Food Vehicles • DAA believes that the use of iodised salt as an ingredient in a chosen food vehicle (e.g. bread), rather than as vehicle in its own right, would not contradict the promotion of the dietary guideline on reduced salt consumption. • Since oils can be iodised, another food vehicle that could be considered would be margarines and margarine spreads since salt is added when manufactured. • Recommends that FSANZ conduct further research into the current consumption patterns of margarine and margarine spreads to determine whether they are still widely consumed foods. *Vulnerable Groups* • DAA is aware of anecdotal evidence indicating that some medical practitioners would recommend to at-risk pregnant women, the use of multivitamin supplements with iodine to improve their iodine levels. • DAA would accept an evidence-based position adopted by the Australian Medical Association to address at risk sub-groups of the population. *Monitoring* • Adequate labelling and monitoring would ensure that individuals or particular groups are not exposed to excessive iodine intakes. • Due to the potential risk of IIH in susceptible people, DAA believes an incremental strategy for increasing the amount of iodine in the food supply should be adopted. • The impacts of voluntary fortification would be harder to monitor compared to mandatory fortification, since voluntary uptake would be determined for commercial reasons rather than health considerations.
25.	New Zealand Dietetic Association (NZDA) (Ms Carole Gibb)	**Supports Option 4 –** Mandatory fortification *Dietary Iodine Intakes* • A diet naturally rich in iodine would need to include regular intakes of fish, seafoods and kelp. Data from the 1997 National Nutrition Survey show that few people regularly consume these foods in sufficient quantities. • Uncertain whether a campaign to push for more consumption of seafood would be effective in raising iodine levels. • Some individuals with chronic iodine deficiency and with thyroid disorders, including thyroiditis, need to avoid high iodine levels. • Dietary modelling is urgently needed to obtain reference iodine intakes based on diets using a range of fortification options. *Appropriate Food Vehicles* • The advantage of fortifying bread with iodised salt is that it will provide a reasonable consistent and not excessive level of iodine. • A recent examination of the price and salt content of foods showed the lower the price of that food, the higher the content of salt.

No.	Submitter	Submission Comments
		• With data demonstrating there is evidence of sub – optimal iodine levels, the current policy of iodised table salt is no longer an adequate strategy for ensuring adequate intakes in the New Zealand population. • For those groups that do not consume bread the continued use of iodised table salt should provide an adequate iodine level. *Monitoring* • It should be the responsibility of the MOH NZ to monitor the population and should be incorporated into national health and nutrition surveys. • Urinary iodine and sodium secretions plus estimates of dietary iodine levels should be monitored.
26.	Private (Dr Mike Croxson, clinical endocrinologist, member of JAGI)	**Supports Option 4 –** Mandatory fortification • Like Tasmania, New Zealand has mild iodine deficiency that has likely re-emerged since the removal of fortuitous iodisation by iodophors in the dairy industry. • A suitable external expert in IDD, such as Delange, would aid the introduction and management of mandatory fortification. *Appropriate Food Vehicles* • Supports the option of mandatory universal iodisation of salt (UIS), combined with the availability of iodine-supplemented vitamin preparations in pregnancy • Recommends an initial fortification level of 15 ppm UIS, combined with a two yearly urine iodide monitoring programme. This would allow for iterative changes in the level of iodisation. *Iodine-Induced Hyperthyroidism* • Re-introduction of optimal iodine intakes would now be timely to minimise future risks of transient IIH (caused when people are exposed to low iodine environments for many years). *Monitoring* • Community based sensitive TSH measurements from a laboratory that samples from approximately a third of the NZ population can be used before and after any planned UIS to monitor changes in the frequency of IIH should they occur. • In NZ routine monitoring of iodine status and adverse outcomes could be carried out as tendered by the Ministry of Health, Dept of Nutrition who have recently established the existence of continuing mild iodine deficiency.
27.	Sydney West Area Health Service (SWAHS) (Dr Stephen Corbett)	**Supports Option 4 –** Mandatory fortification • We believe mandatory fortification is the only viable option. *Iodine Deficiency* • Iodine deficiency is a massive health problem in over 133 countries worldwide. • Australia could face serious health problems if there is a re-emergence of iodine deficiency in our diets. This is a public health issue that cannot be ignored.

No.	Submitter	Submission Comments
		• Previously, Australia had improved its iodine deficiency by supplying iodised salt, iodine supplemented bread and population health messages. • Due to the decline in salt intakes as a result of public health efforts (and less than 10% of the population using iodised salt), stopping iodine-supplementation of bread and the lower iodine content of milk, there may be a re-emergence of iodine deficiency. • It is unacceptable to maintain the *Status Quo*. Experience elsewhere shows that Options 2 & 3 rarely works. There is a significant equity issue involved with voluntary fortification as it is likely to benefit only those with the means and knowledge to take it up. • This submission notes various studies showing the re-emergence of iodine deficiency. *Appropriate Food Vehicles* • Australia should follow WHO/UNICEF/ICCIDD policy and implement Universal Salt Iodisation (USI). This seems to be an appropriate response to the potential re-emergence of iodine related disorders. *Costs* • The costs incurred are quite small in comparison to the benefits gained and justify the adoption of USI.
28.	Tasmanian Thyroid Advisory Committee, Royal Hobart Hospital (A/Professor John Burgess)	**Supports Option 4 -** Mandatory fortification • We strongly recommend that any measures to address iodine nutrition be mandatory and also be appropriately monitored. • We note the failure of voluntary iodine fortification programs in Germany and other European countries (Remer & Neubert, JEMC, 2005;83:3755-3756). • We concur with the Tasmanian Department of Health and Human Services submission (*see Submission No. 12)* and reinforce their comments.
29.	University of Otago (Dr Sheila Skeaff & A/Prof Christine Thomson)	**Supports Option 4 –** Mandatory fortification • Iodine deficiency is prevalent in New Zealand and there is sufficient evidence to support this view. *Appropriate Food Vehicles* • Proposes mandatory iodine fortification of cereals in NZ and Australia, including bread, pasta and some bakery products. • Is concerned that the inclusion of iodised salt in bread, alone, will not reach the important target groups who have high iodine requirements. These groups include pregnant and lactating women, infants and toddlers, as well as a large numbers of children. • Believes that USI is not an appropriate strategy for New Zealand. Iodised table salt is not an appropriate choice to ensure consistently adequate population intakes. *Costs* • The costs of mandatory fortification will be smaller than the public health costs associated with long-term iodine deficiency. *Education* • Strongly recommends that a public education campaign be undertaken in

No.	Submitter	Submission Comments
		both countries to highlight the health consequences of iodine deficiency. *Iodine-Induced Hyperthyroidism* • The frequent mention of IIH in the Initial Assessment is misleading. *Monitoring* • To date, there has not been regular monitoring of the iodine status in the population. Applauds the Swiss example whereby iodine status is monitored every five years. • Believes nation-specific governmental bodies, such as Ministry of Health in New Zealand, should provide adequate funds for the monitoring of iodine status and IIH in the population.
30.	Westmead Hospital – Institute of Clinical Pathology and Medical Research. (Prof C J Eastman) The Australian Centre for Control of Iodine Deficiency Disorders (ACCIDD) and the Asia Pacific Regional Office of ICCIDD)	**Supports Option 4 –** Mandatory fortification *Iodine Deficiency* • Since 1992 there has been an increase in iodine deficiency in Victoria, New South Wales and Tasmania. Of particular concern, is that a significant proportion of pregnant women are showing mild to moderate iodine deficiency. • The major cause of the decline in iodine status appears to be changes in work practices within the dairy industry and a decrease in iodised salt consumption. • The re-emergence of iodine deficiency has prompted the ACCIDD to convene the National Iodine Nutrition Survey (NINS). *Recommended Dietary Iodine Intakes* • Advises that FSANZ use the new NHMRC guidelines for nutrient reference values for Australia and New Zealand as the values quoted in the Initial Assessment (Section 4.4.2) underestimate the optimal daily iodine requirements. • The WHO will recommend that the minimum daily iodine requirement for adults is 150 ug/day, increasing to 250 ug/day during pregnancy with the same requirement during lactation. The recommended intake for neonates and young infants is approximately 100 ug/day. • Advises that the daily iodine intake of pregnant women is calculated to be approximately 132 ug /day – just over half the recommended daily intake. This is a serious problem and may be even worse in New Zealand. These are not trivial deficiencies. *Sources of Iodine in the Australian Diet* • Experimental data from their laboratory (available on request) indicate that iodine concentrations in milk have more than halved over the past decade. *This adventitious source of iodine had never been adequately regulated and we are now paying the price.* • Wide variations in the iodine content of milk still occur and will need to be addressed if USI is implemented. • Milk and dairy products remain the major source of iodine in our diet. *Appropriate Food Vehicles* • Australia and New Zealand should follow WHO/UNICEF/ICCIDD policy

No.	Submitter	Submission Comments
		and implement a programme of mandatory iodine fortification of all salt for human consumption. This policy has been implemented in over 100 countries and provides enormous benefits for little cost. *Vulnerable Groups* • Pregnant and breastfeeding women in Australia and New Zealand should currently receive daily iodine supplements. • Recent evidence from Italy has shown that attention deficit hyperactivity disorder (ADHD) is highly prevalent in children born in areas of moderate iodine deficiency. Whether this is relevant to Australia remains to be determined. *Currant Salt Permissions* • The iodine salt permission needs to be reviewed as the concentration of 25 - 65 mg/kg allows for too much variation and is not in keeping with recommendations from WHO and ICCIDD. Believes the range should be 20-40 mg iodine/kg salt. *Current Salt Intakes* • The figure of 15% of Australian households that use iodised salt, as reported in the Initial Assessment, is inflated. • It is estimated of average salt intake is around 10 g per adult per day. *Current Iodine Fortification Strategies* • The experiment undertaken in Tasmania is a compromise and should not be encouraged elsewhere. The results to date appear disappointing. • The use of iodised bread may simply mask the problem and not address the underlying issue of ensuring optimal iodine nutrition for the most vulnerable. *Regulatory options* • Strongly supports mandatory fortification (USI). It is unlikely that other options for increasing iodine status in the population will work. • Maintaining the Status Quo is completely unacceptable. • Experience shows that the voluntary options rarely work. *Iodine-Induced Hyperthyroidism* • IIH is a well-recognised consequence of excessive iodine supplementation in elderly people with autonomous multinodular goitres from long standing iodine (lifelong) deficiency. • Iodine deficiency in Australia is not longstanding and has been present for around a decade at most. This is important to note when introducing additional iodine into the food supply. There is no data to suggest adverse health effects in populations that have recently become iodine deficient. • At worst, we could expect an additional 4.5 cases of hyperthyroidism per 100,000 population per year. • Only two articles show adverse effects from short-term exposure to excessive iodine. The administered dose was between 1700 - 1800 ug. The WHO states there are no physiological benefits in a daily iodine intakes exceeding 500 ug.

No.	Submitter	Submission Comments
		Monitoring • It is essential that a specific and comprehensive national monitoring program be put in place to monitor iodine fortification programs.
31.	Women's & Children's Hospital - Adelaide (Dr Basil S Hetzel) Chairman Emeritus ICCCIDD	**Supports Option 4 -** Mandatory fortification • Current data on iodine nutrition in Australia measured by urine iodine excretion indicates iodine deficiency is now present throughout the population as indicated by the recent NINS. • Strongly supports WHO/UNICEF/ICCIDD policy to adopt mandatory iodine fortification for all salt for human consumption. The policy has been successful in over 100 countries and provides enormous benefits for little cost. A World Bank report estimated that for each US$1 spent on IDD, there is a return of US$28.
Government Agencies		
31.	Australian Department of Agriculture, Fisheries and Forestry (DAFF) (Mr Richard Souness)	**Supports Option 2 and 3 -** Extension and promotion of voluntary permissions • Options 2 and 3 may not be exclusive and could be in conjunction with health promotion /community education strategies. • Geographical differences in iodine intakes/status (as in Tasmania) may mean different strategies are appropriate for different regions, or at different times for a particular region. • Monitoring results shows that Tasmania's Iodine Fortification program is helping to increase the population's iodine status. • The s*tatus quo* appears not to have been effective in ensuring adequate iodine status in Australian and New Zealand populations. • With respect to mandatory fortification, based on the information contained in FSANZ's Initial Assessment, it is not clear that the Specific Order Policy Principles, as set out in the Ministerial Council's Policy Guideline on Fortification, have been met. • DAFF notes the potential to increase the incidence of IIH. Approaches might include a staged approach to the range for food categories/and to ingredients. *Health Promotion and Education Strategies* • There may be a need to increase community awareness of IDD at a national level which could lead to a marketing advantage. • One of the contributing factors, resulting in a decrease in iodine status, appears to be the increased use of commercially prepared foods using non-iodised salt. • Health promotion and education strategies, if pursued in conjunction with Option 2 and/or 3, have the potential to reinforce the beneficial outcomes from pursuing either option alone. This would lead to heightened community awareness, leading to a more informed population, with a greater capacity to choose between iodine enriched products. This may stimulate industry development and diversification of new products as part of a generic 'healthy eating' campaign.

No.	Submitter	Submission Comments
		Monitoring • Continuous monitoring of the food supply and iodine status of the population would play an important role in risk management.
33.	Department of Health and Human Services, Tasmania (DHHS) (Ms Judy Seal)	**Supports Option 4 –** Mandatory fortification • Believes voluntary fortification is an inadequate response to an important public health concern and that a mandatory response is required for the protection of public health and safety. *Tasmanian Interim Iodine Supplementation Program* • The Tasmanian Interim Iodine Supplementation Program as described in the Initial Assessment was instigated as an **interim** measure until such times as a national approach could be developed. • This interim program demonstrates that small but significant changes to iodine nutrition can be achieved through bakeries switching to iodised salt. • Concerns remain about the sustainability of the program, given its voluntary nature. These concerns include changes in costs, the percentage of non-participating bakeries, encouraging consumers to ask for fortified bread and ensuring that disadvantaged population sub-groups are reached. • The costs of a voluntary program are higher for government compared to the costs associated with a mandatory program, thus diverting limited resources away from other public health priorities. • The barriers to using iodised salt in bread predominantly relate to use of premixes and lack of awareness of bakers of the need to use iodised salt. • A survey of small to medium sized bakeries in Tasmania in 2003 demonstrated the impact of bakeries switching to iodised bread had no significant impact of industry or consumer acceptance. *Appropriate Food Vehicles* • Agrees with the WHO recommendation of universal salt iodisation and prefers iodised salt either universally or as a component of staple food products already containing salt, such as bread. • Bread is a reasonable choice, however, a number of people don't consume bread and so additional staples may be needed. • Margarine may be a possibility, if technically feasible, especially given it already contains salt and is fortified with other nutrients. *Vulnerable Groups* • It may be necessary to implement additional measures to reach at risk population such as unborn babies via pregnant women. *Mandatory* • Mandatory fortification could be more closely controlled and increments increased to the level required to assure iodine sufficiency, while at the same time minimising the risk of IIH. *Voluntary* • DHHS are not supportive of ongoing voluntary iodine fortification mainly because of concerns with reach and sustainability.

No.	Submitter	Submission Comments
		Monitoring • A decision to fortify food with any nutrient (mandatory or voluntary) requires careful monitoring to ensure protection of public health and safety. • DHHS strongly recommend a monitoring program be developed in parallel with the commencement of a fortification program. • The responsible agency's for monitoring needs to be clarified. Iodine monitoring should form part of an overall nutrition monitoring and surveillance program at a national level. Possible suggestions include development of a: - National Nutrition Monitoring and Surveillance Unit, outsourced to a University or within the Australian Institute of Health and Welfare (AIHW); and/or - Commonwealth State program such as the Ozfood-net program.
34.	Department of Health – South Australia (Ms Joanne Cammans)	**Supports Option 4 –** Mandatory fortification tentatively *Appropriate Food Vehicles* • Offers tentative support for the implementation of mandatory fortification with iodine, using iodised salt in bread as the food vehicle. *Monitoring* • Supports the establishment of a monitoring and surveillance system in conjunction with such a strategy – to determine present iodine status in the whole population and especially in vulnerable subgroups.
35.	Department of Human Services – Victoria (Mr Victor Di Paola)	**No specific option selected at this stage** • The current Proposal does not adequately address the Specific Order Principles of the Ministerial Council's Policy Guideline on Fortification. This should be addressed at Draft Assessment. • The current research simply indicates that there are areas of the population which are iodine insufficient, not that the entire population is iodine deficient. • Data used to demonstrate a whole of population deficiency is more than 10 years old (from 1995 National Nutrition survey) and cannot be relied upon. *Appropriate Food Vehicles* • In determining the most appropriate food vehicle, FSANZ needs to ensure that the fortification option selected will deliver effective amounts of iodine to the target population. For example, if salt were chosen as the vehicle and salt consumption continued to decline, due to current National Nutrition policies, would mandatory fortification continue to achieve the desired outcome? • Previously the addition of iodised salt to bread in Tasmania to combat goitre resulted in arise in the incidence of thyrotoxicosis. • Interactions with other nutrients, foods and drugs have yet to explored e.g. the fluoride – iodine antagonism has been shown to impact on iodine status and should be explored in the Draft Assessment.

No.	Submitter	Submission Comments
		Current Salt Permissions • The current permission for salt iodination is too broad (25-65 mg/kg) and could potentially result in a state of iodine excess in the community. FSANZ should determine a more precise range (i.e. 20-40 mg/kg) and review current voluntary permissions. *Monitoring* • Mandatory fortification should be introduced incrementally and monitored to reduce the likely occurrence of any deleterious health effects. • In the absence of available data, a comprehensive monitoring program must be put in place to determine if mandatory fortification is effective. Mandatory fortification must be accompanied by a requirement that the standard should be reviewed every two years.
36.	Ministry of Health - New Zealand (MOH) (Dr Ruth Richards)	**Supports Option 4 –** Mandatory fortification • MOH state that food standards should decrease health inequalities and not markedly increase the cost of healthy food. • It is difficult for New Zealanders to choose a diet naturally rich in iodine. • MOH believe that a Code of Practice or MoU is not appropriate or adequate to address this serious public health issue. The responsibility for monitoring the MoUs is also onerous in terms of human and financial resources. *Iodine Deficiency* • The weight of evidence in New Zealand is that iodine status of New Zealanders has fallen substantially since the early 1980's. • Iodine status is at a point where experts on the Joint Advisory Group on Iodine (JAGI) agree that iodine should be urgently added to the food supply. • MOH have provided further data on the iodine status of New Zealanders in this submission and a summary of New Zealand iodine status from 1936 to 2002. *Appropriate Food Vehicles* • It is recognised that more work is required in establishing the most appropriate food vehicle for fortification and that the vehicles could include universally iodised salt, bread or possible milk. • MOH are not in favour of fortifying sugar or cooking oils. • The choice of salt may be inconsistent with MOH stance on oil and sugar but follows WHO's preferred method of increasing iodine intake. • More work needs to be done looking at sodium excretion in at-risk groups. MOH provided various data on estimated sodium intakes for different population groups. • Food modelling work undertaken by the University of Otago showed that bread was consumed by sufficient people for it to be considered a suitable food vehicle. • Milk may also be a suitable vehicle.

No.	Submitter	Submission Comments
		Communication Strategies • A communication plan and strategy will be necessary for any action to increase the iodine intake in New Zealand. • It will be necessary to engage relevant health professionals to assist in promoting increased iodine intakes and to alert clinicians as to the possible side effects of increased intakes for some individuals. *Vulnerable Groups* • Due to increased requirements for iodine, pregnant and breastfeeding women are at-risk of deficiency, which is a public health concern. • JAGI believe it may be desirable to supplement pregnant women with iodine, however there are no such products currently available as registered medicines. • MOH is aware of a recent WHO meeting of experts to consider iodine requirements during pregnancy and breastfeeding and understand the levels will be revised upwards for this group. *Estimated Average Requirements* • The proposed RDIs for iodine is designed to meet the needs of 97.5% of the population and should be used rather than the United States Estimated Average Requirement (EAR). *Iodine-Induced Hypothyroidism* • The phased introduction of fortification of foods with iodine may be used to minimise the effect of IIH. *Monitoring* • FSANZ needs to clearly identify a monitoring plan with each food vehicle option and to seek Ministerial agreement for organisational responsibility. • MOH believe that monitoring of iodine is the shared responsibility of FSANZ, NZFSA and MOH. • The components of monitoring that need consideration are thyroid disease surveillance, iodine status, and the iodine content if foods. Targeted studies are also probably needed to monitor iodine status in at-risk groups.
37.	New Zealand Food Safety Authority (NZFSA) (Ms Carole Inkster)	**Supports option 4 –** Mandatory fortification • NZFSA believes that Proposal P230 has understated the public health importance of iodine deficiency and has not adequately reflected the size and significance of the problem. • Strongly recommends that FSANZ consider Universal Salt Iodisation (USI) or fortification of a range of staple foods. • Does not support a voluntary approach because iodine is a significant public health issue which needs to be addressed through mandatory fortification. • Believes voluntary fortification is difficult to monitor and keep abreast of the actual levels of iodine in the total food supply. • NZFSA has provided information on the use of iodine sanitisers used in milk production.

No.	Submitter	Submission Comments
		Appropriate Food Vehicles • Iodised table salt is not an appropriate choice to ensure adequate population iodine intakes. • The fortification of flour is problematic due to the vast variety of different types of flour and the wide variety of food products that contain flour as an ingredient. • The amount of salt added to bread differs depending on the brand and type of bread and the method of production. • Rather than a single food, a range of staple food products should be considered e.g. bread and pasta, bread and table salt (still providing a choice for non-bread consumers), or USI at low levels. • NZFSA have commissioned Massey University to undertake research on the technological issues with iodine fortification and will be in a better position to comment on shelf-life, taste of sugar, oil, milk and flour at the Draft Assessment stage. • Most foods would be suitable for extended permissions for voluntary iodine fortification but would be difficult to monitor. *Iodine-Induced Hyperthyroidism* • NZFSA are unsure as to the extent of people that would be affected by IIH. The most susceptible individuals would be older people who are severely iodine deficient. • NZFSA state the benefits of correcting iodine deficiency far outweigh the risks (Delange & Lecomte, 2000). *Vulnerable Groups* • FSANZ should note that supplementation of at-risk populations with folic acid has not been successful. *Monitoring* • Changes to agriculture practice, such as adding iodine to drinking water and in drenches, is occurring. This practice appears to be increasing and should be considered as part any monitoring for iodine fortification. • Quantitative data on flour consumption is unable to be extracted from national nutrition surveys making it difficult for future monitoring programs, if flour is chosen as the preferred vehicle. • The roles and responsibilities of different organisations need to be considered as part of any fortification program with the level of monitoring dependent on the proposed fortification strategy.
38.	Queensland Public Health Services Branch (Mr Gary Bielby)	**Tentatively supports option 4** – Mandatory fortification • Option 4 is made on the condition that a satisfactory monitoring and surveillance system is established prior to implementation and at regular intervals thereafter. • The studies on iodine status in the population are relatively small. How applicable is this data to the rest of the population? • How transferable is the Tasmanian iodine supplementation program to the mainland of Australia?

No.	Submitter	Submission Comments
		• A voluntary program would be difficult to control and monitor. A mandatory program would be more effective because it provides more control over the food supply. *Appropriate Food Vehicles* • If iodised salt were used in breads, alternative options may need to be made available for those who do not eat bread. • Oil and sugar are not appropriate foods to fortify with iodine. • From information provided by FSANZ, the use of iodised salt in a range of breads, including gluten free breads, seems to be appropriate. *Iodine-Induced Hyperthyroidism* • What percentage of the population is at risk of developing IIH should a fortification program be instigated? • Who will ensure that health professionals (especially GPs) are adequately informed regarding the risk of IIH? *Monitoring* • Recognises the need for regular national nutrition surveys, including information on dietary and supplement use, nutritional and health status, and food composition. Until a commitment is given from all government agencies for these initiatives, this Proposal should **not** proceed**.** • At a minimum, there needs to be baseline data and a commitment to obtain repeat data at least every ten years. • The Commonwealth supported by State/Territory jurisdictions would be responsible for routine monitoring of adverse outcomes such as IIH incidence.