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

9-04
15 December 2004

INITIAL ASSESSMENT REPORT

PROPOSAL P230

IODINE FORTIFICATION

DEADLINE FOR PUBLIC SUBMISSIONS: **6pm (Canberra time) 23 February 2005**
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

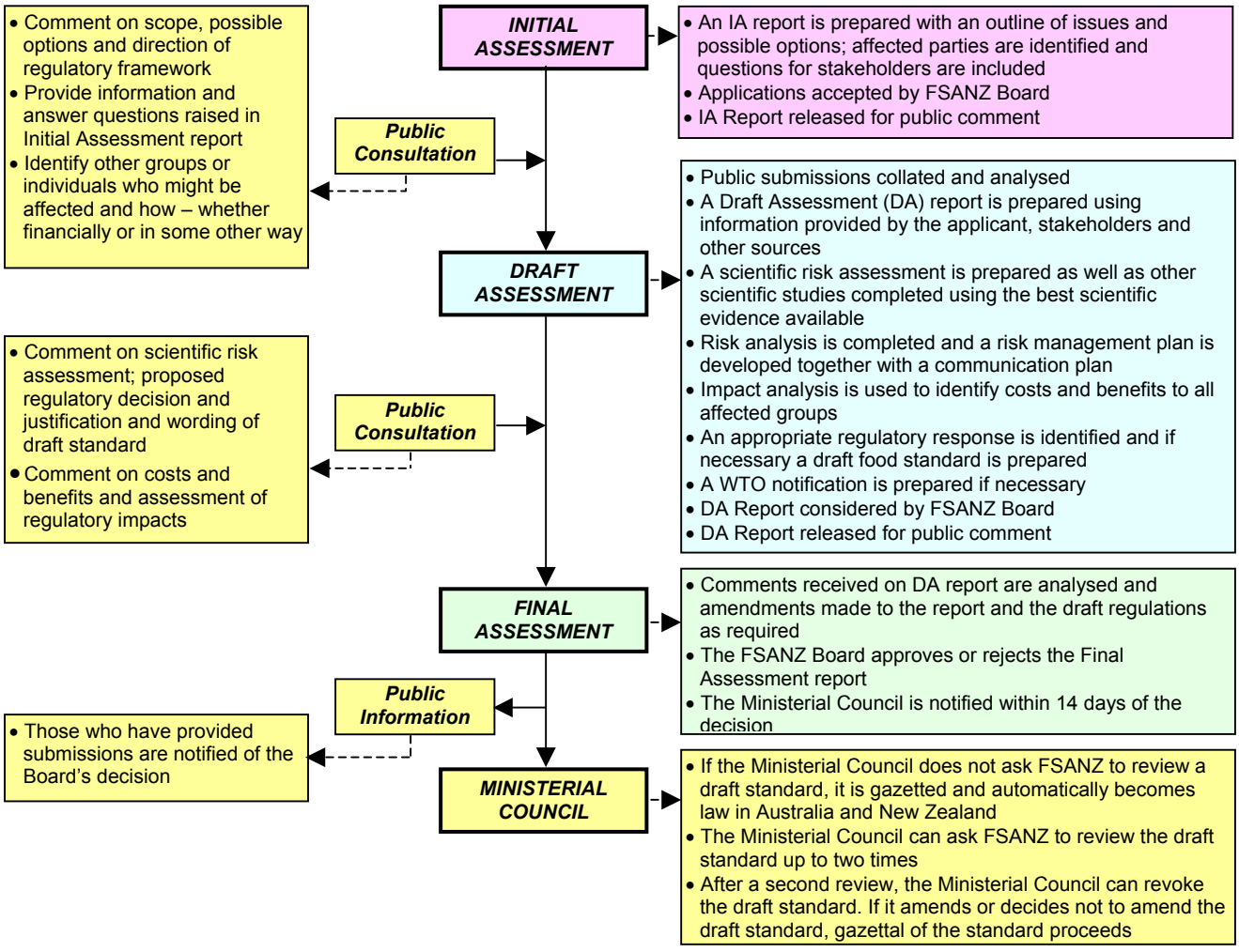
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Australian Government; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Australian Government, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Australian Government, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Proposal P230, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report 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 Draft Assessment for 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 (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions need to be received by FSANZ **by 6pm (Canberra time) 23 February 2005**.

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.

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Executive Summary

A diet deficient in iodine is associated with a wide range of adverse health effects collectively referred to as iodine deficiency disorders (IDD). Depending on the severity and stage of development, iodine deficiency can result in a broad spectrum of health problems, ranging from mild intellectual impairment and subtle deficits in visual motor skills, hearing and intelligence to severe mental retardation. Goitre, an enlargement of the thyroid gland, is the most recognisable and noticeable feature of iodine deficiency. The foetus, neonate, young children, preadolescents and women of child-bearing age are at greatest risk of IDD.

The iodine content of food reflects the background levels of iodine in the environment. Some areas in Australia and many areas in New Zealand have soils with very low levels of iodine resulting from leaching caused by glaciation, snow and rain. Early last century endemic goitre was prevalent in these areas but because of various intervention strategies and changes to the food supply, goitre was virtually eradicated.

Currently Standard 2.10.2 – Salt and Salt Products of the *Australia New Zealand Food Standards Code* (the Code) permits the voluntary fortification of salt with iodine at a concentration of 25–65 mg iodine/kg salt. Approximately 50% of salt manufactured for household use is iodised in New Zealand but only about 15% in Australia. Iodised salt is also permitted to be added to other foods as long as the food is appropriately labelled.

Recent studies suggest that the uptake of the current regulations are not effective in ensuring adequate iodine status of the Australian and New Zealand population. The observed decrease in iodine status appears to be attributable to a reduction in the consumption of household iodised salt, the increased use of commercially-prepared foods (manufactured mostly with non-iodised salt) and the declining use of iodine containing sanitising agents in the dairy industry.

Having sufficient iodine in the diet can prevent IDD. Current estimates of dietary iodine intake indicate, however, that the majority of people in Australia and New Zealand are likely to have intakes below their respective dietary reference intakes. Additional strategies are therefore needed to improve the iodine status of the Australian and New Zealand populations.

Iodine intake can also produce adverse health effects at high levels and particular care is required where populations have had low intakes of iodine over time. Iodine induced hyperthyroidism is considered a possible side effect of iodine supplementation and has been reported in almost all supplementation programs. Any program to increase the iodine status of a population has to be implemented in a controlled manner and monitored carefully.

In May 2004, the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council) asked FSANZ to investigate mandatory fortification with iodine as a possible means of improving the iodine status of New Zealanders and Australians. The Ministerial Council also issued a Policy Guideline on *Fortification of Food with Vitamins and Minerals* to guide FSANZ's consideration of the issues.

The specific objective of this Proposal is to determine the most effective mechanism to improve the iodine status of Australian and New Zealand populations to iodine sufficiency as defined by authoritative international guidelines, and in so doing reduce the risk of iodine deficiency for vulnerable population groups such as the developing foetus and young children.

The risks and benefits to the general population from increased dietary iodine intake will be taken into consideration when making this determination.

In order to determine the most effective mechanism to improve the iodine status of Australian and New Zealand populations, FSANZ is considering the following four regulatory options:

1. Maintenance of the *status quo*;
2. Extension of permissions for voluntary iodine fortification;
3. Promotion of voluntary options to increase industry uptake; and
4. Mandatory iodine fortification.

The impact analysis provides initial consideration of the potential impact of each option on consumers and the community, industry and governments.

FSANZ now seeks comment and information from stakeholders on the range of issues raised in this Report. Input from all sectors of the community, including consumers, industry, health professionals and government, is welcomed and encouraged. The submissions provided during this consultation will inform the Draft Assessment and assist FSANZ to determine the most appropriate means for increasing iodine intake and thereby increase the iodine status in Australia and New Zealand.

1. Introduction

Iodine is an essential nutrient required for normal thyroid function, growth and development. A lack of iodine in the diet is associated with a range of adverse health effects, collectively referred to as iodine deficiency disorders (IDD). Depending on the severity and stage of development, iodine deficiency can result in a broad spectrum of health problems, ranging from mild intellectual impairment to severe mental retardation. Goitre, an enlargement of the thyroid gland, is the most recognisable and noticeable feature of iodine deficiency.

Recent studies reveal that the iodine status of the Australian and New Zealand population appears to be declining and mild iodine deficiency is re-emerging as a widespread problem in the general population. This evidence is sufficient to warrant consideration of further iodine fortification of the food supply.

In May 2004, the Ministerial Council agreed that mandatory fortification of food with iodine should be considered as a priority and referred this work to FSANZ. At that time, the Ministerial Council also adopted a Policy Guideline on *Fortification of Food with Vitamins and Minerals*. This Guideline provides the policy framework for both voluntary and mandatory fortification.

The purpose of this Initial Assessment Report is to:

- clearly articulate the regulatory problem to be addressed;
- identify the objectives of any regulatory action;
- identify any relevant issues associated with mandatory fortification of foods with iodine (including addressing issues in the Ministerial Council Policy Guideline as detailed above);
- detail the potential impacts on all affected parties; and
- seek the views of stakeholders and any further available evidence on all of the above issues.

2. Regulatory Problem

A diet deficient in iodine is associated with a wide range of adverse health effects, with the foetus, neonate, young children and preadolescents being at greatest risk from IDD. The most damaging effect of iodine deficiency is on the developing brain, especially during the foetal and neonatal periods. Mild iodine deficiency can cause subtle deficits in visual motor skills, hearing and intelligence. For women of child-bearing age, iodine deficiency reduces fertility and increases the risk of miscarriage or stillbirth. Thus, IDD represent a significant threat to the health, wellbeing and productivity of the Australian and New Zealand community.

Recent studies show that the iodine status of the Australian and New Zealand population appears to be declining and mild iodine deficiency is re-emerging as a widespread problem in the general population (Thomson 2002).

The decrease in iodine status appears to be attributable to a reduction in the consumption of household[1] iodised salt, the increased use of commercially-prepared foods (manufactured mostly with non-iodised salt) and the declining use of iodine containing sanitising agents in the dairying industry.

The World Health Organization (WHO) recommends universal fortification of all 'food-grade' salt as the key strategy to eliminate IDD. The Code currently permits the voluntary addition of iodine to all salt. While there is no regulatory impediment to increasing the iodine status of the population through either a greater proportion of available iodised household salt and/or increased use of iodised salt in manufactured foods, the current passive iodine fortification, as applied, is not effective in ensuring iodine sufficiency in the population.

3. Objective

The specific objective of this Proposal is to determine the most effective mechanism to improve the iodine status of Australian and New Zealand populations to iodine sufficiency as defined by authoritative international guidelines[2], and in so doing reduce the risk of IDD for vulnerable population groups such as the developing foetus and young children.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives that 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.

[1] Household salt refers to salt that is purchased by the general public for discretionary use in cooking and at the table.

[2] World Health Organization (WHO) and International Council for the Control of Iodine Deficiency Disorders (ICCIDD) criteria (as outlined in Section 5.1.2.1).

4. Background Information

4.1 International Recommendations

Iodine deficiency is recognised as the single most important cause of preventable brain damage and mental retardation in the world. In more than 130 countries iodine deficiency has been identified as a significant public health problem, with 1.5 billion people, or nearly one-third of the world's population, living in areas at risk of iodine deficiency. In response to this, in 1993, the World Health Organization (WHO), in collaboration with UNICEF, the International Council for the Control of Iodine Deficiency Disorders (ICCIDD) and other international organisations recommended universal salt iodisation as the main strategy for the control of IDD.

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).

4.2 Regulation of iodine content of foods in Australia and New Zealand

Current provisions in Standard 2.10.2 - Salt and Salt Products of 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, subclause 10(3) of Standard 1.1.1 permits, *inter alia*, the use of iodised salt in mixed foods; this is discussed further in Section 5.6.3. 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.

Prior to the establishment of the Code, Australian food regulations permitted the voluntary addition to table salt of only 25-40 mg iodine/kg in the form of sodium or potassium iodates or iodides. New Zealand allowed the voluntary addition of iodide to all salt at a concentration of 40-80 mg iodide/kg.

4.3 International regulation of iodine in foods

4.3.1 Codex Alimentarius

The Codex Alimentarius does not mandate the addition of particular nutrients to certain 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 IDD 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* (Codex Alimentarius Commission 1991) provide that essential nutrients may be added to foods for the purposes of: restoration; nutritional equivalence of substitute foods; fortification; or ensuring the appropriate nutrient composition of a special purpose food.

4.3.2 Regulation of iodine fortification overseas

A number of countries, including Denmark and Canada, have introduced mandatory requirements for iodine fortification of foods in an effort to reduce the incidence of IDD. Voluntary fortification is also permitted for certain foods in a number of countries including The United States, Germany and The Netherlands.

Further information about international experience of iodine fortification (and the impact on iodine nutrition) is included in Section 5 and Attachment 2.

4.4 Nutritional aspects and implications

4.4.1 Iodine function

Iodine is an important trace element that is required for the synthesis of the thyroid hormones, thyroxine (T_4) and triiodothyronine (T_3). These hormones have a key role in influencing cellular metabolism and metabolic rate.

Greater than 97% of all iodine consumed is absorbed from the gastrointestinal tract, generally as iodide. 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 (TSH) from the pituitary gland and is highly sensitive to dietary iodine intake. At low intakes representative of iodine deficiency, uptake of iodide into the thyroid gland is increased whereas at very high intakes, iodide uptake into the thyroid gland decreases. Once the physiological requirements for thyroid hormone synthesis have been met, the thyroid gland does not accumulate more iodide and any excess is excreted, primarily in the urine. Although iodine is an essential component of the diet, intakes in excess of physiological requirements may result in adverse effects, particularly on the thyroid gland and the regulation of thyroid hormone production and secretion.

4.4.2 Recommended Dietary Intake

Recommended Dietary Intakes (RDIs) have been calculated based on the prevention of goitre, a clinical sign of iodine deficiency. Section 4.5.1 describes in more detail the range of effects on iodine deficiency. Goitre is usually observed in populations where iodine intake is less than about 50 μg/day and about 70 μg/day of iodine appears to be necessary to avoid signs of goitre in a population. The Australian RDI for adult males is 150 μg/day and for adult females is 120 μg/day based on an estimate of 1 μg/day/kg body weight for the prevention of goitre plus 100% as a margin of safety (Truswell et al 1990). In New Zealand, the Adequate Daily Intake (ADI) for adult New Zealanders is considered to be 200 μg/day (Department of Health 1991).
The recommendation for additional iodine intake by pregnant and breastfeeding females is 25 and 50 μg/day respectively. Currently both the Australian RDI and New Zealand ADI are under review.

Internationally, the dietary reference values for iodine for different population groups vary between 120 μg/day for Australian females to 200 μg/day for all adults in Germany and Austria. Table 1 provides a summary table of recommendations for dietary iodine intakes in western countries.

Table 1: Values for Recommended Daily Intakes of Iodine (μG/Day)

Age	Australia[1]	UK[2]	US/ Canada[3]	WHO[4]	Germany[5]	Austria[5]	Switzerland[5]
7-10 yrs	120 (8-11 yrs)	110	120 (9-13yrs)	120 (6-12 yrs)	140	140	120
Pregnant Women	150	140	220	200	230	230	200
Adults 15 yrs plus	120 females 150 males	140	150	150	180-200	180-200	150

[1] Truswell AS et al
[2] Department of Health (UK) 1991
[3] Institute of Medicine 2001.
[4] ICCIDD, UNICEF, WHO 2001
[5]German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society, Swiss Society for Nutrition Research. 2000

4.5 Iodine metabolism

4.5.1 Iodine deficiency

Iodine is required throughout pregnancy and into childhood and particularly in the first three months of gestation; infants born to severely deficient mothers are likely to suffer from cretinism, the world's largest category of preventable brain damage and retardation.

Goitre, the most visible sign of iodine deficiency, is an attempt by the thyroid to adapt and produce more thyroid hormones during iodine deficiency. When dietary intakes of iodine are low, thyroid hormone synthesis is reduced and secretion declines. This stimulates a feedback mechanism, resulting in increased secretion of TSH, which in turn promotes iodine uptake by the thyroid. If iodine intakes are low over a period of time the thyroid hypertrophies, resulting in iodine deficiency goitre (Gibson 1990). Endemic goitre is where the prevalence of goitre in the population exceeds 5%.
A diminished production of the thyroid hormones is referred to as *hypothyroidism* (and may be accompanied by goitre) whereas increased thyroid hormone synthesis and secretion 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* (IIH) if iodine exposure increases rapidly later in life..

Table 2 describes the spectrum of effects of IDD throughout the life cycle (WHO 2001).

Table 2: 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

Although the most severe effects of iodine deficiency on human development are observed at the foetal to infant period of life, less obvious iodine deficiency has been shown to detrimentally affect the mental performance of school children. The degree of health effect is related to the severity of the deficiency and the stage in life at which the deficiency occurs. 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 low intellectual quotients (IQ).

Mild iodine deficiency is an important risk factor for impaired psychomotor development in infants (Pop *et al* 1999, Haddow *et al* 1999). There is also evidence of intellectual impairment in children of mothers who had mild iodine deficiency in pregnancy (Utiger 1999).

Mild iodine deficiency over long periods of time can result in an autonomous or overactive thyroid that produces thyroid hormone in direct correlation with iodine intake regardless of the circulating thyroid hormone levels.

When a dietary intake of iodine increases in a person with an autonomous thyroid, the result will be IIH. Overactive thyroid nodules may be a result of multi-nodular goitre caused by prior iodine deficiency. The correction of mild iodine deficiency helps prevent the formation of autonomous thyroid and therefore minimises IIH but only for those that haven't already got autonomous thyroid (Hetzel and Clugston 1998).

4.5.2 Excess iodine intake

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 both the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and the US Agency for Toxic Substances and Disease Registry (ATSDR).

These studies indicate that the primary effect of excess iodine is on the thyroid gland and regulation of thyroid hormone production and secretion.

Like iodine deficiency, excess iodine can also result in the formation of a goitre and/or affect the production of the thyroid hormones.

The human response to excess iodine can be quite variable. Some individuals can tolerate relatively large intakes (up to 50 μg/kg/day) while others may respond adversely to levels close to recommended intakes (3-7 μg/kg/day). Individuals responding adversely to relatively low intakes 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 TSH concentration while serum thyroid hormone concentration is maintained within the normal range of values for healthy individuals. While not clinically adverse, such an effect, if persistent, could lead to clinical hypothyroidism. In healthy adults, such an effect has been associated with acute intakes of 1700 μg/day (24 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).

Iodine intakes of approximately 1000 μg/day however, appear to be well tolerated by healthy adults. This level has been used by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to establish a provisional maximum tolerable daily intake (PTDI) for iodine of 17 μg/kg body weight from all sources. Previously FSANZ has adopted this level as a safe upper intake when assessing iodine related applications.

4.5.3 Sensitive Individuals

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

The effect of high iodine intake on thyroid function is largely dependent on the health of the thyroid gland. High dietary intakes (1000 – 2000 μg/day) have little long term effect when the thyroid is healthy. The normal thyroid will stop producing thyroid hormone, due to a shutdown process called the Wolff-Chaikoff effect. Once the thyroid tissue adapts to the higher circulating levels of iodine, the production of thyroid hormone returns to normal.

In people with thyroiditis, frequently caused by Graves' or Hashimoto's disease, high intakes of iodine stop the production of thyroid hormones as a result of the Wolff-Chaikoff effect, but no adaptation takes place, resulting in hypothyroidism. Conversely, people with thyroid nodules that are 'autonomous' or 'overactive' produce thyroid hormones in direct correlation to iodine intake, as the nodules possess no feedback control mechanism. This results in IIH in people who are exposed to high iodine intakes. Symptoms of IIH include weight loss, weakness, apathy and cardiac problems.

Thus, people likely to respond adversely to increases in iodine intakes include those exposed to habitually low intakes of iodine, those sensitive to iodine and those with pre-existing abnormalities of the thyroid gland.

4.6 Dietary intake

4.6.1 Sources

Diet is the major source of iodine intake for humans. Food categories contributing to dietary intake in addition to iodised foods such as salt are: dairy products, seafood, fruits, vegetables, eggs, meat and cereals. The iodine content of food reflects background levels in the environment (e.g. soil), which means that vegetables, fruit and cereals grown in soils of low iodine content will be poor dietary sources of iodine. In addition, iodine and its compounds in food production, processing and manufacturing also contribute to dietary iodine intake. The iodine content of animal feeds can contribute to the iodine content of animal products (meat, milk, eggs, fish and poultry). Mineral supplementation (including iodine) is routinely added to pig and poultry feeds. Kelp and seaweed, which can contain high levels of iodine, are occasionally used in feeds given to cattle and sheep. In addition to food, iodine prophylaxis of animal products includes salt licks, drenches, fortified water and teat sprays.

Cooking procedures – time, temperature and nature of the food being cooked, will produce varying levels of iodine loss (Wang et al 1999 in Thomson et al 2004).

Milk has been an important source of dietary iodine due to its adventitious contamination by iodophors. Iodophors have been used since 1962 as sanitisers by the dairy industry in both Australia and New Zealand (Thomson 2002). Dairy products had been a major source of iodine in the New Zealand diet, but a move away from the use of iodophors has apparently resulted in lower iodine concentrations in dairy products (Thomson 2002). Iodine is still used in agricultural practice in some parts of Australia and milk is still considered an important source of iodine where these practices exist (Seal 2004).

Fortified bread improvers have also been used in Australia and have provided an additional source of iodine as iodates.

In addition to dietary sources, various mineral supplements and medical preparations can further increase iodine intake.

4.6.2 Dietary intake

The mean iodine intake based on National Nutrition Survey (NNS) data for both Australians (2 years of age and older) and New Zealanders (over 15 years of age) is, coincidentally, 94 μg/person/day. Estimates of dietary iodine intake suggest that, regardless of age and sex, the mean intake of both Australian and New Zealand populations are below their RDI or equivalent. Details of dietary intake relative to dietary indicators of inadequacy are given in Section 5.1.2.2.

There are a number of factors that require consideration in interpreting the dietary intake information. The iodine content of foods used to establish the estimated dietary iodine intakes were derived from a number of Australian and New Zealand food composition data sources including the 2003-4 New Zealand Total Diet Survey, as well as overseas data on the iodine content of food.

Another limitation is that NNS data for both countries are based on 24-hour dietary surveys, and these tend to over estimate habitual food consumption amounts for high consumers. In addition, household salt consumption was not measured in neither the Australian nor the New Zealand NNS and therefore household iodised salt consumption was not included in this estimation of iodine intake.

4.6.3 Use of iodine supplements

Current intake of iodine from dietary supplements is difficult to estimate. National nutrition surveys in both Australia and New Zealand collected qualitative information around supplement use, however there is no formal mechanism or survey that quantitatively measures supplement intake. Neither survey collected any information specific to iodine supplements. NNS data showed that about 5% and 19% of Australians and New Zealanders respectively reported using a *multi*-vitamin and mineral supplement at least once during the previous year, although no information was collected on the nutrient profile or content, including iodine content, of these supplements.

In February 2004, the NZFSA conducted a brief assessment of the types and numbers of iodine supplements available to the Wellington public, as well as the sources of iodine used in dietary supplements. Forty-seven iodine-containing dietary supplements from 19 different manufacturers were identified from four Wellington retail stores. With the exception of kelp supplements and supplements designed for "thyroid support", supplements that most commonly contained iodine were multi- vitamin and mineral supplements. The recommended daily consumption of all of the identified supplements ranged from the equivalent of 8.33 to 7900 μg iodine/day. The results of this survey should not be extrapolated to all available dietary supplements rather, viewed as a snapshot of dietary supplements available from a small number of retailers at a point in time.

4.7 Previous strategies for elimination of IDD in Australia and New Zealand

Historically, both Australia and New Zealand populations have had longstanding problems in maintaining iodine sufficiency. A variety of interventions have been undertaken to varying degrees of success. These interventions are described in the following section.

4.7.1 Salt fortification

Voluntary fortification of salt began in New Zealand in 1924 at 4 mg iodine/kg salt. In 1938, the level of iodisation was increased to 40-80 mg iodine/kg of salt. The introduction of iodised salt was accompanied by a public health advertising campaign promoting the benefits of using iodised salt. At that time, a greater proportion of salt intake was derived from household salt than in more recent times due to the greater reliance on home-prepared foods. Although non-iodised salt has always been available to consumers, goitre had virtually disappeared in New Zealand by the 1950s (Aitken 2001).

Iodised household salt has been available in Australia since the 1920s (Thomson 2001).

In recent times, there has been no active health promotion activity undertaken to improve the iodine status of New Zealanders and Australians.

However, notwithstanding the emphasis of the New Zealand Food and Nutrition Guidelines for Healthy Adults to reduce salt intake, the commentary in relation to salt use advises that iodised salt should be used when preparing food requiring salt.

4.7.2 Tasmania – supplementation

Levels of iodine in the Tasmanian soil are lower than in other parts of Australia, thus leaving the Tasmanian population at high risk of an inadequate intake. In 1949, the Tasmanian Health Department began to monitor goitre rates and urinary iodine excretion in school children. Evidence of poor iodine status resulted in a State-wide iodine supplementation program for the prevention of goitre in school children commencing in 1950.

Children were given one 10 mg potassium iodide tablet per week, however there were many administrative and practical problems with the supplementation program. The distribution of supplements varied widely within both districts and schools and tablets distributed for home consumption were often forgotten and thus the iodide deteriorated. Surveillance surveys also suggested that there was no correlation between regular tablet consumption and improvement in iodine status of this group with the result that goitre rates became unacceptably high in the 1960s. Due to the lack of improvement, the supplementation program was discontinued and a change to iodisation of bread was made.

4.7.3 Tasmania – fortification from iodised bread improvers

Potassium iodate was first used in 1966 as a bread improver until 1976 when it ceased due to the incidence of IIH.

5. Relevant Issues

5.1 Current fortification strategies and the iodine status of Australians and New Zealanders

There are several activities which are currently being implemented to increase the iodine status of the population. These activities have achieved varying degrees of success. Current activities are discussed below.

5.1.1 Current fortification strategies

5.1.1.1 Salt

Standard 2.10.2 – Salt and Salt Products of the Code permits the voluntary addition of iodine to all salt at a concentration of 25 - 65 mg iodine/kg. Such iodised salt is then permitted to be used in other foods providing those foods are appropriately labelled. The requirements in relation to the labelling of foods manufactured with iodised salt are further discussed in Section 5.6.3.

Dominion Salt is the company responsible for all salt iodisation in New Zealand. Their data from 2003 indicates that of the retail salt produced, 2000 tonne (57%) is iodised for the New Zealand retail/household market, in other words, 57% of household salt available for consumption in New Zealand is iodised.

It is estimated that 5-7% of salt used in commercial food production is iodised salt (although produced for retail sale), however the majority of the products are produced for overseas markets. It is also estimated that 15-18% of all salt for human consumption in New Zealand is iodised. These figures are broad estimates as the proportion of salt-containing food products exported is unknown[3].

In Australia, only 1% of all salt produced is used in food for humans and animals. Between 10-12% of salt used in foods is retail salt and about 1300 tonne (15%) of that retail salt is iodised. In July 2004 0.5% of commercial salt sold was iodised[4].

Comparison of iodised salt manufactured in the two countries suggests that iodised salt has a far higher market share in New Zealand than in Australia.

5.1.1.2 Bread fortification – Tasmania

As a result of an observed decrease in iodine status in Tasmania in 2001, the Tasmanian Department of Health and Human Services (TDHHS) established a Memorandum of Understanding (MoU) with bakeries for the use of iodised salt in bread making. Details of the fortification program in Tasmania are given at Attachment 4.

Initially, several food vehicles for fortification were considered, however, bread was decided as the most appropriate because it was supported by both bread and salt industries and did not require any legislative change. Bread is widely consumed and produced locally. Bakeries responsible for 80% of the bread manufactured in Tasmania signed the MoU and began to use salt specially iodised for this purpose at a level of 40 mg iodine/kg.

A monitoring program was established to assess the iodine content of bread, the iodine status in the Tasmanian population and to determine any negative effects of the fortification program. The impact of this strategy is described in Section 5.1.2.2.

5.1.1.3 Summary

The current regulations for the use of iodised salt are broad and place no restriction on the use of iodised salt in manufactured foods providing the product is appropriately labelled. To date, the Tasmanian bread industry is alone in taking advantage of the current regulatory arrangements and using salt fortified with iodine in the manufacturing process. However, this action was the direct result of the MoU established between the TDHHS and bakeries in response to a decline in the iodine status of Tasmanians.

Question:

Are there other foods manufactured either locally or imported that contain iodised salt?

[3] Information as provided by Dominion Salt to JAGI in 2003 and FSANZ in 2000
[4] Information as provided by Cheetham Salt to FSANZ 2004

5.1.2 Current iodine status

5.1.2.1 International Council for the Control of Iodine Deficiency Disorders and World Health Organization recommendations

The ICCIDD and the WHO have determined criteria for assessing population iodine status based on median urinary iodine concentrations. Many researchers have chosen to use these criteria in assessing their study population. Table 3 lists the criteria for assessing iodine nutrition the population. Urinary iodine measures are more indicative of population iodine status than measures of dietary iodine intake. The WHO ICCIDD recommend cross sectional surveys of a target population for iodine status assessment. Target populations being either school-aged children or women of child bearing age.

Table 3: Epidemiological Criteria for Assessing Iodine Nutrition, based on Median Urinary Iodine Concentrations in School-Aged Children (Iccidd)

Median urinary iodine (μg/L)	Iodine intake	Iodine nutrition
< 20	Insufficient	Severe iodine deficiency
20 – 49	Insufficient	Moderate iodine deficiency
50 – 99	Insufficient	Mild iodine deficiency
100 – 199	Adequate	Optimal

Daily urinary iodine excretion closely reflects iodine intake (Gibson 1990), and corresponds to 85-90% of the amount of iodine consumed per day.
Urinary iodine from representative populations can provide an indication of the severity of iodine deficiency in a region (Lamberg 2003). The ICCIDD suggest that, in adults, a urinary iodine concentration of 100 μg/L corresponds approximately to a daily iodine intake of about 150 μg under steady state conditions (ICCIDD 2001). Both the WHO and the ICCIDD suggest that no more than 20% of a population should have a urinary iodine levels less than 50 μg/L, and that a median urinary iodine concentration of 100 μg/L or greater is indicative of iodine sufficiency (ICCIDD 2001).

5.1.2.2 Current iodine status of the Australian and New Zealand populations

It was reported in the early 1990s that there was no evidence of iodine deficiency anywhere in Australia (Stanbury et al 1996). In more recent years however, a downward trend in iodine status has been noted in both Australian and New Zealand populations (Thomson 2002).

Studies indicate that iodine deficiency exists to various extents in both Australian and New Zealand population groups. A Sydney hospital study (n=263) showed moderate iodine deficiency in 19-34% of the four groups studied and mild iodine deficiency of an additional 30-47% (Gunton 1999). Another Sydney study (n=unknown) found 16% of primary school children from the western suburbs had urinary iodine levels less than 100 μg/L (Eastman 1999, editorial). In 2001 a sample of 607 Melbourne private school children 11-18 years showed only 24% had urinary iodine levels greater than 100 μg/L and 27% of those studied had urinary iodine levels consistent with a moderately severe deficiency state (McDonnell 2003).

In New Zealand, studies of 282 children aged 8-10 years of age (Skeaff 2002) and 233 adults 18-49 years of age (Thomson 2001) showed mean urinary iodine levels of 66 and 59 μg/L respectively. Attachment 3 provides a summary of the results of these studies.

In Australia, no national surveys have been undertaken to assess the iodine status of Australians, although national data collection in a National Iodine Nutrition Study (NINS) is currently in progress with results expected in early 2005. It is anticipated that the results from this survey will be available for consideration at Draft Assessment stage of this Proposal.

New Zealand has regularly monitored national iodine status due to the low iodine content of its soils with the most recent results available from the National Children's Nutrition Survey. These results show a median urinary iodine concentration of 66 μg/L with 28% of the study population having a urinary iodine concentration of less than 50 μg/L. According to the WHO criteria these results indicate that the population could be classified as iodine deficient. Routine monitoring of iodine status also occurs in Tasmania as discussed in Section 5.1 and Attachment 4.

Results of a random survey of Tasmanian school children aged 4 -14 years prior to the fortification program (2000-2001) showed that 21% had urinary iodine levels below 50 μg/L. In 2004, the proportion of children with urinary iodine levels below 50 μg/L had fallen to 10.9% suggesting an improvement in iodine status to sufficiency according to the WHO criteria (Seal 2004).
The monitoring results to date suggest that Tasmania's iodine fortification program is helping to increase the iodine status of its population.

Population intake of iodine compared to Estimated Average Requirements (EAR)

The dietary reference value EAR is defined as the level below which 50% of the population may be at risk of having inadequate dietary intake; this reference is used to estimate the prevalence of inadequate intakes in a population. National food consumption data have been utilised to determine the percentage of Australian and New Zealand populations not meeting the EAR for iodine intake (baseline intake data). Dietary reference values for Australia and New Zealand are currently under review and hence the US EAR[5] has been used in the interim. The food consumption data used in the dietary iodine intake assessment were as measured in the 1995 Australian National Nutrition Survey and the 1997 New Zealand National Nutrition Survey. Such data reflect the food consumption patterns prevailing at those times as well as being prior to the bread fortification program in Tasmania. Table 4 illustrates these results.

[5] Note that the calculation of a RDI from the US EAR data will result in a higher RDI than is currently endorsed in both Australia and New Zealand.

Table 4: Estimated Percentage of Respondents for Australian and New Zealand Population Groups Consuming Less than the US EAR For Iodine

Country	Population group	US EAR µg/day	Percentage of Respondents with Dietary Intakes of Iodine < US EAR (%)
Australia	2-3 years	65	43
	4-8 years	65	41
	9-13 years	80	45
	14-18 years	100	52
	19 years and above	100	65
New Zealand	15-18 years	100	64
	19 years and above	100	65

Although the data are limited (as discussed in Section 4.6.2), the figures in Table 3 support the conclusions from the research on more direct measures of iodine status summarised in Attachment 3 that a considerable proportion of Australians and New Zealanders are mildly iodine deficient.

5.1.2.3 Summary

The current regulatory arrangements do not restrict addition of permitted forms of iodine to all salt nor the use of iodised salt in manufactured foods however there is generally a low level of industry uptake.

There is mounting evidence that both the Australian and New Zealand populations can be classified as mildly iodine deficient as evidenced by comparison of results of iodine status studies to the WHO/ ICCIDD population criteria. With the exception of Tasmania, the current level of iodine available from the food supply in both countries has not been effective in maintaining optimal iodine status of the Australian and New Zealand populations.

Question:

Are there other data available that supports or does not support the evidence of inadequate iodine intake in Australians and New Zealanders?

5.2 Possible future strategies other than food fortification to enhance the iodine status of Australians and New Zealanders

The Ministerial Council Policy Guideline *Fortification of Food with Vitamins and Minerals* states that before a decision in relation to mandatory fortification is made that:

- consideration must be comprehensive and include, for example, assessment of voluntary fortification and education programs;

- be assessed as the most effective public health strategy to address the health problem; and
- be consistent as far as possible with the national nutrition polices and guidelines of Australia and New Zealand.

Two alternate strategies to fortification for increasing the iodine status of Australians and New Zealanders are public health promotion and supplementation strategies.

Question:

What programs or activities to reduce salt consumption are currently being undertaken in Australia and New Zealand?

5.2.1 Public health promotion

Regardless of the quality of an individual's diet, the current food supply generally provides insufficient available iodine to sustain an adequate intake of iodine, unless iodised salt is a dietary component. Iodised salt still remains the one food with a consistent concentration of iodine (i.e. 25-65 mg/kg) and is the only food with potential to be promoted as a confidently known source of iodine. Milk has varying amounts of iodine depending on the agricultural practices of the farm from which the milk is sourced. Fish is also considered a good natural source of iodine but is possibly not eaten regularly enough or in amounts sufficient to combat compromised iodine status. Furthermore, strategies to increase the discretionary use of iodised salt would be contrary to public health and nutrition guidelines in both Australia and New Zealand, which state respectively:

- 'choose food low in salt'. This general recommendation for Australian adults is that dietary sodium intake be under 2300 mg (100 mmol) per day (NHMRC 2003).
- 'prepare foods or choose prepared foods, drinks and snacks that are low in salt; if using salt, use iodised salt' (Ministry of Health 2003).

Question:

Would advice to consumers to choose a diet naturally rich in iodine be likely to achieve replete iodine status of Australian and New Zealand populations?

5.2.2 Supplementation

Supplementation is an alternative strategy to fortification, and although the most important members of the population to reach are children and pregnant and lactating women due to adverse effects of IDD on growing children and the developing foetus, the entire population and other subgroups also require consideration for iodine prophylaxis. Previous experience in Tasmania has illustrated that supplementation of school children proved difficult and ineffective in the elimination of IDD. This suggests that broader supplementation of entire populations would not be the most effective method of controlling IDD in Australia and New Zealand. Nevertheless, there may be merit in promoting the use of one of the available multi-vitamin and mineral supplements that contain iodine to particular subgroups of the population that may be at most risk.

Question:

Are medical practitioners currently advocating the use of iodine supplements to any parts of the population?

5.2.3 Agricultural Practices

Universal salt fortification is defined as the fortification of salt for both human and animal consumption, and includes fortification of salt used in feeds for animals. Iodine fortified animal feeds can increase the iodine intake of humans by increasing the iodine content of meat, fish, eggs and poultry.

The iodine content of supplemental feeds varies with seasons in response to the use of silage and grains with added vitamins and minerals. This seasonal variation in feeding is reflected in the iodine content of milk. Other vehicles for iodine consumption by animals in addition to feeds are salt licks and drenches. Drinking water for dairy herds can also be dosed with iodine to assist with animal reproduction.

Milk and dairy products, through the adventitious contamination from iodophors as well as other agricultural practices, have been an important source of dietary iodine for both the Australian and New Zealand population over several decades. Other cleaning compounds have recently replaced the use of iodophors. Several reasons have been given for this: cost, effectiveness compared to other cleaning/sanitising agents and effect on the shelf life of liquid milk.

In the UK, cows' milk is the major contributor to dietary iodine intake among consumers. Concentrations of iodine in milk in the UK are influenced by animal feeds. The iodine may be naturally present in the feeds or added via supplements to protect animal health in addition to providing a source of iodine in human diets. The supplementation of animal feed in the UK is controlled by legislation with a maximum permitted level of 10 mg iodine/kg of feed for dairy cattle.

In Germany, iodised salt for livestock is voluntary. Fortification of cattle feed began in Norway in the 1950s at a concentration controlled by legislation as part of a whole of food supply approach to correcting iodine deficiency. Under this approach there is careful apportioning of iodine to various delivery vehicles. Norway permits iodisation of 2 mg iodine/kg in animal feed, relatively low levels of 5 μg iodine/kg in table salt and does not permit the use of iodised salt in processed foods. Iodophors are not used for sanitation or disinfection (Dahl et al 2003).

As soil levels of iodine are low in parts of Australia and in New Zealand, the question has been raised as to the possibility of adding iodine to fertiliser as a method of getting it into the food chain. Fertilisers containing iodine are available to farmers in New Zealand, however they are not often used unless livestock are deficient. With Australia and New Zealand's decentralised approach to farming, the amount of regulatory control of use of iodine containing fertilisers, feeds and/or animal health products required to minimise the risk and effects of excess iodine consumption would be significant.

Questions:

To what extent are iodine-containing products intended for agricultural or animal health purposes (and that would ultimately result in increased iodine content of human food) used?

To what extent are iodine sanitisers (iodophors and teat dips) used in milk production? and how has this changed over time? What use is likely in the future?

5.2.4 Summary

A supplementation strategy of school children did not prove to be effective in increasing the iodine status of the Tasmanian population in past years. It is unclear whether promotion of natural dietary sources of iodine alone could result in sustainable and adequate iodine population intakes.

The iodine content of foods reflects the environment and iodine can enter the food supply via agricultural produce grown in iodine-rich soil or by animals given iodine feeds. Although agricultural practice has been used as a vehicle for increasing humans' dietary consumption of iodine, the amount of control required in order to minimise the risk and effects of excess iodine consumption is significant.

The addition of more iodine to the food supply has been a commonly promoted and adopted solution to address inadequate iodine status of populations overseas. The following sections discuss the issues associated with the possible further iodine fortification of food.

5.3 Potential vehicles to enhance the iodine status of Australians and New Zealanders

The following discussion relates to the selection of appropriate food vehicle(s) that, through increased iodine content, would improve the iodine status of the population. A food vehicle is the final iodine-containing food that is consumed. Fortification means either the direct addition of a fortificant, in this case, iodine in the permitted chemical form of iodide or iodate, or use of an ingredient so fortified in another food. Some examples of fortified food vehicles with iodine are: iodised household salt, or bread that contains either an iodised ingredient such as salt or bread made from dough to which an iodine fortificant has been directly added.

The selection of appropriate food vehicle(s) for fortification is an important consideration. A number of organisations (Codex Alimentarius Commission 1991; Darnton-Hill 1998; Nutrivit 2000) have published criteria for selecting appropriate food vehicle(s), including 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);
- be available to the target population regardless of socio-economic status;
- supply optimal amounts of micronutrient without risk of excessive consumption or toxic effects;

- 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/fortified ingredient or undergo changes to taste, colour or appearance as a result of fortification.

Another important consideration is to determine the appropriate quantity of fortificant that should be added to the food ingredient or food vehicle(s), in order to deliver an effective public health outcome.

FSANZ will further investigate possible food vehicle(s) and/or food ingredients that could be subject to fortification at appropriate levels at Draft Assessment. Consideration will also be given to the practical impacts of fortification in terms of manufacturing processes, for example:

- the purchase and storage of the permitted form of the fortificant or fortified ingredient(s);
- adjustment to processing and manufacturing practices to ensure the successful addition of the fortificant or fortified ingredient(s) to a product;
- analytical testing to confirm the appropriate levels of iodine in a product; and
- modification to labels to reflect the modified composition of the food.

5.3.1 Salt Iodisation

WHO and UNICEF selected salt as their recommended food vehicle because it is widely available, is consumed in regular amounts throughout the year, and the costs of iodising salt are extremely low (WHO/UNICEF/ICCIDD 1994). These organisations state that iodine concentration in salt at the point of production should be within the range of 20-40 mg iodine/kg in order to provide 150 μg iodine/person/day. The iodine should be added as potassium (or sodium) iodate. Under these circumstances median population urinary iodine levels are predicted to vary from 100–200 μg/L (WHO/UNICEF/ICCIDD 2001).

Due to international recommendations, FSANZ will consider iodised salt, either for household use and/or as an ingredient in commercial food manufacture, as a vehicle for passive delivery of increased amounts of iodine to the populations.

5.3.1.1 Salt Consumption

New Zealand

As 24-hour urine collections are not generally undertaken as part of the NNS, New Zealand data on sodium intake have been estimated from results of several smaller surveys. It is estimated that the daily sodium intake of New Zealanders is approximately 150 mmol/day. This equates to a daily salt intake of 9 g, which is considerably higher than the recommended intake of 40-100 mmol/day (2.5-5.9 g) (Ministry of Health 2003[1]).

Approximately 75% of dietary sodium intake comes from salt added to food during manufacturing and processing. Fifteen percent of dietary sodium intake derives from the use of household salt. The remaining 10% is from sodium naturally present in foods (Ministry of Health 2003[1]).

Results from the National Children's Nutrition Survey show that approximately half (51.7%) of New Zealand children never add salt to their meals at the table and 32% of New Zealand children never have salt added to their meal during preparation.

Australia

The Australian NNS did not collect information on salt consumption.

Two small surveys with systematic samples showed similar findings with men having an average urinary sodium excretion of 170 and 190 mmol/day and women averaging 118 and 140 mmol/day (Riley and Beard 2003). These outputs equate to salt intakes of about 10 g/day in men and 9 g/day in women.

5.3.1.2 Salt as a vehicle for iodine

Identified advantages are:

- salt, be it household or in processed foods, is widely consumed across the population in varying amounts;
- a few suppliers are responsible for the majority of salt manufacture in New Zealand and Australia;
- addition of iodised salt to foods is currently not restricted in the Code;
- addition of iodine to all salt-containing food via iodised salt would mean that public health campaigns would not be required to promote consumption of a particular food; and
- compared to iodising only household salt, iodising all salt (including that used in food processing) has the advantage of supplying a more consistent amount of additional iodine when consumers limit their discretionary salt intake.

Whereas disadvantages are:

- where there is a high variability of household salt use and of consumption of salt-containing processed foods among individuals, thus reducing the validity of current approaches to dietary scenario modelling;
- the use of iodised salt in processed foods may restrict trade where compatible regulations do not exist in other countries;
- there is the potential for a significant increase in the incidence of IIH if all salt is iodised and depending on the level of iodine fortification;

- labelling of foods containing iodised salt would need to be changed to reflect the inclusion of iodised salt; and

- there are limited data on salt intake in children from which to estimate prospective iodine intake.

- studies conducted in China have shown that the iodine content of iodised salt can decrease continuously throughout the whole manufacturing process, from the salt plant to the consumer, due to manufacturing methods, packaging materials and storage time (Chen and Wu 1998).
  If these losses also reflect those found under Australian and New Zealand conditions, or are highly variable or unpredictable, there amounts of iodine consumed from iodised salt could not be as accurately predicted;

Questions:

If salt were selected as an appropriate vehicle for fortification, FSANZ would need to consider the following issues and so seeks further input to help guide future decision-making:

What is the total intake of salt in the most vulnerable subgroups i.e. pregnant woman, infants and children?

Does the variability in salt consumption, and current strategy of promotion of reduced salt intakes render iodised salt an appropriate choice to ensure consistently adequate population iodine intakes?

Are there any groups of the population for whom an increase in iodine consumption would be especially harmful?

5.3.2 Fortification of other basic ingredients

There are other basic food ingredients that can be fortified with iodine including sugar, oil, milk and flour. Although listed as possible fortified ingredients in processed foods by the FAO, FSANZ is unaware of any country that has implemented a fortification program using iodine-fortified versions of these ingredients.

Questions:

What would be the effect of adding currently permitted forms of iodine on the shelf-life and taste of sugar, oil, milk and flour?

Are there any other basic ingredients that could be used as a fortification vehicle for iodine?

Are there any countries currently implementing a fortification program using iodised forms of sugar, oil, milk or flour as a fortified ingredient?

5.3.3 Fortification of other foods through the use of iodised salt

An alternative to fortifying all salt for human consumption would be to fortify all household salt only or the salt produced for use in one or more food commodities such as bread. As illustrated in Table 5, iodised salt is currently used in bread making in The Netherlands, Denmark, Germany, and Tasmania. The Netherlands permit the voluntary use of iodised salt in bread and pasta products whereas in Denmark the use of iodised salt is mandatory in the production of bread and cakes as well as for household salt. Attachment 2 gives a detailed description of international fortification programs, and Attachment 4 details the decision to fortify bread in Tasmania and the results and implications of that decision.

Table 5: Summary of Countries where Iodised Salt may be added to Baked Goods

Country	Bread/Pasta/ Cakes/Baked Products	Level of iodisation (mg iodine/kg)	Type of iodine fortificant used	Other sources of iodine in the diet	Mandatory vs. Voluntary Fortification	Iodine sufficiency
The Netherlands	Iodised salt is used in bread and pasta products	42-50	Potassium iodide	Iodised household salt is permitted	Voluntary	Sufficient
Denmark	Iodised salt is used in bread and cakes	13	Potassium iodide	Iodised household salt	Mandatory	Sufficient
Germany	Iodised salt use permitted by food industry (80% of bakers use iodised salt)	20	Potassium iodate	Iodised salt for household, food industry use and livestock feed permitted	Voluntary	Sufficient

5.3.3.1 Bread Consumption

Bread is a widely consumed commodity in both New Zealand and Australia. Only 5% of New Zealand adults (4% males, 6% females) consume less than one serving of bread per day (Ministry of Health 1999) however 29% of New Zealand children reported eating bread less than once per day (Ministry of Health 2003).

Data from the Australian NNS food frequency questionnaire, indicated that 15% of people surveyed never ate (or consumed less than once a month) white bread, toast and rolls, and 22.5% of people surveyed never ate (or consumed less than once a month) wholemeal/grain bread, toast and rolls. There was no data on the percentage of the population who did not eat bread at all.

5.3.3.2 Technical feasibility of using iodised salt in bread manufacture

The TDHHS chose bread baked with iodised salt as the most appropriate vehicle to supplement the Tasmanian population for the following reasons (Department of Health and Human Services 2004):

- bread is a nutritious food widely consumed in the Tasmanian community;
- a large proportion of bread consumed in Tasmania is locally produced;
- using only iodised salt in bread manufacture is simple, safe, effective and inexpensive;
- substitution of iodised salt in lieu of non-iodized salt does not require an amendment to the Code;
- bread in Tasmania has previously carried higher levels of iodine due to supplementation of iodate in the bread improver; and
- it has high consumer acceptability.

Dr John Burgess (Endocrinologist, Royal Hobart Hospital) conducted a trial in order to evaluate the efficacy and safety of the then proposed Tasmanian interim iodisation program. The trial indicated that the addition of iodised salt (40 mg iodine/kg salt) to bread is an effective means of increasing dietary iodine intake (Seal 2004). Furthermore, there were no adverse events reported in relation to the consumption of the bread baked with iodised salt during the trial. The baker who baked the bread reported no problems with the baking process, that is, the iodised salt did not have an effect upon the taste, texture or quality of the product (Seal 2004).

Kuhajek and Fiedelman (1973) evaluated the effects of iodine from potassium iodate and potassium iodide added to salt at a concentration of 77 mg iodine/kg salt, on processing characteristics and quality of white bread. The stability of iodine during processing and storage was also assessed. No flavour or processing abnormalities were found and iodine retention was 50 to 80% throughout processing and throughout storage for 10 days in a freezer (Kuhajek and Fiedelman 1973).

Research in Tasmania has shown that an even distribution of iodine throughout the crust and inner portion of a loaf of bread is feasible (Seal 2004).

5.3.3.3 Bread as a vehicle for iodine

Identified advantages are:

- consumption of bread is widespread in the Australian and New Zealand population;
- fortification of bread or bread and baked goods, has proven to be an effective way in ensuring iodine sufficiency overseas and locally;
- bread (with the exception perhaps of some premixes) is made locally and not imported, therefore, it would be reasonably free of trade issues sometimes associated with a fortification program; and
- bread is widely consumed by a large proportion of the population. However, iodisation of bread through the use of iodised salt would need to include breads for special dietary purposes in order to ensure that those with wheat allergies and people with coeliac disease who must avoid all gluten-containing foods including most breads would not be disadvantaged.

Identified disadvantages are:

- the use of iodised salt in bread making would disadvantage people for whom bread is not a staple. Alternative dietary advice would be required for these people;
- the use of iodised salt in bread would necessitate labelling changes to the ingredient list;
- the amount of salt added to bread differs depending on the brand and type of bread and the method of production. Salt free bread is available; and
- some people do not buy, or consume bread at all.

Questions

Are there any other advantages or disadvantages of the fortification of bread through the use of iodised salt?

Are there any other food commodities for which the use of iodised salt would be suitable in order to increase iodine intake across the general population?

5.4 Risks in the rapid increase in iodine consumption

As discussed in Section 4.4, rapidly increasing the iodine intake of populations with characteristically low iodine intakes can result in IIH. This was well-documented in Tasmania, where between 1960 and 1966, two or three sources contributing to iodine intake unintentionally increased simultaneously and an on-going register displayed an increase in the incidence rate of overt IIH (Richards 1995).

IIH is considered a possible side effect of iodine supplementation and has been reported in almost all iodine supplementation programs (Garcia-Mayor et al 1999). The risk of IIH, however, should be weighed against the many benefits that iodine sufficiency has on the whole population, particularly in women and children. The increase in IIH is frequently transitory and within 5-10 years following the introduction of an iodine fortification program, a new steady state in the occurrence of thyroid disease is reached (ICCIDD, UNICEF, WHO 2001).

In areas where iodine intakes have been low for many years, it is recommended that intakes above 300 μg iodine/day be discouraged in order to reduce the incidence of IIH. Switzerland adopted an incremental strategy for iodine fortification in order to reduce the effect of the fortification program on rates of IIH. In 1922 all salt was permitted the voluntary addition of iodine at the low level of 1.9-3.75 mg iodine/kg. 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) (Delange et al 2002).

Question:

Would a mandatory fortification program mean that iodine intake could be more closely controlled and the increments increased at the level required to assure iodine sufficiency at the same time minimising the risk of IIH more successfully than in a voluntary fortification program?

5.5 Monitoring

The Ministerial Council Policy Guideline also states that any iodine fortification program should be accompanied by a monitoring system. A monitoring program should cover three areas:

- monitoring of iodine status of the population;
- monitoring of the iodine content of targeted foods, and industry and manufacturer compliance where this is relevant; and

- monitoring of adverse effects of increased iodine intake such as IIH.

The occurrence of IIH with fortification programs in areas where dietary iodine intake has been low for many years is expected. To help reduce this, a fortification program that commences with a low amount of fortified iodine and is gradually increased as and if necessary is an option. Monitoring will be particularly important if the preferred option is one that is incremental to ensure that each increase in available dietary iodine occurs at the appropriate time.

An incremental increase in iodine in the food supply would be most effective with mandatory fortification due to the amount of control over fortification of designated foods.

Monitoring of iodine status has been discussed in the context of the Tasmanian Iodine Supplementation Program in Attachment 4. Monitoring will also be discussed in further detail once a preferred regulatory option is identified at Draft Assessment. If a regulatory option of mandating iodine fortification is chosen, FSANZ can take responsibility for monitoring food industry response and food composition. However the monitoring of iodine status and public health impact of the fortification is more appropriately undertaken by other authorities.

Questions:

Who should be responsible for routine monitoring of iodine status?

Who should be responsible for the routine monitoring of adverse outcomes such as IIH incidence?

5.6 Other FSANZ Work Plan items and issues that may impact on this Proposal

5.6.1 Application A493 Iodine as a processing aid

FSANZ is currently processing Application A493 - Iodine as a Processing Aid. The Application discusses an amendment to the Code to permit the use of iodine as a washing agent for fruit, vegetables, nuts and eggs at good manufacturing practice levels. A range of issues was considered during draft assessment, including the technological justification for the use of iodine and the potential impact on public health and safety.

The risk assessment indicates that the use of iodine as proposed may result in a small increase in iodine intake but not to a level that would raise safety concerns for the vast majority of the population or pose any adverse nutritional risks. The potential for the safe intake level for iodine to be exceeded is low and any observed increase in iodine intake is unlikely to cause imbalances with other nutrients. In the case of vulnerable individuals, the proposed use of iodine is considered unlikely to pose any additional risks.

Application A493 Final Assessment Report is likely to be complete before the Draft Assessment Report for this Proposal, and its outcome and actual industry response will be considered in the dietary modelling of any potential fortification strategy.

5.6.2 Application A528 Maximum Iodine Limit in Formulated Supplementary Foods for Young Children

Application A528 – Maximum Iodine Limit in Formulated Supplementary Foods for Young Children is concerned with a request to amend Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods of the Code to increase the maximum permitted quantity of iodine from 35 to 70 μg/serving in formulated supplementary foods for young children (FSFYC). The basis for the request was the natural variation of iodine in dried milk solids, the base ingredient for many FSFYC, not as a request for permission to add additional iodine to products.

Application A528 is likely to reach Final Assessment stage before the Draft Assessment for this Proposal, and thus any resultant change in the Code will be considered in the processing of this Proposal.

5.6.3 Addition of 'other foods' to food

Clause 10(3) of Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Provisions, deals with the 'addition of other foods' to foods. Clause 10(3) provides, 'In cases where no specific foods are authorised for addition in a standard, any other food or anything that may be lawfully added to the food may be added'. This means that for example, iodised salt can be added to food more generally provided that the resulting product is correctly described.

Depending on the preferred regulatory option, this Proposal may necessitate a change in some commodity standards that permit salt but not iodised salt, or result in the permission for the addition of iodised salt to be confined to particular foods.

6. Regulatory Options

In order to determine the most effective mechanism to improve the iodine status of Australian and New Zealand populations, FSANZ is considering the following four regulatory options:

1. Maintenance of the *status quo*;
2. Extension of permissions for voluntary iodine fortification;
3. Promotion of voluntary options to increase industry uptake; and
4. Mandatory iodine fortification

6.1 Options

6.1.1 Option 1 - Maintenance of the status quo

Maintenance of the *status quo* would see the continuation of the existing permissions for the voluntary addition of iodine to certain foods, the main food category being salt.

6.1.2 Option 2 - Extension of permissions for voluntary iodine fortification.

This would allow industry to voluntarily add iodine (in the forms of potassium or sodium iodide or iodate) to an increased number of food categories and/or to add iodised salt to food commodity Standards, such as cheese, that currently only allow the addition of iodised salt if the word iodine is a part of the product name.

The additional food categories selected would be based on their ability to effectively deliver and sustain an increase in the iodine status of the target population. The effectiveness of this option for increasing and sustaining the iodine content of the food supply will ultimately depend on industry participation.

6.1.3 Option 3 - Promotion of voluntary options to increase industry uptake.

Currently there is no regulatory impediment for increasing the amount of iodine in the food supply. Industry, however, have not actively taken the opportunity to increase the extent of voluntary addition of iodised salt to manufactured foods. Initiatives, such as a Code of Practice or a MoU, could be developed with industry to promote an increased uptake. These initiatives could be used in conjunction with Option 1 - Maintenance of the *status quo* or with Option 2 - Extension of permissions for voluntary iodine fortification.

The main feature of Option 3 is that permissions for the addition of iodine to certain foods would remain voluntary but a greater level of commitment would be given by industry to increasing and sustaining the iodine content of the food supply.

6.1.4 Option 4 - Mandatory iodine fortification.

Option 4 would require the mandatory addition of iodine to a prescribed food vehicle(s). The prescribed food vehicle(s) would be selected on the basis of its ability to effectively deliver and sustain an increase in the iodine status of the population. The vehicle selected could either be a specific food category such as bread or an ingredient that is added to many foods, for example salt, sugar or oil.

6.2 Other options for increasing iodine status

Non-regulatory options, such as health promotion campaigns (section 5.2.1), supplementation (section 5.2.2) and agricultural practices (section 5.2.3) are not likely to be considered possible strategies for increasing the iodine status of the population in this Proposal, as evidence to date, show they have not delivered the desired public health outcomes. Reasons for this include:

- contradictory public health messages in relation to eating salt;
- difficulties in supplementing the entire population due to cost and resource constraints, compliance issues and public acceptance;
- changes in agricultural practices are difficult to implement, monitor and enforce; and
- large variations in the amount of iodine generated make it difficult to guarantee an effective measured quantity of iodine in the food supply.

Question:

Is a program that promotes the supplementation to at-risk populations a potential solution to increasing the iodine status of the population?

7. Impact Analysis

7.1 Affected Parties

The parties most likely to be affected by this Proposal are:

- **consumers and the community,** particularly the foetus, neonate, young children, preadolescents and women of child-bearing age, as well as the general population;

- **industry,** including manufacturers who currently have permissions to voluntarily fortify their product(s) with iodine, manufacturers who wish to obtain further permissions to voluntarily fortify their product(s) with iodine, manufacturers of potential food vehicles eligible for mandatory fortification, importers and exporters; and

- the **Governments** of Australia and New Zealand, including State and Territory Governments who are responsible for monitoring, enforcement and education.

7.2 Impact Analysis

7.2.1 Option 1 - Maintenance of the Status Quo

7.2.1.1 Impacts on consumers and the community

Under this option there is no assurance to the community that there is sufficient iodine in the food supply to guarantee iodine sufficiency. It is likely the population would continue consuming diets with inadequate amounts of iodine and that widespread mild iodine deficiency would persist. The possibility of deficits in visual motor skills, hearing and intelligence would remain, representing a significant threat to the wellbeing and productivity to the community.

The magnitude and extent of this risk will be more evident once definitive data is available on the prevalence of iodine deficiency in the community. While the social and economic consequences of iodine deficiency are difficult to quantify, they are obviously considerable.

There is also an additional economic cost to the community resulting from iodine deficiency due to the decreased production of milk, eggs, meat and wool (Reardon 2002) but this impact falls outside FSANZ's regulatory responsibilities.

With voluntary fortification, there is a risk that permissions will not be taken up by industry and so the community will remain iodine deficient. Alternatively, if industry actively takes up all the voluntary permissions, for example, iodised salt is added to all manufactured foods, there is a risk that the rapid increase in iodine status could potentially increase the incidence of IIH in the population.

This risk of IIH can be minimised by adopting an incremental strategy for increasing the amount of iodine in the food supply and ensuring the additional iodine is added in a controlled manner and monitored carefully.
With voluntary fortification, however, it is much harder to guarantee and sustain the amount of additional iodine in the food supply, making it harder to adopt a successful incremental approach for adding additional iodine to the food supply.

7.2.1.2 Impacts on industry

Overall, this option would have minimal impact on industry. Currently all salt is permitted to be iodised, however industry information has revealed that currently only household salt is fortified with iodine.

Questions:

Is it likely that manufacturers would replace non-iodised salt with iodised salt in their products?

Is this technologically feasible?

What are the barriers to using iodised salt in manufactured foods including labelling requirements?

7.2.1.3 Impacts on governments

Due to the widespread incidence of iodine deficiency in the Australian and New Zealand populations, governments would continue to be exposed to health and education costs associated with IDD. It is difficult, however, to quantify the precise medical costs associated with a possible reduction in cognitive capacity, hearing ability and impaired psychomotor developments and the increased educational costs due to poor school performance.

Governments would need to continually monitor the food supply and assess the iodine status of the population.

7.2.2 Option 2 - Extension of permissions for voluntary iodine fortification

7.2.2.1 Impacts on consumers and the community

Extending permissions for voluntary fortification to new food categories could potentially increase the iodine status of the population. However, this would only occur if industry takes up these new permissions and increases the number of fortified foods available. In order to deliver a significant public health benefit, there would need to be considerable uptake by industry.

Permissions could be given to single ingredient foods, such as oil or sugar, which could potentially be added to many other foods. This may result in the widespread distribution of additional iodine sources in the food supply and has the advantage of giving consumers increased opportunities to consume additional iodine.

Extending permissions for voluntary iodine fortification may result in consumers having more choice and access to iodine-rich foods. Voluntary fortification also has the advantage of providing consumers with more choice to select non-fortified foods when compared to mandatory fortification.

The main risk to the community from increasing iodine intakes is to increase the incidence of IIH. To date, voluntary permissions for iodine have not delivered increases in the amount of iodine in the food supply and on this basis, it is unlikely there will be an increase the incidence of IIH. In the future, however, if industries did decide to take up these permissions and add iodine to a large number of foods, this could cause a rise in the incidence of IIH. As with Option 1, it would be difficult to introduce a successful incremental approach for adding additional iodine to the food supply in order to minimise the risk of IIH.

The impact on consumers would ultimately depend on the extent to which industry embraces additional fortification options and so the outcome is unpredictable. With voluntary fortification, it is harder to guarantee an effective measured quantity of iodine in the food supply.

7.2.2.2 Impacts on industry

Extending permissions for voluntary iodine fortification would allow industry to potentially develop new innovative products and provide opportunities for product differentiation. Manufacturers that chose to fortify their products with iodine would benefit from normal commercial returns. Manufacturers would not be forced to bear the costs associated with mandatory fortification. Amendment of the current permissions for iodised salt use in commodity Standards would enable manufacturers of commodity Standards to use iodised salt in the production process without having to use the word iodine in the product name.

7.2.2.3 Impacts on governments

There would be no additional enforcement responsibility and hence no resource costs under this option for Governments**.** If a reduction in IDD did occur, Governments would benefit from lower public health costs. This would be offset, to some extent, by a possible increase in the incidence of IIH. However, the benefits from reducing IDD would be significantly greater than the expected costs arising from an increase in IIH.

Governments would need to continually monitor the food supply and assess the iodine status of the population.

Questions:

What food products are suitable for extending permissions for voluntary iodine fortification?

Should permissions be given to allow iodine to be added to single ingredient foods, such as oil or sugar?

7.2.3 Option 3 - Promotion of voluntary options to increase industry uptake

7.2.3.1 Impacts on consumers and the community

An agreement, such as a Code of Practice or a MoU with industry, could be developed to actively promote the increased production of iodised ingredients and/or uptake of use of iodised ingredients. Compared with Options 1 and 2, Option 3 provides the community with a greater level of assurance that the iodine content of the food supply could be increased and sustained.

In terms of consumer choice, as more foods become fortified with iodine, this further restricts consumers ability to select non-fortified foods. The extent of this restriction would depend on the number of industries that agree to take advantage of the liberal regulatory approach to allow use of iodine fortified ingredients and the food vehicles selected.

The risk of IIH would be slightly greater under this option, when compared with Options 1 and 2, as it is likely there would be a greater increase in the amount of iodine in the food supply. However, this risk can be minimised by adopting an incremental strategy for increasing the amount of iodine in the food supply and ensuring the additional iodine is added in a controlled manner and monitored carefully.

7.2.3.2 Impacts on industry

The main feature of Option 3 is that permissions for the addition of iodine to certain foods would remain voluntary but a greater level of assurance would be given by industry to increasing and sustaining the iodine content of the food supply.

Industries who decide to take up these permissions and enter into an agreement such as a Code of Practice or MoU could be faced with increased costs due to changes in production processes, monitoring requirements and labelling changes. If the public's awareness increases, as to the extent of iodine deficiency in the population, there could be a marketing advantage in adding iodine to certain foods and this may offset some of the costs associated with adding iodine. Depending on the food vehicle chosen, the cost of adding iodine is likely to be minimal.

7.2.3.3 Impacts on governments

While there would be no additional enforcement responsibility under this option, governments would face increased costs, when compared to the *status quo*, arising from initiating and maintaining agreements with industry to promote the voluntary uptake of iodine permissions. In Tasmania, for example, the iodine fortification program (detailed in Attachment 4) required dedicated resources and staff in order to implement the program and ensure its ongoing effectiveness. This cost to governments may divert resources away from other public health priorities.

Compared with Options 1 and 2, it is more likely that Option 3 would increase the iodine status of the population and so governments would benefit from the lower public health costs associated with a reduction in IDD. As there would be more control in increasing the iodine status of the population, it is likely the incidence of IIH would be reduced.

Governments would need to continually monitor the food supply and assess the iodine status of the population.

Questions

Who would be responsible for promoting voluntary uptake?

Would a Code of Practice or Memorandum of Understanding with industry be appropriate – who would be responsible for this?

How likely is it that industry would take up voluntary permissions for the use of iodine-fortified ingredients?

7.2.4 Option 4 - Mandatory iodine fortification

7.2.4.1 Impacts on consumers and the community

Option 4 would guarantee the delivery of more iodine into the food supply in a more controlled and sustained way, when compared with the other three options. Depending on the food vehicle(s) selected, mandatory fortification would facilitate the passive uptake of increased dietary iodine in the whole population, without the need for consumers to change food selections.

Mandating the addition of iodine to a food ingredient has the advantage of ensuring the widespread distribution of iodine throughout the food supply, thereby increasing opportunities for people to consume additional iodine. The main disadvantage, however, is that the distribution of iodine intakes will be large and there is a risk that some subgroups of the population may receive too little iodine while others receive too much.

Mandating the addition of iodine to a specific food category has the advantage of making it easier to more accurately predict the expected increase of iodine in the food supply and the likely impact on the iodine status of the population. It has the disadvantage, however, of excluding those sections of the population who choose not to eat this food category.

Mandatory fortification would further restrict consumers' freedom to choose unfortified foods. The extent of this, however, would depend of the food vehicle(s) selected for fortification.

Consumers may choose to avoid foods fortified with iodine and this may have other unintended nutritional consequences. The cost of mandatory fortification may be passed onto consumers and, depending on the extent of the price increase, may also impact on food selections.

A mandatory fortification program would allow iodine intakes to be more closely controlled and increments increased at levels required to assure iodine sufficiency, thereby minimising the risk of IIH.

7.2.4.2 Impacts on industry

Manufacturers of the prescribed food vehicle(s) for fortification would face increased costs including:

- analytical testing costs to confirm the appropriate levels of iodine in their product;
- production related costs, including the cost of adding iodine; and
- the cost of changing labels.

However, based on international experience and information from Tasmania on adding iodine to bread, the increased costs are unlikely to impact significantly on overall operating costs.

Depending on the food vehicle(s) chosen for fortification, mandatory iodine fortification may impact on importers and exporters if they need to alter their product in order to comply with domestic and/or overseas regulations.

7.2.4.4 Impacts on Governments

There would be additional enforcement and monitoring responsibilities and hence resource costs under this option to ensure that manufacturers comply with the mandatory fortification requirements. Based on the experience from Tasmania, it is anticipated that the costs governments would incur under this Option would be less than the costs encountered in Option 3, as governments would not be faced with the ongoing costs associated with maintaining agreements with industry to promote the voluntary uptake of iodine permissions.

Option 4 has the potential to deliver a more controlled and sustained increase in the amount of iodine in the food supply and as such governments would benefit from the lower public health costs associated from a greater reduction in IDD. It is also expected that the risk of IIH would be reduced with this Option.

Governments would need to continually monitor the food supply and assess the iodine status of the population.

Questions:

Will the benefits of mandatory fortification outweigh all the costs?

Would consumers be concerned about a lack of consumer choice if mandatory iodine fortification were instigated?

What would be an appropriate food vehicle(s) for mandatory fortification?

From industry's perspective, what are the advantages and disadvantages of mandatory iodine fortification?

What would be the overall cost of adding iodine to a food product and the likely impact on the price to consumers?

What monitoring should be undertaken to assess the effectiveness of mandatory fortification and which government agencies are responsible for, and will undertake, such monitoring?

8. Consultation

8.1 Public Consultation

This Initial Assessment Report seeks early input on a range of specific issues known to be of interest to various stakeholders on the likely regulatory impact of this Proposal. The views of stakeholders will assist in the development of a Draft Assessment and a preferred approach to further improve the iodine status of the Australian and New Zealand population. Further public comment will be sought at Draft Assessment, including any proposed draft variation/s to the Code.

In addition to the statutory requirement for two rounds of public consultation, it is envisaged that FSANZ will convene a Fortification Standards Development Advisory Committee (SDAC) comprising a broad range of stakeholders. This committee will help identify the views and opinions FSANZ will need to consider in progressing this Proposal. It is also envisaged that an Iodine Scientific Advisory Group (ISAG) will be established in order to provide advice on scientific matters.

Given the significant potential public health, social and economic impact of this Proposal, FSANZ also proposes to undertake a series of targeted consultations to inform and engage interested stakeholders and the general public. As opportunities arise and as recommended by the SDAC and ISAG, FSANZ expects to conduct key stakeholder meetings, present at relevant conferences and seminars, engage in targeted public forums and be proactive in sharing information with the wider community.

8.2 World Trade Organization (WTO)

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.

This issue will be fully considered at the Draft Assessment stage and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade and Sanitary and Phytosanitary Measure Agreements. This will enable other WTO member countries to comment on proposed changes to Standards where they may have a significant impact on them.

9. Conclusion and Recommendation

There is increasing evidence to suggest that the iodine status of Australians and New Zealanders is compromised, and that the current regulatory arrangements for voluntary fortification of foods via iodised salt are possibly not effective.

Baseline iodine intake data, although somewhat limited, are available for Australian and New Zealand populations groups and can be used to estimate dietary iodine intakes from potential fortification scenarios to compare against dietary targets.
International and Tasmanian experiences of iodine fortification also guidance to help determine an appropriate level of fortification and give an indication of which food vehicle(s) are the most effective means of increasing iodine intake.

This Initial Assessment Report outlines four options FSANZ is considering to determine the most effective strategy to further increase the intake of iodine. These options range from maintaining the status quo to changes in mandatory or voluntary fortification.

FSANZ now seeks comment and information from stakeholders on the range of issues raised in this Report. Input from all sectors of the community, including consumers, industry, health professionals and government, is welcomed and encouraged. The submissions provided during this consultation will inform the Draft Assessment Report. Stakeholders will be given further opportunity to comment when the Draft Assessment Report is released.

Information regarding how to make a submission to Proposal P230 is included in the section 'Invitation for Public Submissions' on page 3 of this Report.

10. Implementation and review

During the Draft Assessment stage, FSANZ, following consultation with other relevant bodies and authorities, will make a decision on which regulatory option is preferred. Depending on the preferred option, the Proposal may or not proceed at Draft Assessment.

In terms of review, the Ministerial Council 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*.

If a regulatory option of mandating iodine fortification is chosen, FSANZ can take responsibility for monitoring food industry response and food composition. However the monitoring of iodine status would need to be undertaken by other more appropriate authorities.

ATTACHMENTS

1 ANZFRMC Policy Guideline - Fortification of Foods with Vitamins and Minerals
2 International experience with iodine fortification programs
3 Table of studies of iodine status undertaken in Australia and New Zealand
4 Tasmanian fortification experience
5 References

Attachment 1

ANZFRMC Policy Guideline
Fortification[1] 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:

[1] 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:

- 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.
- Be required only if it is assessed as the most effective public health strategy to address the health problem.
- Be consistent as far as is possible with the national nutrition policies and guidelines of Australia and New Zealand.
- Ensure that the added vitamins and minerals are present in the food at levels that will not result in detrimental excesses or imbalances of vitamins and minerals in the context of total intake across the general population.
- Ensure that the mandatory fortification delivers effective amounts of added vitamins and minerals with the specific effect to the target population to meet the health objective.

Additional Policy Guidance - Mandatory Fortification

Assessment of alternative strategies – consideration must be comprehensive and include for example assessment of voluntary fortification and education programs.

Requirement to label – no mandatory requirement to label as fortified however, consideration should be given, on a case by case basis, to a requirement to include information in Nutrition Information Panel.

Monitor/Review – 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.

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 sub-clinical 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[2]).

  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.
- 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.

[2] 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.

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 2

International Experience With Iodine Fortification Programs

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[6].

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[7]. 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.

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

[7] 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. 2003[1])

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 T 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 2003[2]).

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[8].

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).

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.

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

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).

Attachment 3

Studies Of Iodine Status Undertaken In Australia And New Zealand

RESULTS FROM STUDIES[1] INVESTIGATING IODINE STATUS OF AUSTRALIAN AND NEW ZEALAND POPULATIONS

Author	Subjects	n	% < 50 μg/L	% <100 μg/L	Median urinary iodine concentration[2]
AUSTRALIA					
Gunton (1999)	Pregnant women	81	19.8	49.6	
	Postpartum women	28	19.2	53.9	
	Patients with diabetes	135	34.1	71.9	
	Volunteers	19	26.3	73.7	
Guttikonda (2003)	Children 5 -13 years	301	14	69	82 μg/L
Li (2001)	Children 6 -13 years	94	13.8		84 μg/L
	Pregnant women from antenatal class	101	20.6		88 μg/L
	Adult volunteers, medical staff	86	18		88 μg/L
	Diabetes patients	85	23		69 μg/L
McDonnell (2003)	Children 11-18 years, Male	167	17	69	
	Female	410	31	79	
	Total	577	27	76	
NEW ZEALAND					
Thomson (1997)	Blood Donors	333	57	92	Male 51 μg/L Female 42 μg/L
Skeaff (2002)	Children 8 - 10 years	282	31.4	79.7	66 μg/L
Thomson (2001)	Men and women 18 - 49 years	233			59 μg/L ±33
MoH (2003) New Zealand National Children's Survey	Children 5 -14 years		28		66 μg/L 68 μg/L males 62 μg/L females

[1]The WHO recommends that the median urinary iodine concentration for populations as a whole should be more than 100 μg/L, and that no more than 20% of the population should have a urinary iodine concentration below 50 μg/L as a measure of nutritional adequacy.

Attachment 4

Tasmanian (Interim) Iodine Supplementation Program

In 1999 and 2000 the Menzies Centre for Population Health conducted research into the iodine status of Tasmanians. The results of the research suggested a re-emergence of mild IDD (Hynes 2004). The matter was referred to ANZFA, however due to the time required to establish a new standard, an interim program was developed. As a direct result, in October of 2001 an iodine fortification program was put in place by the Tasmanian Department of Health and Human Services (TDHHS). Bakeries were asked to use iodised salt in place of regular salt. A Memorandum of Understanding (MoU) was established between the TDHHS and those in the baking industry who agreed 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 Choice of bread as a food vehicle

Several options were considered for iodine fortification in Tasmania. Under consideration was; milk supplementation, deliberate milk contamination, bread supplementation, agricultural supplementation, water iodisation, iodised table salts and iodised salt in bread.

Milk fortification

As milk is produced and processed at a local level in Tasmania and dietary information suggested that milk is a widely consumed food, it was considered to be an appropriate potential vehicle for supplementation. Discussion with the dairy and milk processing industries revealed a reluctance to use either adventitious or planned procedures to fortify milk with iodine. Iodophor use has decreased over recent years due to their lesser effect as a cleaning agent and negative effect on the shelf life of milk compared to other sanitisers. Because of this, it was not considered an appropriate method to increase the iodine content of milk. Direct addition of iodine to milk raised concerns over the effect on taste and texture as well as to cost and industry infrastructure.

In addition to reluctance from the dairy and milk processing industries, fortification of milk would have required a change in the Code resulting in time delays associated with the standards setting process.

Fortification of animal feed

Dairy cattle nutrition is based on pasture feeding. Depending on the pasture and seasonal conditions (i.e. drought and harsh winters), dairy cattle are supplemented using grain and concentrate feeds. The level of supplementation varies widely among herds, as does the supplement. Addition of iodine to supplements would be difficult to control as they are manufactured in both Tasmania and in other Australian states. Supplementation of cattle feeds would require a degree of control to ensure that cattle were not being over supplemented. Although an option offered for discussion, the prospect of using animal feed as a fortification instrument was considered logistically difficult to manage and overall inappropriate.

Supplementation of the water supply

As water is a necessity and consumed daily, it was considered a potential option as a fortification vehicle.

There are approximately 140 State water suppliers in Tasmania and a number of private suppliers. Although technically and financially water is a feasible option for fortification, the logistics of the legislative change and potential public concern over water supplementation, this option was not considered.

Banning the use of non-iodised salt

Banning the use of non-iodised salt was considered akin to universal salt fortification, and would result in all domestically and commercially used salt being iodised. Due to the lack of regulatory provisions for prohibiting the sale of non-iodised salt special legislation would have been required.

This option was not considered for two reasons; mixed public health messages, and difficulty in monitoring the outcome. Encouraging the use of table salt is contrary to the Australian Dietary Guidelines that advise a reduction in salt consumption, and thus was not considered a viable option. Monitoring of mandating the mandatory use of iodised salt in commercially prepared food would be difficult as much of Tasmania's commercial products are manufactured outside of the state. The level of fortification required to have an effect on iodine status would be difficult to assess and further complicated by lack of data on the sodium content of Australian food.

Bread fortification

Bread was also considered a viable option as a vehicle for iodine fortification as it is a widely consumed food and produced predominantly within the State. Consultation between the TDHHS and the bread/baking flour industry was encouraging and the bread industry expressed an 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 solution that would not require a change in the Code. 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 a fortification program.

2 Memorandum of Understanding for voluntary use of iodised salt

In October 2001, a MoU was established between the baking industry and the TDHHS for voluntary use of iodised salt in bread making. The major salt supplier assured the TDHHS that they would be able to supply quantities of iodised salt at a reasonable cost. It was agreed that;

- bakeries use iodised salt at 40 ppm for bread making;
- bakers signing the MoU are permitted to bake other 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 with in which time 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.

3 Monitoring

The Tasmanian iodine monitoring program commenced in July 2002, with the objective being to determine the effect of fortification on 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.

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. Other barriers include low awareness of the incidence of IDD and its clinical impact on children and the habits of individual bakers. 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

Monitoring of the iodine content of bread from bakeries participating in the MoU began in March 2002. Initially bread samples from 29 bakeries were analysed. The result of the analysis showed a wide variation in iodine concentration. Twelve samples had iodine concentration less than 30 μg/100g, 12 had levels between 30 and 70μg/100g and 5 samples had concentrations higher than 70 μg/100g. A variety of factors were thought to explain the variation including: variable levels of iodine in the salt, variable levels of salt in the bread, gassing off of iodine during baking and/or storage and laboratory errors.

Between March and December 2002 a multiple loaves from four bakeries were tested for iodine content. Again the distribution of iodine concentration was varied between and within bakeries. Of the two bakeries – four appeared to be returning more consistent results. In February 2003 bread from these two bakeries was then used to investigate day-to-day variation of iodine content over a five day period, the loss of iodine over a week and whether in fact, consistent iodine levels can be achieved in bread through the use of iodised salt.

The results from the February research suggest that consistent and expected levels of iodine in bread through the use of fortified salt can be achieved, iodine content remains stable as bread ages and dries and that composite sampling does reflect the iodine content of single loaf samples.

Results of this monitoring suggest that baking bread with iodised salt increases the level of iodine in bread.

6 Effect on iodine status

The results of two random surveys of Tasmanian school children aged 4 -14 years in 1998-99 and 2000-01 previous to the implementation of the Tasmanian iodine fortification program had median urinary iodine levels of 75μg/L and 77 μg/L, with 13% and 21% respectively, of urinary iodine levels below 50 μg/L (Hynes 2004).

The TDHHS have an ongoing monitoring program, the results of which can be found on the Tasmanian iodine monitoring program website[9]. To date (October 2004), urine samples have been collected from 347 children, in 31 different classes from 29 different schools. Collection of specimens from school children requires parental consent. Sixty-eight percent of parents returned consent forms, and 73% of these gave consent for urine to be collected from their child. From those children whose parents had given consent a sample was obtained from 88.7%. This gives an overall response rate of 44%. In a study such as this, low participation rates create the risk that the results do not reflect the situation in all children, but only that of the groups that are participating. An increased participation rate will enable us to draw more accurate and meaningful conclusions from the data. The median urinary iodine level from the current study was 105 μg/L (98.5 μg/L - 111.5 μg/L), with 10.9% below 50 μg/L. This suggests the population is now iodine replete.

7 Implications of a voluntary scheme

The Tasmanian experience has highlighted several implications of a voluntary scheme.

- In order for a voluntary scheme to be effective manufactures have to be committed to the process. Having knowledge of the effects of fortification on the population helps to facilitate commitment.

- Memorandums of Understandings are purely an indicator of intent to participate, but not binding. Some manufactures were using iodised salt irrespective of not having signed the MoU with TDHS.

- Without a binding agreement, changes in baking practices over time may result in reduced participation. For example, if future reliance on premixes and frozen dough from interstate were to increase, participation may be jeopardised.

[9] www.iodine.com.au

Attachment 5

REFERENCES

AC Nielsen Grocery Report. Accessed 09/02/04 at: http://www.acneilson.co.nz/MRI_pages.asp?MRIID=4

Aitken E. Iodine Status in New Zealand: Is History Repeating Itself? Journal of NZDA 2001 55,4-5

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.

BRI Australia 2003 The Australian Baking Industry – A profile. Australian Government, Department of Agriculture, Fisheries and Forestry.

Chen J, Wu H. 1998. Fortification of Salt with Iodine. Food and Nutrition Bulletin. Tokyo: United Nations University Press. Vol 19, Number 2.

Codex Alimentarius Commission. 2001. Codex standard for food grade salt. CX Stan 150 – 1985, Rev. 1-1997 Amend. 1-1999, Amend 2-2001.

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

Dahl L, Opsahl J, Meltzer H, Julshamn K.2003. Iodine concentration in Norwegian milk and dairy products. British Journal of Nutrition 90, 679-685

Darnton-Hill,I. 1998. Rationale and elements of a successful food-fortification program. Scrimshaw,N.S. 2 (19). Tokyo, United Nations University Press. Food and nutrition bulletin. http;//www.unu.edu/unupress/food/V192e/begin.htm

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

Department of Health. 1991. Food for Health. Report of the New Zealand Nutrition Task Force. Wellington. Department of Health

Department of Health 1991 Dietary reference values for food energy and nutrients for the Untied Kingdom. London. Department of Health

Department of Health and Human Service. 2004. Tasmanian iodine supplementation program. Accessed at 09/02/2004 at; www.dhhs.tas.gov.au/publichealth/foodand nutrition/iodine/

Food and Nutrition Board IoM 2001 Dietary reference intakes for vitamin A, vitamin K, Arsenic, Boron, Chromium, Copper, Iodine Iron Manganese, Molybdenum, Nickel, Silicon, Vanadium and Zinc. Washington DC: National Academy Press.

Food Fortification Technology. http://www.fao.org/docrep/W2840E?w2840e03.htm at 28 August 2004

Garcia-Mayor R, Rios M, Fluiters E, Mendez L, Garcia-Mayor E, Andrade A**.** 1999. Effect of iodine supplementation of paediatric population with mild iodine deficiency. Thyroid 9(11), 1089-1093.

German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society, Swiss Society for Nutrition Research. 2000 Referenzwerte fur die Nahrstoffzufhr. 1 Auflage. Frankfurt am Main: Umschau/Braus

Gibson R. 1990. Assessment of iodine status. Principles of Nutrition Assessment. New York: Oxford University Press. pages 527-532.

Gunton J, Hams G, Fiegert M, McElduff A. 1999. Iodine deficiency in ambulatory patients at as Sydney teaching hospital; Is Australia Truly Iodine Replete? Med J Aust. 171, 467-470.

Guttikonda K, Burgess J, Hynes K, Boyages S, Byth K, Parameswaran V. 2002 Recurrent iodine deficiency in Tasmania, Australia: A salutary lesson in sustainable iodine prophylaxis and it monitoring. Journal of Clinical Endocrinology and Metabolism 87(6), 2809-2815

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

Hetzel B, Clugston G. 1998. Iodine. In Shils et al (Ed) Modern nutrition in Health and Disease pp 253-264 9th ed.

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.

Hynes K, Blizzard C, Venn A, Dwyer T, Burgess J. 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, 476-81

ICCIDD, UNICEF, WHO 2001 Assessment of Iodine Deficiency Disorders and Monitoring their Elimination. Second edition. Geneva: WHO publishing

IDD Newsletter. 2001. 17(1),8

IDD Website. 2003[1]. IDD Prevalence and Control Program Data – Germany. www.people.virginia.edu/~jtd/iccidd/mi/idd_062.htm. Accessed August 2004.

IDD Website. 2003[2]. 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[1]. Implementation and Monitoring of Iodine Supplementation in Denmark: The Dan Thyr Program. IDD Newsletter Vol 19 (4), 55-59.

ICCIDD. 2003[2]. IDD Prevalence and Control Program Data, The Netherlands. www.iccidd.org.

ICCIDD. 2003[3]. 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

Institute of Medicine 2001. Dietary reference intakes for vitamin A, vitamin K, Arsenic, Boron, Chromium, Copper, Iodine, Iron, Manganese, Molybdenum, Nickel, Silicon, Vanadium and Zinc. Washington DC: National Academy Press

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

Kuhajet E, Fiedelman H. 1973. Nutritional iodine in processed foods. Food Tech 27, 52-53

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.

Lamberg B. 2003. Iodine Deficiency Disorders and Endemic Goitre. Eruo J Clin Nutr 47, 1-8

Li M, Ma G, Guttikonda K, Boyages S, Eastman C. 2001. Re-emergence of iodine deficiency in Australia. Asia Pacific J Clin Nutr. 10, 200-203.

McDonnell C, Harris M, Zacharin M. 2003. Iodine deficiency and goitre in school children in Melbourne, 2001. Med J Aust. 178, 159-162.

Mannar M, Dunn J. 1995. Salt iodisation for the elimination of iodine deficiency. Netherlands: International council for the control of iodine deficiency disorders

Ministry of Health 2003 Food and Nutrition Guidelines for Healthy Adults; A Background paper. Wellington. Ministry of Health

Ministry of Health and the University of Auckland. 2003[1]. Nutrition and the Burden of Disease: New Zealand 1997 – 2011. Wellington: Ministry of Health.

Ministry of Health. 2003[2]. NZ Food: NZ Children. Key Results of the 2002 National Children's Nutrition Survey. Ministry of Health.

Ministry of Health. 1999. NZ Food: NZ People. Key Results of the 1997 National Nutrition Survey. Ministry of Health.

NHMRC 2003. Dietary Guidelines for Australian Adults. A guide to Healthy Eating. Commonwealth of Australia 2003.

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

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

Rasmussen L, Andersson G, Haraldsdóttir J, Kristiansen E, Molsted K, Laurberg P, Overvad K, Perrild H, Ovesen L. 1996. *Iodine: Do we need an enrichment program in Denmark?* Int J Food Sci Nutr. 47,377-381

Reardon M. 2002 Iodine Status of the Tasmanian Population – Development of a Monitoring and Surveillance Program. Masters Thesis. Curtain University of Technology.

Remer T, Neubert A. 1998. A Never-Ending Story of an Insufficient Status without Mandatory Iodization of Foods? – A German Experience. Journal of Clinical Endocrinology and Metabolism 83(10),3755-3756.

Richards P. 1995. Iodine nutrition in two Tasmanian cultures. Med J Aust. 163, 628-630.

Riley M, Beard T. 2003 Choose Food Low in Salt in Dietary Guidelines for Australian Adults. National Health and Medical Research Council. Commonwealth of Australia

Seal J, Johnson E, Doyle Z, Shaw K. 2003 Tasmania: doing its wee bit for iodine nutrition. Medical Journal of Australia 170, 451

Seal J. 2004 Personal Communication, TDHHS, October 2004

Sivakumar B, Brahmam G, Madhavan Nair K, Ranganathan S, Vishnuvardhan Rao M, Vijayaraghavan K, Krishnaswamy K.2001 Prospects of Fortification of salt with iron and iodine. British Journal of Nutrition 8(suppl.2),167-173

Skeaff S, Thomson C, Gibson R. 2002. Mild iodine deficiency in a sample of New Zealand school children. Eur J Clin Nutr. 56, 1169-1175.

Thomson C, Colls A, Conaglen J, MacCormack M, Stiles M, Mann J. 1997. Iodine status of New Zealand residents as assessed by urinary iodide excretion and thyroid hormones. British Journal of Nutrition 78, 901-912.

Thomson C, Woodruff S, Colls A, Joseph J, Doyle T. 2001. Urinary iodine and thyroid status of New Zealand residents. Eur J Clin Nutr. 55, 387-392.

Thomson C. 2002. Australian and New Zealand Nutrient Reference Values for Iodine- Technical report for Ministry of Health. University of Otago.

Thomson C. Revised 2003. Australian and New Zealand Nutrient Reference Values for Iodine. A report prepared for the Ministry of Health. Dunedin: University of Otago.

Thomson C. 2004. Review article – Selenium and iodine intakes and status in New Zealand and Australia. British Journal of Nutrition 91, 611-672

Turnbull F, Lee S, Seal J, Johnson E, Shaw K. 2004 Tasmanian iodine supplementation program: participation by small-medium sized bakeries. Dietitians Association of Australia National Conference

Truswell A, Dreosti I, English R, Rutishausser I, Palmer N. 1990. Recommended Nutrient Intakes. Australian Papers. Sydney: Australian Professional Publications.

Vannoort R. 2004. Personal Communication

Vannoort R, Cressey P, Silvers K. 2000 1997/1998 New Zealand total diet survey Part 2. Elements. Client Report FW9947. Wellington Ministry of Health

Vitti P, Pinchera A, Delange F, Moiner B. 2002. Europe is still iodine deficient! IDD Newsletter. 18(4),51-55

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.

WHO/UNICEF/ICCIDD. 1994. Indicators for Assessing Iodine Deficiency Disorders and their Control through Salt Iodisation. Geneva: World Health Organization.

WHO/UNICEF/ICCIDD. 2001. Assessment of Iodine Deficiency Disorders and Monitoring their Elimination. Second edition. Geneva. WHO Publishing.

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 Endocrin. 144,595-603.

World Health Organisation. 2001. Assessment of Iodine Deficiency Disorders and Monitoring their Elimination. A guide for program managers.

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: