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

5-05
3 August 2005

FINAL ASSESSMENT REPORT

APPLICATION A528

MAXIMUM IODINE LIMIT IN FORMULATED SUPPLEMENTARY FOODS FOR YOUNG CHILDREN

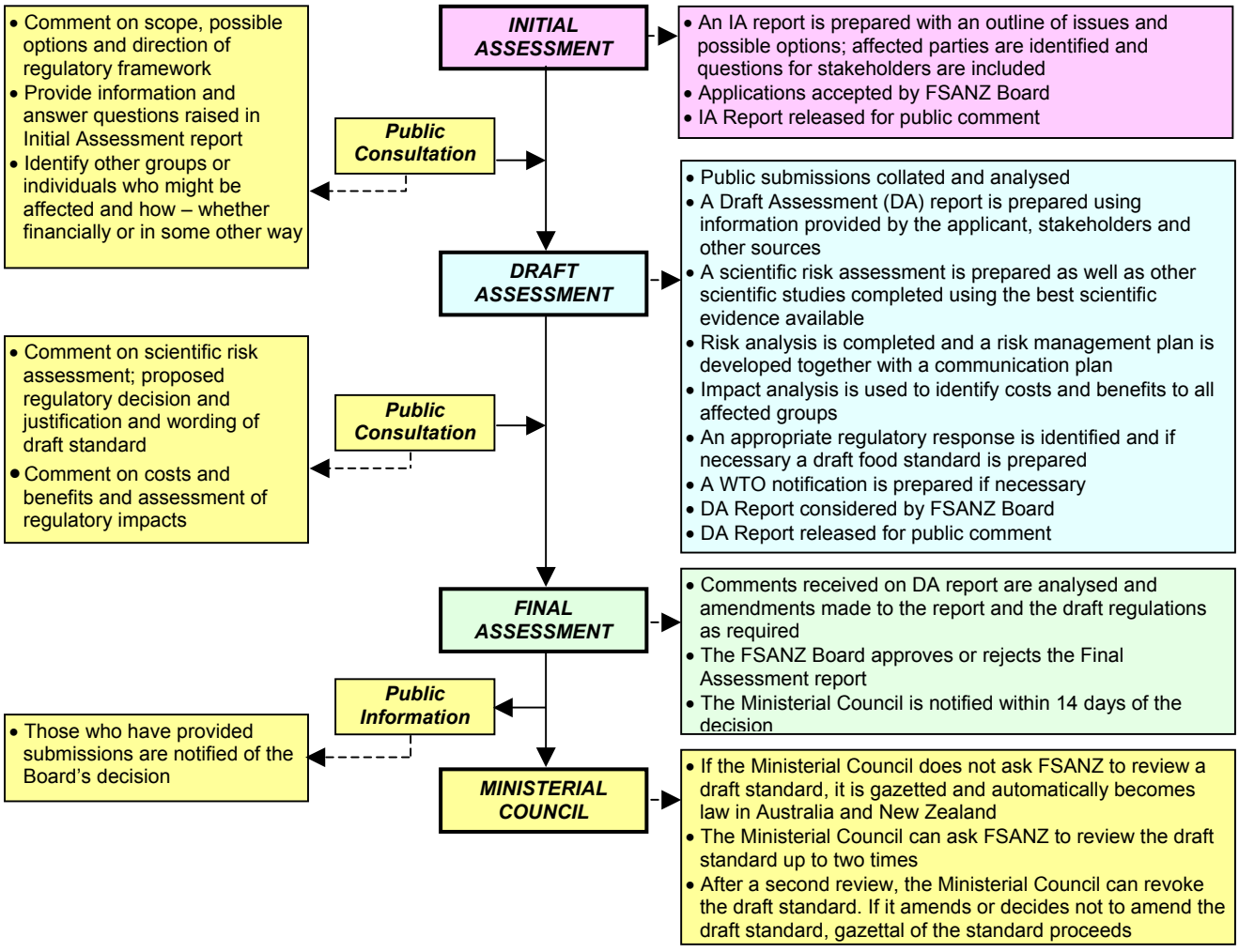
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Application. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

In New Zealand, the New Zealand Minister of Health gazettes the food standard under the New Zealand Food Act. Following gazettal, the standard takes effect 28 days later.

Further Information

Further information on this Application and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.

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Executive Summary and Statement of Reasons

Food Standards Australia New Zealand (FSANZ) received an Application from Wyeth Australia Pty Limited on 20 January 2004 seeking to amend Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods of the *Australia New Zealand Food Standards Code* (the Code) to increase the maximum permitted quantity of iodine per serving from 35 to 70 micrograms (μg) in formulated supplementary foods for young children (FSFYC). FSFYC are defined in the Code as formulated supplementary foods for children aged 1 – 3 years.

This Final Assessment Report discusses issues involved with this Application, including issues raised in submissions in response to the Draft Assessment, and recommends a variation to the Code as at Attachment 1.

Regulatory Problem

The Applicant has requested an increase in the maximum permitted quantity of iodine in FSFYC to accommodate levels of naturally occurring[1] iodine in ingredients used to manufacture FSFYC. Some manufacturers of FSFYC claim that on occasions the endogenous quantity of iodine can exceed the maximum permitted iodine quantity due to seasonal and geographical variation in the iodine content of ingredients. The Applicant suggests that their milk-based FSFYC could exceed the current upper limit of 35 μg iodine/serve approximately 30% of the time even if the iodine in the product is contributed solely from milk and milk ingredients. This being the case, the Applicant has requested that FSANZ consider the iodine variability that exists in raw materials, specifically milk, and to raise the upper limit of iodine permitted in FSFYC from 35 to 70 μg/serve.

Risk Assessment

FSANZ has undertaken three separate assessments to inform an overall assessment of risk. These assessments are the Safety Assessment, the Dietary Intake Assessment, and the Nutrition Assessment. Full details on these assessments are provided at Attachments 2, 3 and 4 respectively.

The overall conclusion from the combined risk assessment is that an increase in the maximum iodine limit from 35 to 70 μg/serve for FSFYC is likely to have a relatively small impact on dietary iodine intakes of young children and therefore does not pose any additional public health and safety risk to young children.

Risk Management

This Final Assessment considers the need to manage any identified public health and safety risks associated with this Application, in addition to issues raised in submissions to the Draft Assessment.

[1] In this case 'naturally occurring' refers to the inate iodine content in addition to any adventitious contamination which may occur during the processing of ingredients e.g. iodophores in milk.

Regulatory Options and Impact Analysis

Two options are considered for this Application at Draft Assessment. These are:

1. Maintaining the *status quo* by not increasing the maximum iodine quantity in FSFYC; or

2. Amending Standard 2.9.3 to increase the permitted maximum quantity of iodine in FSFYC from 35 to 70 μg per serving.

For each regulatory option, an impact analysis has been undertaken to assess potential costs and benefits to various stakeholder groups associated with its implementation.

Consultation

FSANZ released for public consultation from 4 August 2004 to 22 September 2004 a Draft Assessment Report for Application A528. A total of nine submissions were received and are summarised in Attachment 5. All submitters except one supported amending Standard 2.9.3 to increase the permitted maximum level of iodine in FSFYC from 35 to 70 μg/serve.

Conclusion and Statement of Reasons

This Final Assessment Report concludes that amending the Code to accommodate the natural variation of iodine in ingredients used to manufacture FSFYC does not pose any additional public health and safety risk to young children. However, to deter the addition of iodine at consistently higher levels in FSFYC the maximum permitted claim limit of 35 μg per serve has been retained. Therefore, FSANZ concludes that Standard 2.9.3 be amended to increase the maximum permitted level of iodine in FSFYC from 35 to 70 μg per serving (Attachment 1) for the following reasons:

- the resultant minor increase in iodine intake as a consequence of raising the maximum permitted quantity of iodine in FSFYC does not raise any public health and safety concerns in the target population;

- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act. Specifically, FSANZ has addressed the protection of public health and safety by undertaking a risk assessment using the best scientific data available;

- the proposed draft variation to the Code will increase compliance with the Code, reduce manufacturing costs, and prevent unnecessary trade barriers; and

- the regulation impact assessment concludes that the benefits from increasing the maximum permitted quantity of iodine in FSFYC outweigh any potential costs to affected parties.

The variation to the Code will come into effect upon gazettal, subject to any request from the Ministerial Council for a review.

1. Introduction

Food Standards Australia New Zealand (FSANZ) received an Application from Wyeth Australia Pty Limited on 20 January 2004 seeking 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 micrograms (μg) per serving in formulated supplementary foods for young children (FSFYC).

In the Code, formulated supplementary foods are considered special-purpose food and are defined as *food specifically designed as a supplement to a normal diet to address situations where intakes of energy or nutrients may not be adequate to meet an individual's requirements*. FSFYC are formulated supplementary foods for children aged 1 – 3 years.

This Final Assessment Report discusses issues involved with this Application, including issues raised in submissions in response to the Draft Assessment, and recommends a variation to the Code as at Attachment 1.

2. Regulatory Problem

The Applicant has requested an increase in the maximum permitted quantity of iodine in FSFYC to accommodate levels of naturally occurring[2] iodine in ingredients used to manufacture FSFYC. Some manufacturers of FSFYC claim that on occasions the endogenous quantity of iodine can exceed the maximum permitted iodine quantity due to seasonal and geographical variation in the iodine content of ingredients. The Applicant suggests that milk-based FSFYC could exceed the current upper limit of 35 μg iodine/serve approximately 30% of the time even if the iodine in the product is contributed solely from milk and milk ingredients. This being the case, the Applicant has requested that FSANZ consider the iodine variability that exists in raw materials, specifically milk, and to raise the upper limit of iodine permitted in FSFYC from 35 to 70 μg/serve.

3. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out, in order of priority, 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:

[2] In this case 'naturally occurring' refers to the inate iodine content in addition to any adventitious contamination which may occur during the processing of ingredients e.g. iodophores in milk.

- 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.

4. Background

4.1 Current Regulations

Division 4 of Standard 2.9.3 sets out the compositional and labelling requirements for FSFYC. Subclause 6(1)(c) of Standard 2.9.3 prescribes the compositional requirements, including vitamins and minerals, of FSFYC as follows:

(1) Formulated supplementary foods for young children must contain in a serving no less than –

> *(c) 20 % of the RDI of no less than one of those vitamins or minerals listed in column 1 of Table 3 in the Schedule, provided the total quantity[3] of each vitamin or mineral in a serving does not exceed the quantity, where specified, set out in relation to that vitamin or mineral in column 2 of Table 3.*

Column 2 of Table 3 in the Schedule to Standard 2.9.3 specifically sets the maximum quantity per serving for iodine as 35 μg, which is 50% of the recommended dietary intake (RDI) for children aged 1 – 3 years[4].

Iodine is allowed to be added to FSFYC, in a permitted form, provided that the total quantity of both the naturally occurring and added amount does not exceed this prescribed maximum level [subclauses 6(2) and (3)]. Where a permitted vitamin or mineral is added, a maximum claim limit of 50% RDI also applies [subclause 7(2)(c)]. However, in relation to this Application, the issue relates to iodine naturally present in raw materials used to manufacture FSFYC, not iodine added during manufacture. Therefore the declaration of iodine, in this case, is subject to the generic nutrition labelling requirements in Standard 1.2.8 – Nutrition Information Requirements of the Code, in addition to the requirement for a FSFYC to contain no less than 10% RDI/serve of iodine for a claim to be made (subclause 7(2)(a)).

[3] In the Code 'total quantity' refer to both naturally occurring and added nutrients.
[4] Column 4 in the Schedule to Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions of the Code specifies the recommended dietary intake (RDI) for iodine in children aged 1 –3 years as 70 μg.

4.2 Current Market

The vast majority of FSFYC available in Australia and New Zealand are milk-based supplementary drinks known as 'toddler formula'. FSANZ is aware of a sliced luncheon meat product available only in New Zealand that is also manufactured as a FSFYC. This product does not contain added iodine and is assumed not to encounter the same manufacturing difficulties with natural iodine content as milk-based supplementary drinks.

Toddler formula is generally promoted as a supplementary milk drink for young children aged 1 to 3 years. Product information advises that toddler formula should be prepared in water, although the Applicant has indicated that in most cases (approximately 70%) the product is made up in milk, using half the number of recommended scoops. In addition toddler formulas are sometimes promoted as being suitable as a replacement for milk in other foods e.g. custards.

There are only a small number of manufacturers/importers of milk-based FSFYC in Australia/New Zealand and on the whole, the market for these products is relatively small and discrete. The Applicant has indicated that the toddler formula market has a turnover of over 640,000 kg/year, with a growth rate in market sales of more than 51% for 2004. Wyeth (the Applicant) is the market leader with approximately 43% of the total market share.

4.3 Historical Changes to Regulations

In 1999 during the development of the Code, FSANZ completed Proposal P199 – Formulated Meal Replacements and Formulated Supplementary Foods. This Proposal reviewed the regulations for formula dietary foods (Standard R4) and supplementary foods (Standard R9) of the former Australian *Food Standards Code* and the equivalent regulations in the *New Zealand Food Regulations 1984.*

In considering the vitamin and mineral permissions for additions to formulated supplementary foods, Proposal P199 recommended a maximum claim limit of 50% RDI/serve on the basis that it is *inappropriate that a supplementary food supply the complete needs of given nutrients.*

In addition to the use of maximum claim limits for added vitamins and minerals, prescribed maximum quantities at the 50% RDI limit were also set for vitamin A, vitamin D and iodine (whether added or naturally occurring) in formulated supplementary foods (including FSFYC).

4.4 International Regulations

4.4.1 Codex Alimentarius

There is no specific Codex Standard for formulated supplementary foods for young children, although guidelines[5] exist on the nutritional and technical aspects of the production of FSFYC. These guidelines do not however specify an upper limit for iodine. In addition the Codex Standard for Follow-up Formula (CODEX STAN 72-1981), which includes formulas used for young children, does not specify a maximum limit for iodine.

[5] Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991)

4.4.2 Other international regulations

FSANZ has identified no other international regulations for FSFYC relevant to this Application except in Chinese food regulation[6] where a permitted range of iodine at 30 – 150 μg per 100g is prescribed.

4.5 Iodine in the Diet

4.5.1 Sources

Iodine in food occurs mostly as inorganic iodides or iodates[7] and its levels in food are dependent on the environment of the food's origin, particularly the levels of iodine in the soil. Australia and New Zealand have low levels of iodine in their soils, which can often expose sections of the population to low iodine intakes[8]. Internationally, the major natural sources of iodine in the diet (i.e. excluding fortified foods) are seafood, milk and eggs[9]. Meat and cereal are secondary sources.

4.5.2 Role

Iodine is an essential component of the thyroid hormones thyroxine (T4) and tri-iodothyronine (T3). T3 and T4 are synthesised within the thyroid gland where iodine is removed from the blood and concentrated before being linked to the hormones. Thyroid hormones are essential for the maintenance of metabolic rate, cellular metabolism and the integrity of connective tissue.

Dietary iodine is easily absorbed from the stomach and upper small intestine however this absorption can be reduced by the calcium, magnesium and iron content in food and water. Additionally the utilisation of dietary iodine in the body is influenced by goitrogens. Goitrogens are found in the vegetables of the Brassica genus (Cruciferae family: cabbage, broccoli, turnips, Brussels sprouts) and interfere with the biosynthesis of the hormones T3 and T4. Heat from the cooking of these vegetables will inactivate most of the goitrogens that are present.

4.5.3 Recommended dietary intakes of iodine

The current Australian and New Zealand RDI for iodine of 70 μg/day for children 1-3 years is at the lower end of other comparable international RDIs (Table 1). It is noted, however, that the National Health and Medical Research Council (NHMRC) is currently reviewing the Australia and New Zealand RDIs, and has proposed a new (draft) value of 90 μg/day.

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[6] National Standard of the People's Republic of China (GB 10767 – 1997) Foods for Infants and Young Children.

[7] COMA, *Dietary Reference Values for Food Energy and Nutrients for the United Kingdom. Report of the Panel on Dietary Reference Values of the Committee on Medical Aspects of Food Policy*. London: The Stationary Office 1999

[8] Gunton JE, 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.

[9] FAO/WHO (2002); *'Human Vitamin and Mineral Requirements: Report of a Joint FAO/WHO Expert Consultation Group'*; FAO/WHO, Bangkok; p181-194.

The Applicant contends that if the maximum quantity of iodine permitted in FSFYC was raised to 70 μg (100% RDI), and a child consumed the recommended two serves per day, then they would receive 140 μg/day from this source. The Applicant believes that whilst recognising this level to be higher than the currently accepted Australian RDI (and proposed draft RDI), is within internationally accepted ranges.

Table 1: Current International Dietary Reference Intake Values for Iodine

Country	Age	Reference Intake (RDI/RDA* or equivalent)
Australia and New Zealand[10,11]	1-3 years	70 μg/day
UK[12]	1-3 years	70 μg/day
WHO[13]	0-59 months (0-5 years)	90 μg/day
Germany/Austria[14]	1-3 years	100 μg/day
Switzerland[12]	1-3 years	90 μg/day
USA and Canada Reference Intake Values for Iodine[15]	1-3 years	90 μg/day

*RDA=Recommended Dietary Allowance

4.6 Variability in Milk Iodine Levels

4.6.1 Extent of iodine variability in milk

Except for iodine, all minerals are contained within milk as components of micelles. As micelle production is regulated during milk formation, the concentrations of these minerals are consistent no matter where the milk is sourced [16]. However, iodine is present as a free form in milk and is therefore subject to external influences. The main external influences on the free form level of iodine in milk are geographical variations and seasonal diets, in addition to the use of iodophores as sanitising agents of milking equipment.

Geographical variations in milk iodine levels are due to differences in the soil iodine content of cattle grazing pastures. Seasonal variations can occur when iodine rich stock feed is given to dairy cattle during winter to compensate for reduced access to grazing pastures[17].

[10] Truswell AS, Dreosti IE, English RM, Rutishauser IHE, Palmer N. (1990). *Recommended Nutrient Intakes. Australian Papers*. Sydney: Australian Professional Publications

[11] Thomson C. (2002). Australian *and New Zealand Nutrient Reference Values for Iodine, prepared for the New Zealand Ministry of Health*

[12] Report of the panel on dietary reference values of the committee on medical aspects of food policy. Dietary Reference values for food energy and nutrients for the United Kingdom 1991. Chapter 35 Iodine

[13] ICCIDD, UNICEF, WHO Assessment of Iodine Deficiency Disorders and Monitoring their elimination. 2nd Edition. Geneva: WHO publishing ,2001

[14] German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society, Swiss Society for Nutrition Research. Reference values for nutrient intakes. Frankfurt am main: Umschau/Braus, 2000 (in Thomson 2002)

[15] Food and Nutrition Board IoM. Dietary reference intakes for vitamin A, vitamin K, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium and zinc. Washington, D.C.: National Academy Press, 2001

[16] United States Board on Agriculture. (1988). *'Designing Foods: Animal Product Options in the Marketplace'*; National Academy Press, Washington D.C., p236; http://books.nap.edu/books/0309037956/html/236.html

[17] United Kingdom Food Standards Agency. (2000). *'MAFF UK – Iodine in Milk'*; http://www.foodstandards.gov.uk/science/surveillance/maffinfo/2000/maff-2000-198.

Iodophores have been used in the past as sanitising agents for teats and milking equipment, and contributed significantly to the iodine content of milk. Australia, New Zealand and many other overseas countries have now moved away from the use of iodophores to other sanitising agents, resulting in a lowering of milk iodine contents. However, some nations (e.g. United Kingdom) still maintain the practice of iodophore use, which contributes to the global variability in milk iodine contents.

Table 2 demonstrates some of the variability that can exist in milk iodine concentration on a global scale; only a selection of countries are provided due to the lack of information on international milk iodine concentrations. New Zealand data have been obtained from the 2003/4 Total Diet Survey (NZTDS) results, while information on Australia is available for Tasmania, where periodic monitoring is undertaken by two major milk producers, for the Northern Victorian District of the Goulburn Valley, and from the results of the 22nd Australian Total Diet Survey (ATDS).

Table 2: Annual Iodine Concentrations in Milk (μg/L)

	Minimum	Maximum	Mean
Australia (Tasmania)[18] (Personal communications: Seal J, 2004)	110	440	265
Australia (Victoria) (Nestlé submission in response to IAR A528)	31	361	155
Australia[19] (22nd ATDS, 2004)	90	210	133
New Zealand (2003 NZTDS)[20]	41	235	86
United Kingdom[21] (United Kingdom Food Standards Agency 2000)	184	426	315
Germany (Preiss 1997)[22]	<100	150	115
International Mean (FAO/WHO 2002)[23]	34	54	46

4.6.2 Impact of iodine variability in milk on FSFYC

The Applicant has stated that because the iodine in milk is highly variable, the use of milk and milk components can result in some FSFYC potentially exceeding the current iodine maximum limit as specified in the Code.

The milk used in the Applicant's FSFYC products is sourced from Ireland, United States/Canada, and Australia/New Zealand depending on the availability of milk at particular times of the year. The Applicant has provided information on the iodine variability of a FSFYC (Progress Toddler Gold®) produced in Ireland.

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[18] Seal J (State Nutrition Officer). (2004). *Personal communication of raw data on the iodine content of milk*; Department of Health and Human Services, Tasmania.
[19] FSANZ, Results from the 22nd Australian Total Diet Survey (2004), Yet to be *published.*
[20] Vannoort, R.W. (2003) *2003/4 New Zealand Total Diet Survey: Analytical Results - Q1 20 November 2003*. www.nzfsa.govt.nz/science-technology/research-projects/total-diet-survey/reports/quarter-1/quarter-1-nztds.pdf. Vannoort, R.W. (2004b) *2003/4 New Zealand Total Diet Survey: Analytical Results - Q3 8 July 2004*. www.nzfsa.govt.nz/science-technology/research-projects/total-diet-survey/reports/quarter-3/quarter-3-nztds.pdf.
[21] United Kingdom Food Standards Agency. (2000). *'MAFF UK – Iodine in Milk'*; http://www.foodstandards.gov.uk/science/surveillance/maffinfo/2000/maff-2000-198.
[22] Preiss U, aro Santos C, Spitzer A, Wallnofer PR. (1997). 'Iodine content of Bavarian consumer milk'. *Z Ernahrungswiss*, **36**:220-224 (In German).
[23] FAO/WHO (2002); 'Human Vitamin and Mineral Requirements: Report of a Joint FAO/WHO Expert Consultation Group'; FAO/WHO, Bangkok; p181-194.

Table 3 is a summary of the statistical analysis of this data. Iodine levels range from a minimum of 21.3 μg/ 44 g serving to a maximum of 42.3 μg/44 g serving, with a mean of 28.9 μg/44 g serving.

Table 3: Statistical Analysis of the Iodine Levels in Progress 3rd Age Toddler Gold

CODE	μg I /100 g	μg I /44 g serving
Mean	65.6	28.9
Min	48.4	21.3
Max	93.9	41.3
Std Dev*	12.1	5.3
Mean + 3 std. dev*	101.8	44.8

* = Standard Deviation

The Applicant currently manufactures its FSFYC in Ireland where the iodine level in this product can reach a maximum of 52 μg per 44 g serving. Production will soon be transferred to Singapore where the iodine level in the milk ingredients for this region can reach a maximum of 56 μg per 44 g serving.

To prevent iodine levels of FSFYC exceeding the maximum permitted quantity without an amendment to the Code, manufacturers would need to screen the iodine content in all ingredients derived from milk. The Applicant has indicated that this is not logistically feasible for manufacturers to undertake, as other attributes of milk ingredients set the quality benchmark for their use e.g. milk protein levels.

4.7 Other Relevant FSANZ Work Activities

4.7.1 Application A493

FSANZ recently completed an assessment of Application A493 – Iodine as a Processing Aid, and approved the use of elemental iodine as a washing agent for fruits, vegetables (including herbs), nuts and eggs with a maximum permitted residue level of good manufacturing practice (GMP).

Given the potential for the iodine residue from the sanitising wash to contribute to dietary iodine intake, Application A493 was originally assessed in tandem with Application A528. However, as the overall impact of Application A493 was considered minimal to the diets of 2-3 year olds, it was no longer deemed necessary to consider these Applications together.

Consequently, the Final Assessment for Application A493 was progressed independently of Application A528 and finalised in March 2005.

At Final Assessment there was some uncertainty around the likely industry uptake of the approved permission. Therefore, FSANZ has proposed to review the use of iodine as a processing aid three years after the date of gazettal. Application A493 was gazetted on 26 May 2005.

4.7.2 Mandatory iodine fortification

Since receipt of this Application, FSANZ has also commenced work on a proposal to assess the need for mandatory fortification of the food supply with iodine. Proposal P230 – Consideration of Mandatory Iodine Fortification is currently at Draft Assessment. In undertaking this assessment, FSANZ will need to consider all indiscriminate sources of iodine in the food supply and may need to reassess iodine permissions in the future, if considered necessary.

5. Relevant Issues

5.1 Risk Assessment

FSANZ has undertaken three separate assessments to inform an overall assessment of risk. These assessments are the Safety Assessment, the Dietary Intake Assessment, and the Nutrition Risk Assessment.

Since Draft Assessment these three risk assessment reports have been revised on the basis of comments received from submitters, and additional scientific information. The following two key changes have been made:

- the 1-3 year old assessment has been divided into separate assessments for 1 year-old and 2-3 year-old children; and

- the use of a tolerable upper intake level (UL)24 in place of the provisional maximum tolerable daily intake (PTDI) level as used at Draft Assessment.

Full reports on the Safety Assessment, the Dietary Intake Assessment, and the Nutrition Assessment are provided at Attachments 2, 3 and 4 respectively. A summary of their findings can be found in the following sections followed by an overall characterisation of risk.

5.1.1 Safety Assessment

A large number of human experimental, clinical, and epidemiological studies on the effects of excess iodine 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.

Excess iodine can produce an enlargement of the thyroid gland (goitre) and/or affect the production of the thyroid hormones. A diminished production of thyroid hormones is referred to as hypothyroidism (and may be accompanied by goitre), while increased thyroid hormone synthesis and secretion by the thyroid gland is referred to as hyperthyroidism.

[24] The tolerable upper intake level is the highest level of daily nutrient intake that is like to pose no risks of adverse health effects in almost all individuals.

The human response to excess iodine can vary. Some individuals can tolerate 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 intake levels often have an underlying thyroid disorder or have a long history of iodine deficiency.

At Draft Assessment, FSANZ used a PTDI value of 1000 µg/day (17 µg/kg bw/day) set by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) as an upper iodine intake limit for its risk assessment. FSANZ has now replaced this value with an UL for iodine in order to be consistent with the normal risk assessment methodology for nutrients. A UL of 1100 µg iodine/day for adults is based on the UL for adults established by the US Institute of Medicine, and is consistent with the draft UL recommended by the National Health and Medical Research Council for Australia and New Zealand[25]. The UL has been adjusted for children on a bodyweight basis; therefore the relevant UL for 1-3 year old children is 200 µg/day.

It needs to be noted, however, that individuals with thyroid disorders or a long history of iodine deficiency may respond adversely at levels of intake below the UL. Therefore, the health risk for these individuals needs to be considered separately from the general population.

5.1.2 Dietary Intake Assessment

Dietary iodine intakes by the target population of 1-3 year old children for FSFYC have been estimated for Australia only, as there are no New Zealand National Nutrition Survey (NNS) food consumption data for children aged 1-3 years. Dietary iodine intakes have been calculated for children aged 2-3 years, based on the 1995 Australian NNS data. Since there are no Australian NNS food consumption data for children below 2 years of age, the dietary iodine intakes for 1 year-old children were calculated from a theoretical diet that was extrapolated from 2 year-old food intakes, and adjusted for a lower body weight and higher milk consumption.

Since Draft Assessment new analytical iodine concentration data have become available for both Australian and New Zealand foods through the 22nd Australian Total Diet Survey and the 2003/4 New Zealand Total Diet Survey. Additionally, through a submission to the A493 – Iodine As A Processing Aid Application, the Department of Health and Human Services (DHHS), Tasmania have supplied FSANZ with data on the iodine concentrations in bread and milk available in Tasmania. These data differ from those derived from a nationally representative sample for these foods. It was deemed necessary to completely review the iodine concentration data sets to ensure that the most up-to-date analytical data were used in the dietary intake assessments.

In Tasmania, bread has higher iodine concentrations due to the majority of bread manufacturers using iodised salt in place of non-iodised salt. To take the higher Tasmanian bread iodine concentration into account, two model types were examined in the dietary iodine intake assessments. These are:

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[25] NHMRC (2004) *Draft Nutrient Reference Values for Australia and New Zealand including Recommended Dietary Intakes*, National Health and Medical Research Council, Canberra. http://www7.health.gov.au/nhmrc/advice/nrv.htm

1. ‘National’ Modelling:
   This model uses nationally representative iodine concentrations for all foods.

2. ‘Tasmanian’ Modelling
   This model uses Tasmania’s bread iodine concentrations in addition to nationally representative iodine concentrations for all other foods. These models are for the Tasmanian population only.

Baseline intakes of iodine were calculated using known concentrations of iodine in food in addition to the assumed consumption of FSFYC with a maximum permitted iodine quantity of 35 µg/serve (if prepared according to directions). One other scenario was examined in the dietary intake assessment: Scenario 1 models for a mean increase in the iodine content of FSFYC to 45.5 µg/serve (if prepared according to directions). The modelled increase of Scenario 1 is based on information from the Applicant, which indicates that natural iodine fluctuations in milk produce FSFYC that exceed the current 35 µg/serve limit 30% of the time. Both baseline and Scenario 1 models have iodine concentration adjustments for different preparation methods, and also include iodine intakes from non-milk food sources. Dietary iodine intakes were estimated in two ways: by ‘market share’ and ‘milk substitution’ methodologies. The methodologies and scenarios used in the assessment of this Application are summarised in Table 4 below.

The Applicant’s FSFYC label instructions state that the product may be made up ‘to taste’ using milk or it can be made up using water. Research data from the Applicant showed that approximately 70% of consumers make up their product using milk. For the Applicant’s product only, it was assumed that consumers of FSFYC made with milk would add 2 scoops of powdered FSFYC to 200 ml of milk (equivalent to 40% product used to make up in water). For all other brands of FSFYC, it was assumed that they are made up with water only and according to label directions since there were no label directions for making the product up with milk for these brands.

TABLE 4. SUMMARY OF METHODOLOGIES USED TO ESTIMATED DIETARY IODINE INTAKES FOR AUSTRALIAN CHILDREN AGED 1 YEAR AND 2-3 YEARS

		BASELINE	**SCENARIO 1**
MARKET SHARE METHOD		**Applies to mean consumers only**	**Applies to mean consumers only**
	National population model 2-3 year olds	Iodine intake from all foods except full fat milk + Iodine intake from full fat milk. Full fat milk iodine concentration was derived from market share weighted iodine concentrations for FSYSC and milk as per Figure 1 (see Section 4.3) (assumes 20% of full fat milk is replaced by FSYSC with an iodine concentration of **35 ug/serve** and adjustments for preparation methods)	Iodine intake from all foods except full fat milk + Iodine intake from full fat milk. Full fat milk iodine concentration was derived from market share weighted iodine concentrations for FSYSC and milk as per Figure 1 (see Section 4.3) (assumes 20% of full fat milk is replaced by FSYSC with an iodine concentration of **45.5 ug/serve** and adjustments for preparation methods)
	Tasmanian population model 2-3 year olds	As for national population model **except** the iodine concentration in bread used in the calculation of iodine intake from all foods except full fat milk is increased from **3 µg/kg** to **350 µg/kg**	As for national population model **except** the iodine concentration in bread used in the calculation of iodine intake from all foods except full fat milk is increased from **3 µg/kg** to **350 µg/kg**
	1 year old National and Tasmanian models	As for 2-3 year old models **except** full fat milk category includes yoghurts **and** the 1 year old dietary intakes are based on a model diet rather than actual dietary records	As for 2-3 year old models **except** full fat milk category includes yoghurts **and** the 1 year old dietary intakes are based on a model diet rather than actual dietary records

TABLE 4. SUMMARY OF METHODOLOGIES USED TO ESTIMATED DIETARY IODINE INTAKES FOR AUSTRALIAN CHILDREN AGED 1 YEAR AND 2-3 YEARS

		BASELINE	**SCENARIO 1**
MILK SUBSTITUTION METHOD		**Applies to mean and high percentile consumers of milk**	**Applies to mean and high percentile consumers of milk**
	National population model 2-3 year olds	Mean iodine intake from all foods except full fat milk, using actual dietary records + For **mean milk** consumer: Iodine intake from **mean** full fat milk consumption – (assuming 1 serve consumed as FSYSC and rest as full fat milk; FSYSC with an iodine concentration of **35 ug/serve**) For **high milk** consumer: As per mean milk consumer **except** 95th percentile full fat milk consumption is used rather than the mean consumption figure, as derived from DIAMOND	Mean iodine intake from all foods except full fat milk, using actual dietary records + For **mean milk** consumer: Iodine intake from **mean** full fat milk consumption – (assuming 1 serve consumed as FSYSC and rest as full fat milk; FSYSC with an iodine concentration of 4**5.5 ug/serve**) For **high milk** consumer: As per mean milk consumer **except** 95th percentile full fat milk consumption is used rather than the mean consumption figure, as derived from DIAMOND
	Tasmanian population model 2-3 year olds	As for national population model **except** the iodine concentration in bread used in the calculation of iodine intake from all foods except full fat milk is increased from **3 µg/kg** to **350 µg/kg**	As for national population model **except** the iodine concentration in bread used in the calculation of iodine intake from all foods except full fat milk is increased from **3 µg/kg** to **350 µg/kg**
	1 year old National and Tasmanian models	As for 2-3 year old models **except** full fat milk category includes yoghurts **and** the mean iodine intake from all foods except full fat milk, is based on a model diet rather than actual dietary records **and** For high consumer of milk model, 95th percentile full fat milk consumption derived by applying a multiplication factor of 2.5 to mean consumption for this category	As for 2-3 year old models **except** full fat milk category includes yoghurts **and** the mean iodine intake from all foods except full fat milk, is based on a model diet rather than actual dietary records **and** For high consumer of milk model, 95th percentile full fat milk consumption derived by applying a multiplication factor of 2.5 to mean consumption for this category

5.1.2.1 Results: 'Market Share' Methodology

In the 'market share' methodology, the iodine concentration in milk was weighted according to reported usage of FSFYC and full fat milk, various FSFYC preparation methods and the market shares held by the FSFYC manufacturers. The dietary intake assessment using this methodology provides information on mean dietary iodine intakes for the population group over a period of time. For Australian children aged 2-3 years and 1 year, the estimated mean dietary intakes of iodine were below the iodine UL for 1-3 year-old children (200 μg/day) for all of the scenarios and model types examined. (See Figures 3-4 and 13-14 of Attachment 3 and Tables A1.1-A1.3 in Appendix 1 of Attachment 3 for full results.)

5.1.2.2 Results: 'Milk Substitution' Methodology

In the 'milk substitution' methodology, it is assumed that 1 serve of FSFYC replaces an equivalent amount of milk for a mean consumer of milk and for a higher consumer of milk. For the 'milk substitution' methodology, the estimated dietary iodine intakes for 1 year-old children (both mean milk consumers and high milk consumers) were below the UL. The estimated dietary iodine intakes for mean milk consumers aged 2-3 years were also below the UL. For high (95^{th} percentile) milk consumers aged 2-3 years, the estimated dietary iodine intakes were at the UL (200 μg/day) for all National models but exceeded the UL for all Tasmanian models. (See Figures 5-8 and 15-18 of Attachment 3 and Tables A2.1-A2.4 in Appendix 2 of Attachment 3 for full results.)

5.1.3 Nutrition Assessment

The iodine status of 1-3 year olds, as measured by urinary iodine data, has been researched only by one study[26]. This study shows that New Zealand 1-3 year old children are mildly deficient subpopulation (mean urinary iodine = 59 μg/L), and that 33% of this group is moderately deficient (urinary iodine < 50 μg/L).

No urinary iodine studies have been conducted in Australian 1-3 year-old children, although older childhood population studies indicate that Australian and New Zealand children have a reduced iodine status. Therefore, it is assumed that Australian 1-3 year old children have an iodine status generally similar to New Zealand 1-3 year old children, although the actual iodine status of Australian 1-3 year-old children may be less severe than has been reported because Australian milk contains higher mean iodine levels than New Zealand milk.

The Nutrition Assessment also compares dietary iodine intakes against the Estimated Average Requirement (EAR) (a reference for measuring nutritional inadequacy). Only the first 24-hour recall data of the NNS were used in this assessment, as second day data were not available for 1-3 year-old children. The results of the EAR assessment show that a substantial proportion (43%) of young children have intakes below the EAR at baseline, although the absence of second day NNS data may mean that the actual level of inadequacy has been overestimated.

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

This level of inadequacy decreases to 37% of 1-3 year old children when the proposed increase to the iodine level in FSFYC is modelled, showing that this change may have a beneficial effect on those 1-3 year old children who are not able to obtain sufficient iodine in the diet.

There is no available scientific literature to suggest that increased iodine intakes inhibit the bioavailability of any other nutrient. However, the presence of low selenium intakes in a population (such as in New Zealand) may exacerbate any iodine deficiencies that are currently prevalent amongst children, because of a relationship between the selenium and iodine status of the human body. This effect magnifies the potential for any reduced iodine status that may exist for New Zealand 1-3 year olds.

In conclusion, there is a significant proportion of 1-3 year old Australian and New Zealand children that do not obtain sufficient quantities of iodine from the diet. As the Dietary Intake Assessment has shown, an increase in the maximum permitted iodine limit as sought by Application A528 and consumption of FSFYC could increase iodine intakes of 1-3 year old children, albeit by a small margin. Such an increase therefore represents a potential health benefit for a section of the 1-3 year old population.

5.1.4 Characterisation of Risk

The public health and safety risk to the Australian and New Zealand 1-3 year old population has been characterised on the basis of the above findings of the Safety Assessment (Section 5.1.1), the Dietary Intake Assessment (Section 5.1.2), and the Nutrition Assessment (Section 5.1.3).

For mean and high consumers in the 1 year old and 2-3 year old populations, the dietary intake assessment using the 'market share' model indicates that there would be only a small increase in iodine intake above the current baseline iodine intake level as a result of the proposed change in the level of iodine in FSFYC. Using this model, the new iodine intake level would be well below the UL for iodine for 1-3 year olds.

For the same population groups using the 'milk substitution' model, the dietary intake for mean and high consumers in the 1 year old population and for mean consumers in the 2-3 year population is higher than in the previous model but below the UL as a result of the proposed change in level of iodine in FSFYC. For the high consumers in the 2-3 year old population, however, the dietary intake of iodine was at the UL (100% UL) using 'National' data and slightly above the UL (<110% UL) using 'Tasmanian' data, as a result of the proposed change in the maximum level of iodine in FSFYC.

While a dietary intake above the UL is not desirable, there are a number of factors that need to be considered before concluding that there is a public health and safety risk in this 2-3 year old population. These factors are:

- firstly, there is considerable uncertainty in the dietary intake modelling, which makes a number of conservative assumptions that tend to overestimate the potential dietary intake;

- secondly, the toxicological endpoint on which the UL is based is sub-clinical hypothyroidism. In most individuals, sub-clinical hypothyroidism represents a transient adaptive response to increased levels of iodine that only rarely progresses to clinical hypothyroidism; and

- thirdly, the baseline intake of iodine for high milk consuming 2-3 year-olds is high and close to, or at the UL before the modelling to replace milk with FSFYC was undertaken.

When these factors are taken in account, it is apparent that the small increase above the UL observed in the high consuming 2-3 year old group is unlikely to result in public health and safety concerns.

At the other end of the dietary intake spectrum, the Nutrition Assessment indicates that 1-3 year old children in Australia and New Zealand appear to have a mildly reduced iodine status. However, this data also carries some uncertainties:

- the iodine status of Australian 1-3 year old children was assumed to be generally similar to New Zealand iodine status data for the same age group; and

- the extent of iodine inadequacy amongst Australian and New Zealand 1-3 year old children may be overestimated due to the absence of second-day adjustment values.

Despite these uncertainties, the evidence presented in the Nutrition Assessment gives a good indication that some level of iodine insufficiency exists amongst Australian and New Zealand 1-3 year old children. This outcome suggests that both extremes of inadequate and elevated iodine intakes may co-exist amongst young children, and that a small increase in iodine intakes may in fact represent a benefit for some individuals in the 1-3 year old population group.

In conclusion, the results of the Safety, Dietary Intake and Nutrition Assessments show that an increase in the FSFYC maximum iodine limit from 35 to 70 µg/serve is likely to have a relatively small impact on dietary iodine intakes of young children. Although the Dietary Intake Assessment indicates that some young children could exceed the UL, the conservative assumptions inherent in the dietary modelling process mean that the likelihood of 1-3 year old children exceeding the UL is low. Therefore, increasing the maximum iodine limit from 35 to 70 µg/serve for FSFYC is not considered to pose any additional public health and safety risk to young children.

5.2 Risk Management

5.2.1 Increase in the Maximum Permitted Quantity for Iodine

The rationale for the Applicant requesting an increase in the maximum permitted quantity of iodine is to overcome a problem facing some manufacturers whereby endogenous iodine quantities in milk and milk ingredients at times exceed the current upper limits of iodine. The intention of this Application is to accommodate seasonal fluctuations and variations in iodine levels rather then to consistently increase iodine levels to 100% of the RDI per serving.

The Risk Assessment concludes that increasing the maximum permitted quantity of iodine in FSFYC from 35 to 70 μg per serving is not considered to pose any additional public health and safety risk to young children.

Data supplied by the Applicant gives the mean endogenous iodine level for their product as 28.9 μg/serve and the 99.7th percentile as 44.8 μg/serve. This means iodine levels would nearly always be below 45 μg/serve, assuming iodine levels are normally distributed. While dietary modelling results, based on an iodine content of FSFYC to 45.5 μg/serve (if prepared according to directions), show the impact on iodine status is within safety limits, in reality the increase in iodine status would be less than predicted by this modelling.

Therefore, based on the risk assessment, increasing the maximum permitted limit iodine content from 35 (50% RDI) to 70 μg (100% RDI) is safe.

5.2.2. Maximum claim limit of 50% RDI/serve.

The Applicant has requested that Standard 2.9.3 be amended to increase the maximum permitted quantity of iodine from 35 μg (50% RDI) to 70 μg (100% RDI) per serving in FSFYC. Previously concerns have been raised about increasing the maximum permitted quantity and/or the maximum permitted claimable quantity to above 50% of the RDI as being inconsistent with the nature of the Code where vitamin and mineral permissions for formulated supplementary foods are restricted to a maximum claim limit of 50% RDI/serve.

In response to this issue, FSANZ at Draft Assessment proposed to increase the maximum permitted quantity to iodine in FSFYC but **not** to increase the maximum permitted claim applying to the addition of iodine. This was seen as a means of deterring manufacturers from adding iodine above the permitted claim limit of 35 μg/serve. The intention of this is to accommodate fluctuating levels of naturally occurring iodine in milk while discouraging the addition of additional iodine to the maximum permitted quantity of 70 μg/serve. This is in keeping with the nature of the Code where vitamin and mineral permissions for formulated supplementary foods are restricted to a maximum claim limit of 35 μg /serve (50%RDI).

Therefore, FSANZ is to retain the maximum permitted claim of 35 μg /serve for iodine. This is consistent with the guiding principles for considering the vitamin and mineral permissions for formulated supplementary foods as outlined in Proposal P199 (See Section 4.3).

5.3 Other Issues Raised in Submissions

5.3.1 Dietary Modelling

At Draft Assessment, one submitter supported maintaining the *status quo* as they considered the dietary intake assessment to underestimate the potential intake of iodine. This concern stemmed from there being no food consumption data for children aged 1 –2 years, and the assumptions used in the dietary modelling regarding the preparation of FSFYC. There was also concern raised about the risk of exceeding the PMTDI (Provisional Maximum Tolerable Daily Intake) for iodine if carers were to substitute the recommended quantities of milk for 1-2 year old children (500-600 ml per day) with FSFYC.

In response to these concerns, FSANZ has significantly revised the dietary modelling at Final Assessment (see Attachment 3 for full details). Specifically, this has involved:

- inclusion of a 'theoretical 1 year old' diet;
- changes to the model regarding preparation of FSFYC, based on current label instructions from all identified commercially available FSFYC; and
- additional dietary intake assessment methodology to address the dietary iodine intakes of high consumers of milk, including FSFYC, in addition to new data provided by the Applicant on the frequency of consumption of FSFYC.

5.3.2 Data availability and monitoring of iodine intake

Two submitters raised concerns about the lack of available data and the difficulties this creates in conducting dietary intake assessments. There was also a request for monitoring iodine levels over the next few years.

FSANZ has since Draft Assessment been able to incorporated new data on the iodine content of food and the consumption patterns of FSFYC in the revised dietary modelling included in this Final Assessment Report (see Attachment 3). Nevertheless, FSANZ has made an assessment on the best available information and does acknowledge that there are data uncertainties and limitations in this assessment.

In relation to on-going monitoring of the iodine content of food, FSANZ will as part of its consideration of mandatory iodine fortification (see Section 4.7.2) and review of iodine as a processing aid (see Section 4.7.1) be continuing to consider iodine in the food supply and recognises that it may need to reassess iodine permissions in the future, if deemed necessary.

5.3.3 Maximum Iodine Permissions for Infant Formula Versus FSFYC

At Draft Assessment, one submitter queried why the Applicant is unable to take measures to comply with the iodine requirements of Standard 2.9.3, when infant formulas must also be manufactured to an upper iodine limit. It was suggested that compliance with Standard 2.9.3 could be achieved by sourcing milk powder with known lower levels of iodine, or blending batches of milk powder with varying iodine levels.

The Applicant and other manufacturers of FSFYC have informed FSANZ that compliance with an iodine upper limit is more difficult for FSFYC than for infant formulas, because infant formulas are manufactured from separate base nutritional components, while FSFYC are manufactured predominantly from whole ingredients.

Infant formulas are highly formulated foods, with most basic nutritional components (e.g. amino acids, sugars, fatty acids, vitamins and minerals) added as singular refined substances. Milk often forms the basis for infant formulas, however the milk is separated into its various constituents, which are then added to the formula in specific quantities. Therefore, the nutritional profile of infant formulas can be controlled to a high degree, including the final iodine content.

FSFYC have a lower degree of processing than infant formulas, given that they are designed for a consumer population that has less specific nutritional needs. Whole ingredients are mostly used in the manufacturing process instead of individual components; e.g. milk powders instead of whey proteins and individual amino acids. The naturally occurring levels of iodine in FSFYC are therefore harder to control than for infant formulas.

Manufacturing processes such as screening iodine levels of milk ingredients and blending batches of milk ingredients would be viable measures for regulatory compliance, were manufacturers consistently sourcing these ingredients from a specific geographic locale. However, the production of FSFYC is conducted for a global market, with milk ingredients sourced from a variety of overseas regions, each with its own unique iodine content profile. Controlling the iodine of milk ingredients in this environment is commercially unviable.

6. Regulatory Options

There are two possible options to progress this Application:

1. maintain the *status quo* i.e. the permitted maximum quantity for iodine in FSFYC remains unchanged; or

2. amend Standard 2.9.3 to increase the permitted maximum quantity of iodine in FSFYC from 35 to 70 μg/serve.

7. Impact Analysis

8.1 Affected Parties

The parties affected by this Application are: **consumers** who are most likely very young children; **industry** being Australian and New Zealand importers and manufacturers of FSFYC; and the **Governments** of New Zealand and Australia.

8.2 Cost Benefit Analysis

This analysis assesses the immediate and tangible impacts of current food standards under Option 1 and of the proposed amendment under Option 2.

8.2.1 Option 1 – Status quo

It is likely that maintaining the *status quo* will have minimal impact on **consumers**. Some manufacturers may be required to conduct regular batch testing of ingredients to ensure they comply with the maximum permitted quantity of iodine. This may increase costs associated with the manufacture of FSFYC, which could be passed on to **consumers** via product price increases.

For **industry** however, maintaining the *status quo* means that potentially, during some periods of the year, some manufacturers will find it difficult to comply with the requirements of the Code due to natural variations in the iodine content of base ingredients. The Applicant claims that under the current requirements in the Code, the maximum limit of iodine is exceeded approximately 30% of the time.

Retaining the *status quo* may require some manufacturers to undertake more frequent monitoring of iodine in raw material batches thereby increasing costs and possibly affecting the supply of their products.

With the exception of China, there appears to be no iodine restrictions for FSFYC anywhere else in the world. Maintaining the current iodine maximum limit for FSFYC is likely to necessitate specific formulation for the New Zealand and Australian markets for some producers rather than using one product for the global market. This situation will potentially restrict trade.

With this Application the issue of exceeding the maximum permitted iodine limits in FSFYC manufacture has been highlighted. Consequently there may be increased costs to **government** and enforcement agencies in monitoring the iodine levels in FSFYC.

8.2.2 Option 2 – Amend Standard 2.9.3 to increase the maximum permitted level of iodine in FSFYC from 35 to 70 μg/serve.

An increase in the permitted maximum iodine content of FSFYC may benefit some **consumers** of FSFYC by providing additional iodine, through the natural variation in milk, in their diet. An amendment to the Code will have the most benefit for **industry** as there is likely to be fewer manufacturing costs, particularly in the testing of raw ingredients for iodine levels, for FSFYC and a greater opportunity for regulatory compliance. Furthermore by increasing the quantity of iodine permitted in FSFYC industry are less likely to be required to specifically manufacture FSFYC for New Zealand and Australian markets, thereby increasing trade opportunities.

There is likely to be no impact on **government** as a result of an increase in iodine permission for these products.

8. Consultation

FSANZ released for public consultation from 4 August 2004 to 22 September 2004 a Draft Assessment Report for Application A528. A total of nine (9) submissions were received and are summarised in Attachment 5. All submitters except one supported amending Standard 2.9.3 to increase the permitted maximum level of iodine in FSFYC from 35 to 70 μg/serve.

8.1 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.

Amending the Code to allow an increase in the maximum permitted quantity of iodine in FSFYC, to accommodate levels of naturally occurring iodine in ingredients used to manufacture FSFYC, is unlikely to have a significant negative impact on trade. Therefore, it was not considered necessary to notify the WTO as a Technical Barrier to Trade (TBT) in accordance with the WTO agreements.

10. Conclusion

This Final Assessment Report concludes that amending the Code to accommodate the natural variation of iodine in ingredients used to manufacture FSFYC does not pose any additional public health and safety risk to young children. However, to deter the addition of iodine at consistently higher levels in FSFYC the maximum permitted claim limit of 35 μg per serve has been retained. Therefore, FSANZ approves the draft variation to Standard 2.9.3 (Attachment 1) to increase the maximum permitted level of iodine in FSFYC from 35 to 70 μg per serving for the following reasons:

- the resultant minor increase in iodine intake as a consequence of raising the maximum permitted quantity of iodine in FSFYC does not raise any public health and safety concerns in the target population;

- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act. Specifically, FSANZ has addressed the protection of public health and safety by undertaking a risk assessment using the best scientific data available;

- the proposed draft variation to the Code will increase compliance with the Code, reduce manufacturing costs, and prevent unnecessary trade barriers; and

- the regulation impact assessment concludes that the benefits from increasing the maximum permitted quantity of iodine in FSFYC outweigh any potential costs to affected parties.

11. Implementation

The variation to the Code is to come into effect on the date of gazettal, subject to any request from the Ministerial Council for a review.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Safety Assessment Report
3 Dietary Intake Assessment Report
4 Nutrition Assessment Report
5 Summary of Submissions

ATTACHMENT 1

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

To commence: On gazettal

[1] ***Standard 2.9.3*** *of the Australia New Zealand Food Standards Code is varied by omitting the entry in* Column 2 *of* Table 3 of the Schedule *for* Iodine*, substituting –*

70 µg (100%)

ATTACHMENT 2

SAFETY ASSESSMENT FOR IODINE AT FINAL ASSESSMENT

CONTENTS

Executive Summary

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. The recommended daily intake for iodine for different population groups varies. For adults, the RDI ranges from 100-200 μg/day.

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

Diet is the major source of iodine intake for humans. The major food categories contributing to dietary intake include dairy products, seafood, fruits, vegetables and eggs, with meat and cereals being secondary sources. The iodine content of food is reflective of background levels in the environment as well as the use of iodine and its compounds in food production, processing and manufacturing. In addition to dietary sources, various mineral supplements and medical preparations can further add to iodine intake.

Greater than 97% of ingested iodine 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 the thyroid-stimulating hormone (TSH), which is highly sensitive to dietary iodine intake. At low intakes representing iodine deficiency, uptake of iodide into the thyroid gland is increased and at very high intakes, iodide uptake into the thyroid gland decreases. Once the physiological requirements for thyroid hormone synthesis have been met, the thyroid does not accumulate more iodide and any excess is excreted, primarily in the urine.

A large number of human experimental, clinical, and epidemiological studies on the effects of excess iodine on human health have been reported and reviewed in detail by 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, and it is these effects that are the focus of the report.

Excess iodine can produce an enlargement of the gland (goitre) and/or affect the production of the thyroid hormones. A diminished production of the thyroid hormones is referred to as hypothyroidism (and may be accompanied by goitre) and increased thyroid hormone synthesis and secretion by the thyroid gland is referred to as hyperthyroidism.

The effect on the thyroid depends on the current and previous iodine status of the individual and any current or previous thyroid dysfunction. For example, individuals with a history of iodine deficiency may be prone to the development of iodine-induced hyperthyroidism if iodine exposure increases later in life. Particular life stages may also be more vulnerable to excess iodine, for example the foetus and newborn infants are particularly susceptible to iodine-induced hypothyroidism, whereas adults older than 40 years of age, particularly those living in iodine deficient areas, may be more vulnerable to the development of hyperthyroidism.

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

For the majority of healthy individuals, the most sensitive endpoint for iodine toxicity is sub-clinical hypothyroidism. Sub-clinical hypothyroidism is defined as an elevation in 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 progress to clinical hypothyroidism in some individuals. 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.

A tolerable upper intake level (UL)[27] of 1100 μg iodine/day for adults has been established by the US Institute of Medicine. This level is also likely to be adopted in Australia by the National Health and Medical Research Council as part of their current review of nutrient reference values. FSANZ has adopted this level as a UL for the purpose of risk assessment for the general healthy population. The UL has been adjusted for children on a bodyweight basis, therefore the relevant UL for 1-3 year old children is 200 μg/day.

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

[27] The tolerable upper intake level is the highest level of daily nutrient intake that is like to pose no risks of adverse health effects in almost all individuals.

1. Introduction

Iodine is an important trace element that is essential for the maintenance of normal thyroid function where it is required for the synthesis of the thyroid hormones, L-triiodothyronine (T_3) and L-thyroxine (T_4) (also called 3,5,3', 5'- tetraiodothyronine). T_3 and T_4 are responsible for regulating cellular oxidation and hence have a key role in influencing cellular metabolism and metabolic rate.

The recommended daily intake (RDI) for iodine varies for individuals. The RDI for adults ranges from 100-150 μg/day, with intakes of 150-290 μg/day recommended for pregnant and lactating women. Intakes of 70 μg/day are recommended for young children.

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

The purpose of this review is to examine the toxic effects associated with excess iodine and establish a safe upper level of exposure.

2. Physical and Chemical Properties

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

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

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

3. Sources

The oceans are considered to be the most importance source of natural iodine. Iodine in seawater enters the air via aerosols or as a gas and from there is deposited onto soil, surface water and vegetation.

Diet is regarded as the major source of iodine intake for the population (WHO 1989). Major food categories contributing to dietary intake in Australia and New Zealand include dairy products, seafood (marine fish, shellfish, algae and seaweed), fruits, vegetables and eggs, with meat and cereals being secondary sources.

Additional sources of intake come from the use of iodine and its compounds in a variety of food-related applications including nutrient fortification (e.g., iodised salt), food additives (e.g., dough conditioning and maturing agents), agricultural chemicals (e.g., herbicides and fungicides), animal drugs (e.g., iodine supplements), and sanitisers (e.g., iodophors).

The iodine content of foods is thus both reflective of background levels in the environment as well as processing technology and manufacturing practices. For example, the high iodine content of milk and dairy products has been attributed to the use of iodine-containing supplements in feed for dairy cattle, iodophor-based medications, teat dips and udder washes as well as iodophors used as sanitising agents in dairy processing establishments. The use of iodophors by the dairy industry has however become less commonplace, resulting in milk becoming a less important source of dietary iodine (Eastman 1999).

In addition to dietary sources, various mineral supplements and medical preparations can further increase iodine intake to a significant extent (WHO 1989).

4. Toxicokinetics

4.1 Absorption

Inorganic iodine is >97% absorbed from the gastrointestinal tract, generally as iodide. Although some absorption occurs in the stomach, the small intestine appears to be the principal site of absorption in both humans and rats (Riggs 1952, Small et al 1961). The mechanism by which iodide is transported across the intestinal epithelium is not known. Gastrointestinal absorption appears to be similar in children, adolescents and adults, although absorption in infants may be lower than in children and adults (ATSDR 2004).

4.2 Distribution

Once absorbed, iodide enters the circulation and is distributed throughout the extracellular fluid where it is taken up by those tissues with specialized transport mechanisms for iodide (Cavalieri 1980). The human body contains about 10 – 15 g iodine in total, the majority of which (>90 %) is stored by the thyroid gland (Cavalieri 1997). The concentration of iodine in serum is about 50 – 100 µg/L under normal circumstances, with about 5% being in the inorganic form as iodide and the remaining 95% consisting of various organic forms of iodine, principally protein complexes of the thyroid hormones.

Other tissues that accumulate iodide include the salivary glands, gastric mucosa, choroid plexus, mammary glands, placenta, and sweat glands. The tissue distribution of iodide and organic iodine are very different and are interrelated by metabolic pathways that lead to the iodination and de-iodination of proteins and thyroid hormones.
The uptake of iodide by the thyroid gland is controlled by the thyroid-stimulating hormone (TSH), which is secreted from the anterior lobe of the pituitary gland. In addition to stimulating iodide transport from the blood into thyroid cells, TSH is also responsible for stimulating the oxidation of iodide to iodine, and iodine binding to tyrosine.

Iodide taken up by the thyroid gland is used for the production of the thyroid hormones, which are stored in the gland. Approximately 90% of the thyroid iodine content is in the organic form and includes iodinated tyrosine residues comprising the thyroid hormones T_4 and T_3, and their various synthesis intermediates and degradation products.

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

Children (1 and 10 year olds) appear to have a similar fractional uptake of iodide in the thyroid gland compared to adults (ATSDR 2004). This contrasts to the situation with neonates, who have much greater fractional uptakes; although this quickly declines to the levels of adults by 5 days of age. After the first few weeks, uptake changes very little with age. The percent turnover rates of iodine in the thyroid does change with age, with 0-4 year olds having an apparent half-life of 20 days compared to 33 days in 4-8 year olds and 83 days in 8-12 year olds. Iodine concentration in the thyroid also increases with age with 1-2 year olds having between 95-130 μg iodine/g thyroid tissue compared to 400 μg/g in adults (Stather & Greenhalgh 1983).

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

4.3 Metabolism

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

Initially iodine is incorporated into monoiodotyrosine and diiodotyrosine, which are then coupled together to form the thyroid hormones T_3 (coupling of a monoiodotyrosine and diiodotyrosine residue) and T_4 (coupling of two diiodotyrosine residues). These reactions occur within a large glycoprotein called thyroglobulin, which is synthesized only in the thyroid gland.

TSH regulates every step in the biosynthesis of the thyroid hormones, from the concentration of iodide to the proteolysis of thyroglobulin (Cavalieri 1980). There is a sensitive feedback mechanism between the thyroid and the pituitary gland to maintain the levels of thyroid hormones. This is influenced by the hypothalamus, with thyrotrophin-releasing hormone mediating the secretion of TSH from the pituitary.

Deiodination reactions are carried out by a family of selenoproteins. Iodotyrosine dehalogenase regenerates iodide from monoiodotyrosine and diiodotyrosine for re-use within the thyroid or release into blood, accounting for the iodide leak in the state of chronic iodine excess or certain thyroid conditions (Cavalieri 1997). The liver contains a considerable amount of T_4, some of which is converted into T_3 and some which is excreted into the bile and ultimately reabsorbed or excreted (Cavalieri 1980).

4.4 Excretion

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

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

5. Toxicity of Iodine

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

JECFA concluded there are three potential types of adverse response to excess iodine. The first is disturbance of thyroid activity, which may alter the size of the gland and/or affect the production of thyroid hormones. There is also evidence to indicate that iodine (or the lack of it) may alter the pattern of thyroid malignancy. The second type of response involves sensitivity reactions, which are unrelated to thyroid gland function. Such reactions are typically associated with large doses of iodine (>300 mg/day), which would not be typical from dietary sources. The third type of response results from acute intakes of large quantities (grams) of iodine (iodine poisoning). Cases of iodine poisoning are only rarely seen.

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

5.1 Disturbance of Thyroid Function

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

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

Definitions

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

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

The two most common causes of simple or non-toxic goitre are iodine deficiency (referred to as endemic goitre) or the ingestion of large quantities of goitrogenic foods or drugs. In these cases, the thyroid gland is unable to meet the demands of the body (i.e., because of an inadequate supply of iodine) and enlarges to compensate. Enlargement of the gland is usually sufficient to overcome the mild impairment to hormone production.

Goitre can also be associated with both hypothyroidism and hyperthyroidism. *Hypothyroidism* refers to the diminished production of thyroid hormone leading to clinical manifestations of thyroid insufficiency and can occur with or without goitre. Typical biomarkers of hypothyroidism are a depression in the circulating levels of T_4 and/or T_3 below their normal ranges. This is usually, but not always, accompanied by an elevation of TSH above the normal range. The most common cause of hypothyroidism is Hashimoto's disease (or lymphocytic thyroiditis). Hashimoto's disease is an autoimmune disease in which abnormal antibodies are produced that impair the ability of the thyroid to produce thyroid hormone. The pituitary gland responds by producing TSH and the additional TSH may cause the thyroid gland to enlarge.

Hyperthyroidism is where accelerated thyroid hormone biosynthesis and secretion by the thyroid gland produce thyrotoxicosis. The term *thyrotoxicosis* refers to the hypermetabolic clinical syndrome resulting from serum elevations in thyroid hormone levels, specifically free thyroxine (T_4), triiodothyronine (T_3), or both. The terms hyperthyroidism and thyrotoxicosis are often used interchangeably but are not synonymous. That is, while many patients have thyrotoxicosis caused by hyperthyroidism, other patients may have thyrotoxicosis caused by inflammation of the thyroid gland, which causes release of stored thyroid hormone but not accelerated synthesis, or thyrotoxicosis, which is caused by ingestion of exogenous thyroid hormone.

The most common cause of hyperthyroidism is Graves' disease (diffuse toxic goitre), an autoimmune disease where the immune system produces antibodies that stimulate the TSH receptors of the thyroid gland resulting in the non-suppressible overproduction of thyroid hormone. This causes the thyroid gland to become enlarged. In the elderly, a condition called toxic nodular goitre may cause hyperthyroidism. Toxic nodular goitre occurs when one or more small benign tumours in the thyroid gland produce excess thyroid hormones.

5.1.1 Iodine-Induced Hypothyroidism

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

The most well known of these is the *Wolff-Chaikoff effect* (Wolff et al 1949), where large dietary or therapeutic intakes of iodine can inhibit organic iodine formation (the binding of iodine to tyrosine in the thyroid), producing a decrease in the circulating thyroid hormone levels, and a subsequent increase in TSH. The effect is typically transient, even if the excess intake continues, with most people being able to escape from the inhibition without a clinically significant change to circulating hormone levels. Escape is thought to be the result of the down regulation of the sodium-iodide symport (the iodide transport mechanism in the thyroid gland), leading to a decrease in intrathyroidal iodine and the resumption of normal thyroid hormone synthesis (ATSDR 2004). Most individuals are therefore able to adapt to excess iodine.

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

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

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

A number of studies have examined the acute effects of increased intakes of iodine on the thyroid hormone status of adults (Gardner et al 1988, Georgitis et al 1993, Namba et al 1993, Paul et al 1988, Robison et al 1998). These studies suggest that acute (14 days) iodine exposures of 1500 μg/day (21 μg/kg/day) above the pre-existing dietary intake can be tolerated without producing a clinically adverse change in thyroid hormone levels, although such doses may produce a reversible depression in serum T_4 concentration and a small rise in serum TSH concentrations, both within the normal range of values for healthy individuals.

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

Acute intakes of approximately 700 μg/day (10 μg/kg/day) had no detectable effect on thyroid hormone status in healthy individuals. One study also found no evidence of disturbances in thyroid hormone status in 6 healthy euthyroid[28] males who received doses of 20 mg/day (0.3 mg/kg/day) (Robison et al 1998), suggesting that, at least under certain conditions, exposure levels >10-24 μg/kg/day may be tolerated by some individuals.

[28] Where TSH levels are in the normal range and the thyroid is neither hypothyroid nor hyperthyroid and considered 'normal'.

The level of 1700 μg/day for sub-clinical hypothyroidism has been used by the Institute of Medicine as a lowest-observable-adverse-effect level (LOAEL) (Institute of Medicine 2001). There was considered to be little uncertainty regarding the range of iodine intakes that are likely to induce elevated TSH concentrations above baseline, therefore an uncertainty factor of 1.5 was considered sufficient to derive a Tolerable Upper Intake Level (UL)[29]. A higher uncertainty factor was not considered necessary because of the mild and reversible nature of the endpoint (sub-clinical hypothyroidism) on which the UL is based. The LOAEL of 1700 μg/day was divided by the uncertainty factor of 1.5 to obtain a UL of 1133 μg/day of iodine, which was rounded down to 1100 μg/day. Because of the dearth of available information, the ULs for other life-stage groups were determined by extrapolation from the UL established for adults on the basis of body weight using reference weights. They were: 900 μg/day for 14-18 year olds, 600 μg/day for 9-13 year olds, 300 μg/day for 4-8 year olds, and 200 μg/day for 1-3 year olds. For infants, a UL was judged not determinable because of insufficient data on adverse effects in this age group and concern about the infants susceptibility to excess iodine intake. The National Health and Medical Research Council (NHMRC) in Australia is in the process of developing revised nutrient reference values, and as part of this process will be establishing ULs for a number of nutrients including iodine (NHMRC 2004). The NHMRC draft UL for iodine is similar to the UL derived by the Institute of Medicine.

Two studies have been conducted in prison populations exposed to iodine through iodination of the water supply. In a study by Freund et al (1966), the health and thyroid function of representative subjects of a prison population were assessed before and during usage of iodinated water for nine months. Water containing 1000 μg/L iodine induced a marked decrease in the uptake of radioactive iodine but protein bound iodine levels did not increase significantly until the iodine concentration was increased to 5000 μg/L. No information on actual intake is provided but it has been assumed that water consumption would have been about 1-2 litres/day (WHO 1989). In another study, iodination of a prison water supply at a concentration of 500 to 750 μg/L (estimated intake 1000-2000 μg/day) for up to 15 years did not result in any change to serum T_4 levels (Thomas et al 1978).

During the same period, 177 women in the prison gave birth to 181 full term infants without any enlargement of the thyroid being noted in the infants (Stockton & Thomas 1978). On the basis of these studies, which indicate that 1000 μg iodine/day is safe for the majority of the population, JECFA set a provisional maximum tolerable daily intake (PTDI) of 17 μg/kg bodyweight for iodine from all sources (WHO 1989).

Populations that are iodine deficient and, in particular, those that include people exhibiting goitre, appear to be particularly sensitive to an increase in their iodine intake. For example, iodine supplementation (200-400 μg/day, 3-6 μg/kg/day) for treatment of endemic goitre has been associated with thyroid dysfunction, including thyroid autoimmunity (Kahaly et al 1997, Kahaly et al 1998).

[29] The tolerable upper intake level is the highest level of daily nutrient intake that is likely to pose no risks of adverse health effects in almost all individuals.

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

Results from an epidemiological study of children suggest that chronic exposure to excess iodine (1150 μg/day, 29 μg/kg/day) can result in or contribute to the development of sub-clinical hypothyroidism (Li et al 1987). The study compared thyroid status in groups of children, aged 7-15 years, who resided in two areas of China with different drinking water iodine concentrations, providing estimated iodine intakes of 29 and 10 μg/kg/day. Both groups were all euthyroid with normal values for serum thyroid hormones and TSH concentrations, although TSH concentrations were significantly higher in the high iodine group. This study was used by the ATSDR to establish a chronic-duration minimal risk level (MRL) for iodine of 10 μg/kg/day based on a no-observed-adverse-effect level (NOAEL) of 10 μg/kg/day and a LOAEL of 29 μg/kg/day for sub-clinical hypothyroidism in healthy human children (ATSDR 2004). The ATSDR noted the intake of 29 μg/kg/day did not induce clinical hypothyroidism and that the adverse effect on which the MRL is based (sub-clinical hypothyroidism) is categorised as 'less serious' meaning it is not considered to cause significant dysfunction nor be indicative of functional impairment.

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

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

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

5.1.2 Iodine-Induced Hyperthyroidism (Thyrotoxicosis)

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

The clinical features of iodine-induced hyperthyroidism are said to be similar to that of Graves' disease, however, in contrast to the diffuse goitres associated with Grave's disease, iodine-induced hyperthyroidism is generally associated with nodular goitres. Nodular goitres are fairly common in elderly subjects and are the result of longstanding iodine deficiency.

Many of these nodules are autonomous, meaning they are independent of regulation by TSH and produce thyroid hormone in direct response to dietary iodine. Thus excess iodine may precipitate or aggravate hyperthyroidism in these subjects.

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

A number of epidemiological studies have been conducted in Europe and Africa to monitor the incidence of iodine-induced hyperthyroidism in iodine deficient populations following the introduction of iodine supplementation programs (DeLange et al 1999, Mostbeck et al 1998, Lind et al 1998, Stanbury et al 1998). These studies confirm that iodine supplementation of iodine deficient diets does result in a detectable increase in the incidence of hyperthyroidism. A well-documented case also occurred in Tasmania, Australia, following the introduction of iodised bread in 1966 and the addition of iodophors to milk by the dairy industry (Connolly et al 1970). Milk iodine (from the seasonal use of feed supplements) has also been a factor in Europe (Barker & Phillips 1984, Phillips 1983). A review of these studies indicates that iodine intakes in the range of 3-7 μg/kg/day may be sufficient to produce an increase in hyperthyroidism in iodine deficient populations (ATSDR 2004).

In the Tasmanian case, a 2- to 4-fold increase in hyperthyroidism occurred within a few months after diets were supplemented with iodide for the prevention of endemic goitre from iodine deficiency (Connolly et al 1970). The supplemental dose was 80-200 μg/day from the addition of potassium iodate to bread, but mean urinary iodide excretion rates suggested a total post-supplementation iodide intake of about 230 μg/day (range 94-398), equivalent to 3.3 μg/kg/day, some of which came from other sources such as milk (Connolly 1971a, 1971b).
The highest incidence of hyperthyroidism after the iodine supplementation began occurred in people over 40 years of age (Stewart 1975, Stewart & Vidor 1976). Stewart (1975) noted that the small increase in the incidence of hyperthyroidism that occurred in people under 40 years of age was largely due to Graves' disease.

Cases of iodine-induced hyperthyroidism in people who were euthyroid and without apparent thyroid disease have been reported (Rajatanavin et al 1984, Savoie et al 1975, Shilo & Hirsch 1986), however only a few have provided dose information. In these cases, effects were observed following doses in the range 0.05 – 23 mg/kg/day.

6.1.3 Thyroid malignancy

Several large-scale epidemiological studies have examined the relationship between iodine intake and thyroid cancer. The results of these studies suggest that an increased iodine intake may be a risk factor for thyroid cancer in certain populations, namely, populations residing in iodine deficient, endemic goitre regions (Franceschi 1998, Franceschi & Dal Maso 1999).

Not all of these studies have found an increased risk of cancer, however, a recurrent observation is an apparent shift in the histopathology towards a higher prevalence of papillary cancers, relative to follicular cancers, after increased iodine intake in otherwise iodine-deficient populations (Bakiri et al 1998, Belfiore et al 1987, Kolonel et al 1990, Petterson et al 1991, 1996). Two studies in particular found a significant excess of thyroid gland cancer in populations from endemic goitre regions whose diets had been supplemented to achieve approximate iodine intakes of 3.5 µg/kg bw/day (Bacher-Stier et al 1997, Harach & Williams 1995).

5.2 Sensitivity Reactions

Oral exposure to excess iodine can produce allergic or sensitivity reactions in certain individuals. The reactions include urticaria (hives), acneiform skin lesions (ioderma), and fevers. Cases of more serious reactions involve angioedema (localised oedema), vasculitis, peritonitis and pneumonitis, and complement activation. Both humoral and cell-mediated immune responses are thought to be involved (Curd et al 1979, Rosenburg et al 1972, Stone 1985). In general, reactions to iodide have occurred in association with repeated oral doses of iodide exceeding 300 mg/day.

Ioderma is thought to be a form of cell-mediated hypersensitivity (Rosenburg et al 1972, Stone 1985) and its occurrence appears to be unrelated to thyroid gland function. Characteristic symptoms include acneiform pustules, which can coalesce to form vegetative nodular lesions on the face, extremities, trunk, and mucous membranes. The lesions regress and heal when the excess iodide intake is discontinued. The literature reports cases of ioderma occurring following oral doses of iodide 300-1000 mg/day. However, in many of these cases, pre-existing disease and related drug therapy may have contributed to the reaction to iodide; thus the dose-response relationship for ioderma in healthy people remains highly uncertain.

Oral exposures to iodide > 1000 mg/day have been associated with the occurrence of fevers, which cease once exposure to the excessive iodide intake is discontinued (Kurtz & Aber 1982, Horn & Kabins 1972). The fevers are thought to have an immunological basis and do not appear to be related to thyroid gland function. Reported clinical cases have almost always involved a pre-existing disease, usually pneumonia or obstructive lung disease in which potassium iodide was administered along with other drugs, such as antibiotics, barbiturates and methylxanthines.

5.3 Iodine Poisoning

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

Cases of iodine poisoning are rare however and are typically associated with intakes of many grams. Symptoms observed in lethal or near-lethal poisonings have included abdominal cramps, bloody diarrhoea and gastrointestinal ulcerations, oedema of the face and neck, pneumonitis, haemolytic anaemia, metabolic acidosis, fatty degeneration of the liver, and renal failure (Clark 1981, Dyck et al 1979, Finkelstein & Jacobi 1937, Tresch et al 1974). Death has occurred from 30 minutes to 52 days after ingestion, although death generally occurs within 48 hours. Where the dose was known, it ranged from 1.1 to 9 g iodine (18-150 mg/kg for a 60 kg adult), although there is a single case report of a 54-year-old male surviving the accidental ingestion of 15 g iodine (Tresch et al 1974).

6. Upper Level for Oral Intake

For the majority of healthy individuals, the most sensitive endpoint for iodine toxicity is sub-clinical hypothyroidism. Sub-clinical hypothyroidism is defined as an elevation in 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 progress to clinical hypothyroidism in some individuals. 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.

A tolerable upper intake level (UL) of 1100 μg iodine/day for adults has been established by the US Institute of Medicine. This level is also likely to be adopted in Australia by the National Health and Medical Research Council as part of their current review of nutrient reference values. FSANZ has adopted this level as a UL for the purpose of risk assessment for the general healthy population. The UL has been adjusted for children on a bodyweight basis, therefore the relevant UL for 1-3 year olds is 200 μg/day.

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

7. Susceptibility of Children to a High Dietary Iodine Intake

Prenatal and newborn infants are susceptible to the effects of a high iodine intake because of an immature thyroid gland. Children in the 1-3 year group, however, have a more mature thyroid gland and are instead vulnerable to iodine toxicity primarily as a result of their lower body weight compared to adults (IOM 2001).

For the majority of healthy individuals, including children, the most sensitive endpoint for iodine toxicity is sub-clinical hypothyroidism. Sub-clinical hypothyroidism is defined as an elevation in thyroid stimulating hormone (TSH) concentration while serum thyroid hormone concentration is maintained within the normal range of values. While not clinically adverse, such an effect could lead to full clinical hypothyroidism over a prolonged period of time.

In children, sub-clinical hypothyroidism has only been associated with relatively high chronic iodine intakes (1150 μg/day, or 29 μg/kg/day for a 40 kg child). This level was derived from a study by Mu *et al* (1987), which is the only study identified by FSANZ that specifically assesses the susceptibility of a childhood population to high iodine intake levels. The results of the study (see Table 4 below) show that although both groups showed no clinical signs of hypothyroidism or hyperthyroidism, the TSH levels, thyroid size and goitre results demonstrate that sub-clinical hypothyroidism was significantly more prevalent in the group exposed to high intakes of iodine.

Table 4: Details of the Study by Mu *Et Al* (1987)

Study Design	Subject Type and Numbers		Iodine in Drinking Water (μg/L)	Mean Serum Thyroid Hormone Results			% Group with Goitre	Thyroid gland volume (mL)
				TSH (mIU/L)	T_3 (nmol/L)	T_4 (nmol/L)		
Prospective controlled parallel group study, conducted in Central Chinese schools. Thyroid volumes assessed by ultrasonography	School children aged 7-15 years	Huanglou village, control (n=51)	54	3.9+1.0	1.9+0.2#	101+14	15.4*	5.9
		Gaojiabu village, test (n=120)	462.5	7.8+11.0#	1.6+0.3	101+19	65*	13.3#

* = the statistical significance of these results was not documented

\# = this value is significantly higher than the value obtained for the other group ($p<0.05$)

The levels of iodine in the diet can vary significantly over a given period of time due to the natural fluctuations of iodine content across the food supply. The variability of iodine in the food supply, and particularly within milk, has lead United Kingdom and European agencies to conduct assessments on the potential risks of dietary iodine fluctuations (ESCF 2002, COT 2000). These assessments recognise that established safety limits for iodine intake do not represent an absolute threshold for toxicity, and that children can tolerate natural iodine fluctuations for a short period of time without any appreciable health risk.

From the available data, young children are no more susceptible to high iodine intakes than adults (relative to body weights), and may be less susceptible. The most sensitive health problem – sub-clinical hypothyroidism – occurs only with relatively high iodine intakes according to the study by Mu et al (1987) in children with adequate iodine intakes. There is no information available on the susceptibility of children with chronic low iodine intakes, although the data from studies in adults suggests this group may be more susceptible to an increase in iodine intake, at least in the short-term.

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ATTACHMENT 3

DIETARY INTAKE ASSESSMENT REPORT AT FINAL ASSESSMENT

CONTENTS

Executive Summary

Dietary iodine intakes by the target population of 1-3 year old children for FSFYC have been estimated for Australia only since there are no New Zealand NNS food consumption data for children aged 1-3 years. Dietary iodine intakes have been calculated for children aged 2-3 years, based on the 1995 Australian NNS data. Since there are no Australian NNS food consumption data for children below 2 years of age, the dietary iodine intakes for 1 year old children were calculated from a theoretical diet that was based on food consumption patterns reported for 2 year old children. The methodologies used to estimate dietary iodine intakes are summarised below in Table 1.

No FSFYC were consumed in the 1995 Australian NNS and, as a consequence, assumptions were made about the consumption of FSFYC in the modelling process. The baseline dietary intake of iodine assumed that 2-3 year old children would replace specified proportions of full fat and unspecified fat content fluid cow's milk (plain and commercially flavoured) consumption, including that used in cooking, with FSFYC. Cheeses, ice creams and ice confections, yoghurts and reduced and low fat milks were not replaced with FSFYC.

For 1 year old children, it was assumed that specified proportions of all milks and yoghurts were replaced with FSFYC. The difference in the foods substituted for 2-3 year old children and for 1 year old children is due to the different methodology used to estimate the dietary iodine intakes of 1 year old children. For this reason, the estimated dietary iodine intakes for 1 year old children are presented separately within this report.

Data were received from DHHS on the iodine concentrations of bread and milk available in Tasmania (DHHS, 2004). From the 22nd ATDS, nationally representative milk iodine concentration data that included data for full fat milk sampled from Tasmania and four other States/Territories were available. Inter-laboratory check sample analyses were conducted on sub-samples of milk tested in the 22nd ATDS using three different laboratories. These confirmatory analyses suggested that the 'nationally representative' milk iodine concentrations determined as a part of the 22nd ATDS, most accurately reflected iodine concentrations in Tasmanian milk. In Tasmania, bread has higher iodine concentrations due to iodised salt being used in bread in the place of non-iodised salt by a number of bread manufacturers. To take the higher Tasmanian bread iodine concentration into account, two model types were examined in the dietary iodine intake assessments. These are:

1. 'National' Modelling:
   This model uses nationally representative iodine concentrations for all foods.

2. 'Tasmanian' Modelling
   This model uses Tasmania's bread iodine concentrations in addition to nationally representative iodine concentrations for all other foods. These models are relevant for the Tasmanian population only.

TABLE 1. SUMMARY OF METHODOLOGIES USED TO ESTIMATED DIETARY IODINE INTAKES FOR AUSTRALIAN CHILDREN AGED 1 YEAR AND 2-3 YEARS

		BASELINE	**SCENARIO 1**
MARKET SHARE METHOD		**Applies to mean consumers only**	**Applies to mean consumers only**
	National population model 2-3 year olds	Iodine intake from all foods except full fat milk + Iodine intake from full fat milk. Full fat milk iodine concentration was derived from market share weighted iodine concentrations for FSYSC and milk as per Figure 1 (see Section 4.3) (assumes 20% of full fat milk is replaced by FSYSC with an iodine concentration of **35 ug/serve** and adjustments for preparation methods)	Iodine intake from all foods except full fat milk + Iodine intake from full fat milk. Full fat milk iodine concentration was derived from market share weighted iodine concentrations for FSYSC and milk as per Figure 1 (see Section 4.3) (assumes 20% of full fat milk is replaced by FSYSC with an iodine concentration of **45.5 ug/serve** and adjustments for preparation methods)
	Tasmanian population model 2-3 year olds	As for national population model **except** the iodine concentration in bread used in the calculation of iodine intake from all foods except full fat milk is increased from **3 µg/kg** to **350 µg/kg**	As for national population model **except** the iodine concentration in bread used in the calculation of iodine intake from all foods except full fat milk is increased from **3 µg/kg** to **350 µg/kg**
	1 year old National and Tasmanian models	As for 2-3 year old models **except** full fat milk category includes yoghurts **and** the 1 year old dietary intakes are based on a model diet rather than actual dietary records	As for 2-3 year old models **except** full fat milk category includes yoghurts **and** the 1 year old dietary intakes are based on a model diet rather than actual dietary records

TABLE 1. SUMMARY OF METHODOLOGIES USED TO ESTIMATED DIETARY IODINE INTAKES FOR AUSTRALIAN CHILDREN AGED 1 YEAR AND 2-3 YEARS

		BASELINE	**SCENARIO 1**
MILK SUBSTITUTION METHOD		**Applies to mean and high percentile consumers of milk**	**Applies to mean and high percentile consumers of milk**
	National population model 2-3 year olds	Mean iodine intake from all foods except full fat milk, using actual dietary records + For **mean milk** consumer: Iodine intake from **mean** full fat milk consumption – (assuming 1 serve consumed as FSYSC and rest as full fat milk; FSYSC with an iodine concentration of **35 ug/serve**) For **high milk** consumer: As per mean milk consumer **except** 95th percentile full fat milk consumption is used rather than the mean consumption figure, as derived from DIAMOND	Mean iodine intake from all foods except full fat milk, using actual dietary records + For **mean milk** consumer: Iodine intake from **mean** full fat milk consumption – (assuming 1 serve consumed as FSYSC and rest as full fat milk; FSYSC with an iodine concentration of 4**5.5 ug/serve**) For **high milk** consumer: As per mean milk consumer **except** 95th percentile full fat milk consumption is used rather than the mean consumption figure, as derived from DIAMOND
	Tasmanian population model 2-3 year olds	As for national population model **except** the iodine concentration in bread used in the calculation of iodine intake from all foods except full fat milk is increased from **3 µg/kg** to **350 µg/kg**	As for national population model **except** the iodine concentration in bread used in the calculation of iodine intake from all foods except full fat milk is increased from **3 µg/kg** to **350 µg/kg**
	1 year old National and Tasmanian models	As for 2-3 year old models **except** full fat milk category includes yoghurts **and** the mean iodine intake from all foods except full fat milk, is based on a model diet rather than actual dietary records **and** For high consumer of milk model, 95th percentile full fat milk consumption derived by applying a multiplication factor of 2.5 to mean consumption for this category	As for 2-3 year old models **except** full fat milk category includes yoghurts **and** the mean iodine intake from all foods except full fat milk, is based on a model diet rather than actual dietary records **and** For high consumer of milk model, 95th percentile full fat milk consumption derived by applying a multiplication factor of 2.5 to mean consumption for this category

Baseline intakes of iodine were calculated using known concentrations of iodine in food in addition to the assumed consumption of FSFYC with a maximum permitted iodine quantity of 35 μg/serve (if prepared according to directions). One other scenario was examined in the dietary intake assessment; Scenario 1 applied the proposed maximum permitted iodine quantity in FSFYC of 70 μg/serve (if prepared according to directions). Both baseline and Scenario 1 models made iodine concentration adjustments for different preparation methods in addition to taking intakes from naturally occurring iodine from all other food sources into account.

From data provided by the Applicant, the current maximum permitted iodine quantity of 35 μg/serve can be met only 70% of the time. Therefore, FSFYC may contain up to 70 μg of iodine per serve approximately 30% of the time. It was assumed that, over a period of time, children will consume FSFYC products with the above concentrations of iodine and in the specified ratios and that they will not be consuming products containing 70 μg of iodine per serve for extended periods of time. Therefore, for dietary modelling purposes, the maximum iodine quantity in FSFYC was considered to be 45.5 μg/serve (if prepared according to directions) for Scenario 1. Iodine from added salt or supplements was not included in the calculation as no data were available on consumption levels.

Summary of Results

‘Market Share’ Methodology

For Australian children aged 2-3 years and 1 year, the estimated mean dietary intakes of iodine were below the upper level for iodine of 200 μg/day for all of the scenarios and model types examined.

For Australian children aged 2-3 years, the major contributors to dietary iodine intake were dairy products (65% for ‘Tasmanian’ models and 80% for ‘National’ models), fruits (10% for both ‘National’ and ‘Tasmanian’ models) and cereal foods (20% for ‘Tasmanian’ models only).

‘Milk Substitution’ Methodology

For the ‘milk substitution’ methodology, the estimated dietary iodine intakes for mean milk consumers and high milk consumers aged 1 year were below the UL. The estimated dietary iodine intakes for mean milk consumers aged 2-3 years were also below the UL. For high milk consumers aged 2-3 years, the estimated dietary iodine intakes were at the UL for all National models but exceeded the UL for all Tasmanian models. The dietary iodine intakes for high milk consumers for the ‘Tasmanian’ – baseline and ‘Tasmanian’ – Scenario 1 models were estimated as being 110% of the UL.

While an upper intake level (UL) has been set for iodine, iodine is also an essential micronutrient. Consequently, dietary intakes were also estimated for the purpose of comparison with the Estimated Average Requirements (EARs) for iodine. Further details on the results of the comparison of dietary intakes with the EARs for iodine can be found in the Nutrition Report at Attachment 4.

The estimated dietary iodine intakes have not been adjusted to take into account iodine intakes over a longer period of time.

Recommendations for improving iodine intake estimates

1. That further iodine analyses be undertaken for mixed foods in the Australian and New Zealand food supplies.

2. That the capacity to estimate dietary iodine intakes for both days of the National Nutrition Surveys be built upon to allow dietary iodine intakes that are more representative of longer term intakes to be estimated.

1. Introduction

An Application was received by FSANZ requesting an amendment to Standard 2.9.3 – Formulated Meal Replacements and Formulated Supplementary Foods of the *Australia New Zealand Food Standards Code* (the Code) to increase the maximum permitted quantity of iodine per serving from 35 μg (50% Recommended Dietary Intake (RDI)) to 70 μg (100% RDI) in formulated supplementary foods for young children (FSFYC). FSFYC are defined in the Code as formulated supplementary food for children aged 1 – 3 years.

A dietary intake assessment was deemed necessary in order to determine the potential impact of granting permission to increase the maximum permitted quantity of iodine in FSFYC from 35 μg/serve to 70 μg/serve on the iodine intake of the target population. The serve size of a FSFYC varies depending on the brand of FSFYC. For the products that FSANZ has examined, one serve is in range of 174 - 236 g. Iodine intakes, based on known concentrations of iodine in foods and the requested permissions for iodine in FSFYC, were assessed to determine if estimated iodine intakes exceeded reference health standards.

Since the Draft Assessment report was written for this Application, new analytical iodine concentration data have become available for both Australian and New Zealand foods through the 22nd Australian Total Diet Survey and the 2003/4 New Zealand Total Diet Survey. Additionally, through a submission to the A493 – Iodine As A Processing Aid Application, the Department of Health and Human Services (DHHS), Tasmania have supplied FSANZ with data on the iodine concentrations in bread and milk available in Tasmania. These data differ from those derived from a nationally representative sample for these foods. It was deemed necessary to completely review the iodine concentration data sets to ensure that the most up-to-date analytical data were used in the dietary intake assessments.

FSANZ has reviewed the labels of FSFYC available commercially and found that the current label instructions for making up FSFYC differ from the instructions used at Draft Assessment. These new data have been included in the Final Assessment.

Through the submissions process, concern was raised about the dietary iodine intake of one year old children. At Draft Assessment, only data directly from the 1995 Australian National Nutrition Survey (NNS) were used. The 1995 NNS collected data for Australians aged 2 years and above. In order to address the concern about one year old children, a ‘theoretical 1 year old’ diet was constructed, based on food consumption data for 2 year old Australian children, with adjustments for a relatively higher milk consumption for younger children and lower body weights.

It was also identified through a submission that the guideline for milk consumption for 1-2 year old children in New Zealand is 500-600 ml per day. Concern was raised about the risk of exceeding the PMTDI (Provisional Maximum Tolerable Daily Intake) for iodine if carers were to substitute the guideline quantities of milk with FSFYC. This report includes an additional dietary intake assessment methodology to address the dietary iodine intakes of high consumers of milk, including FSFYC. Additionally, the Applicant provided data on the frequency of consumption of FSFYC.

At Draft Assessment, the reference upper health standard used for comparison with dietary iodine intakes was a Provisional Tolerable Daily Intake (PTDI) of 17 µg/kg bw/day (WHO, 1989). Since Draft Assessment, the National Health and Medical Research Council (NHMRC) have reviewed the Nutrient Reference Values (NRVs) and published a draft report (NHMRC, 2004). The NHMRC proposed UL for iodine for 1-3 year old children is 200 µg/day. This is the same as the UL set for the United States (Institute of Medicine, 2001; NHMRC, 2004). In this Final Assessment report, the proposed NHMRC UL was used as the reference upper health standard, not the PTDI.

For the reasons listed above, the dietary intake assessment for A528 has been revised for Final Assessment.

The dietary intake assessments presented in this report are estimates only and incorporate a number of assumptions and limitations. While the best available data and the assumptions deemed as being most appropriate have been considered, care needs to be taken in interpreting the results. Potential variation in the results (e.g. due to natural variation in the iodine concentrations in foods) has not been incorporated in the estimates of dietary iodine intake. These results should be used as a guide to risk management decisions.

2. Background

Iodine is a substance that is found naturally in the environment, particularly in seawater, igneous rocks and soils (UK FSA 2002). Iodine is an essential micronutrient. Foods rich in iodine include seafood, milk, eggs and iodised salt. In the Code, salt is permitted to be iodised at a level no less than 25 mg/kg and no more than 65 mg/kg of iodine. This permission is voluntary.

The Applicant has requested an increase in the maximum permitted quantity of iodine in FSFYC to accommodate levels of naturally occurring[30] iodine in ingredients used to manufacture FSFYC. On some occasions, the endogenous quantity of iodine can exceed the maximum permitted iodine quantity due to seasonal and geographical variation in the iodine content of ingredients. The Applicant will not change their current practices but the requested increase in iodine concentration will cover the cases where the raw materials for FSFYC do not meet the current iodine limit of 35 µg per serve approximately 30% of the time, as claimed by the Applicant. The Applicant has requested that FSANZ raise the upper limit of iodine permitted in FSFYC from 35 µg per serve to 70 µg per serve.

[30] In this case 'naturally occurring' refers to the innate iodine content in addition to any adventitious contamination which may occur during the processing of ingredients e.g. iodophors in milk.

3. Dietary Intake Assessment Provided by the Applicant

The Applicant submitted iodine dietary intake assessment data for British children aged 1½ - 4½ years indicating that estimated iodine dietary intakes may vary between 87 µg/day and 309 µg/day, with almost all iodine being derived from the consumption of milk.

The dietary intake assessment submitted by the Applicant was not detailed enough to allow FSANZ to determine a conclusion since the dietary intake data submitted relate to dietary intake for British children. Since no Australian or New Zealand dietary intake assessment data were provided, FSANZ conducted its own dietary intake assessment.

4. FSANZ Dietary modelling

Dietary modelling was conducted by FSANZ to estimate potential dietary intakes of iodine for Australian children aged 1-3 years should the maximum permitted iodine level in FSFYC be increased from 35 µg/serve to 70 µg/serve to take into account natural variation in the iodine concentration in FSFYC raw ingredients. The dietary intake assessments include iodine from food sources in the diet, but not from supplements or discretionary use of iodised salt. Information on iodine intake from supplements was not available. Discretionary salt use was not measured in the 1995 NNS nor the 1997 New Zealand NNS, therefore intake of iodine from discretionary salt use could not be accurately determined.

The dietary intake assessment was conducted using dietary modelling techniques that combine food consumption data, derived from the 1995 NNS, with food iodine concentration data to estimate the intake of iodine from the diet. The dietary intake assessment for 2-3 year olds was conducted using FSANZ's dietary modelling computer program, DIAMOND. A model diet was constructed for 1 year old children.

Dietary intake = food chemical concentration x food consumption

4.1 Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. The New Zealand data were not used for this assessment as they did not include children in the target age group (1-3 years). Both of the NNSs used a 24-hour food recall methodology. These data were sufficient to estimate baseline intakes of iodine from food sources.

4.2 Iodine Concentration Levels

For the Final Assessment, new analytical iodine concentration data was available for both New Zealand and Australian foods through the 2003/4 New Zealand Total Diet Survey and the 22nd Australian Total Diet Survey. Additionally, DHHS supplied FSANZ with data on the iodine concentration in bread and milk available in Tasmania. It was deemed necessary to completely review the iodine concentration data sets to ensure that the most up-to-date analytical data were used in the dietary intake assessment. Additionally, FSANZ also reviewed the FSFYC products available commercially and found that the current label instructions for making up FSFYC differ from the instructions used at Draft Assessment. These new data have been included in the Final Assessment for this Application.

The levels of iodine in foods that were used in the dietary intake assessment were derived from the A528 Application, Australian and New Zealand food composition and Total Diet Survey data, overseas food composition data, the Applicant for A493 – Iodine as a Processing Aid, and the DHHS. The foods and concentrations of iodine used in the intake assessment are shown below in Tables 2 and 3 for 2-3 year old and 1 year old children, respectively.

Concentrations of iodine were assigned to food groups using DIAMOND food classification codes, based on raw agricultural commodities. The foods proposed by the Applicant to contain iodine were matched to the most appropriate DIAMOND code for dietary modelling purposes.

4.2.1 Iodine in Milk and FSFYC

Through the submissions process, it was raised that FSANZ should be performing dietary modelling using an iodine concentration for FSFYC derived from the manufacturers' instructions for the product. The Applicant's (Wyeth's) product label states that consumers can make up the product 'to taste' using milk and previous research data from the Applicant showed that approximately 70% of consumers make up their product using milk. For the Applicant's brand of product only, it was assumed that consumers of FSFYC made with milk would add 2 scoops of powdered FSFYC to 200 ml of milk (equivalent to 40% product used to make up in water). For all other brands of FSFYC, it was assumed that they are made up with water only and according to label directions since there were no label directions for making the product up with milk for these brands. In determining the iodine concentration for FSFYC, the percentage of the FSFYC market held by the Applicant was also taken into account.

The Applicant reported that it holds approximately 43% of the FSFYC market. This figure was rounded to 45% for dietary modelling purposes. Since the Applicant's FSFYC label instructions state that the product may be made up 'to taste' using milk or it can be made up using water, these market share data were used in determining the overall iodine concentration of FSFYC. The Applicant also provided research data that showed that, for consumers of FSFYC, the average number of serves of FSFYC per day is one.

TABLE 2: CONCENTRATIONS OF IODINE IN FOODS USED IN THE INTAKE ASSESSMENT FOR AUSTRALIAN CHILDREN AGED 2-3 YEARS

Food Code	Food Name	Mean or Median[#] Iodine Concentration Level (µg/kg)				Baseline Data Source
		Baseline		Scenario 1		
		'National'	'Tasmanian'	'National'	'Tasmanian'	
AP0001	Honey	6	6	6	6	4
DM, GS	Sugars	6	6	6	6	4
CF, GC	Cereal foods	73	73	73	73	9
CF0081, CF0600, CF0654, CM	Bran	10	10	10	10	4
CF0645, CF1255, GC0656	Maize/Corn	7	7	7	7	4
CF1210	Germ	20	20	20	20	2
CF1266, CM1205, GC0649	Rice	9	9	9	9	4
CP	Breads	12	350[#]	12	350[#]	4,10
CP1211	Bread, white	3	350[#]	3	350[#]	4,10
CP1212	Bread, wholemeal	5	350[#]	5	350[#]	4,10
DF	Dried fruits	13	13	13	13	2,3,4
DF0014	Dried prunes	8	8	8	8	4
DF0269	Dried grapes	17	17	17	17	4
DF0295	Dried dates	15	15	15	15	2,3
DT	Teas	63	63	63	63	4
DV	Dried vegetables	931	931	931	931	7
FB	Berries and other small fruits	4	4	4	4	4
FB0269	Grapes	5	5	5	5	4
FB02691	Wine	7	7	7	7	4
FB0275	Strawberries	2	2	2	2	4
FC	Citrus fruits	73	73	73	73	6
FI	Tropical fruits – inedible peel (smooth skinned)	1	1	1	1	4
FI0326	Avocado	5	5	5	5	9
FI0341	Kiwifruit	1	1	1	1	4
FI0353	Pineapple	10	10	10	10	2
FI0332, FI0338, FI0343, FI0358	Tropical fruits – inedible peel (rough skinned)	3	3	3	3	4,9
FP	Pome fruits	5	5	5	5	9
FP0226	Apples	5	5	5	5	9
FP0230	Pears	1	1	1	1	4

TABLE 2: CONCENTRATIONS OF IODINE IN FOODS USED IN THE INTAKE ASSESSMENT FOR AUSTRALIAN CHILDREN AGED 2-3 YEARS

Food Code	Food Name	Mean or Median[#] Iodine Concentration Level (µg/kg)				Baseline Data Source
		Baseline		Scenario 1		
		'National'	'Tasmanian'	'National'	'Tasmanian'	
FS	Stone fruits (smooth skinned)	30	30	30	30	6
FS0240	Apricots	85	85	85	85	2
FS0245	Nectarines	30	30	30	30	6
FS0247	Peaches	51	51	51	51	6
FT, DM0305	Tropical fruit – edible peel	15	15	15	15	5
GC0647	Oats	75	75	75	75	9
HH	Herbs	76	76	76	76	7
HS	Spices	76	76	76	76	7
IM	Molluscs	1,050	1,050	1,050	1,050	1
IM1004	Oysters	1,600	1,600	1,600	1,600	1
IM1005	Scallops	1,500	1,500	1,500	1,500	1
MF	Other mammalian fats (not cattle, pig or sheep)	38	38	38	38	1,2
MF0812	Cattle fat	100	100	100	100	1
MF0818	Pig fat	16	16	16	16	2
MF0822	Sheep fat	20	20	20	20	2
ML	Dairy products	133	133	133	133	9,10
ML08121	Cattle milk – full fat fluid milk only	140	140	148	148	7,9,10
MM0812	Cattle meat	7	7	7	7	9
MM0818	Pig meat	10	10	10	10	9
MM0822	Sheep meat	4	4	4	4	9
MO	Mammalian offal	49	49	49	49	4
OC, OR	Fats and oils	5	5	5	5	9
PE	Eggs	366	366	366	366	9
PF, PM, PO	Chicken meat and offal	4	4	4	4	9
SB	Coffee, cocoa, cola	56	56	56	56	4
SO, CO0691, TN	Oilseeds and nuts	58	58	58	58	1
SO0697	Peanuts	38	38	38	38	1
TN0663	Cashews	100	100	100	100	1
VA	Bulb vegetables	4	4	4	4	4
VA0386	Onions	4	4	4	4	4
VB	Brassica vegetables	4	4	4	4	2,4
VB0041	Cabbage	5	5	5	5	9
VB0400	Broccoli	5	5	5	5	9

TABLE 2: CONCENTRATIONS OF IODINE IN FOODS USED IN THE INTAKE ASSESSMENT FOR AUSTRALIAN CHILDREN AGED 2-3 YEARS

Food Code	Food Name	Mean or Median[#] Iodine Concentration Level (µg/kg)				Baseline Data Source
		Baseline		Scenario 1		
		'National'	'Tasmanian'	'National'	'Tasmanian'	
VB0404	Cauliflower	1	1	1	1	4
VC	Cucurbit vegetables	3	3	3	3	4,6,9
VC0046	Melons, except watermelon	27	27	27	27	6
VC0424	Cucumber	1	1	1	1	4
VC0429	Pumpkin	5	5	5	5	9
VC0431	Zucchini	2	2	2	2	4
VC0432	Watermelon	1	1	1	1	4
VD	Pulses	10	10	10	10	9
VL	Leafy vegetables	76	76	76	76	6
VL0482	Lettuce	76	76	76	76	6
VO	Other fruiting vegetables (smooth skinned)	4	4	4	4	4,9
VO0051	Capsicum	1	1	1	1	4
VO0448	Tomato	6	6	6	6	9
VO0442, VO0446	Other fruiting vegetables (rough skinned)	7	7	7	7	2,4
VO0447	Sweetcorn	40	40	40	40	2
VO449, VO0450	Mushrooms	3	3	3	3	4
VP	Legume vegetables	5	5	5	5	9
VP00611	Beans, green	5	5	5	5	9
VP0529	Peas, garden	5	5	5	5	9
VR	Root and tuber vegetables	7	7	7	7	4,9
VR0508	Sweet potato	3	3	3	3	4
VR0574	Beetroot	16	16	16	16	9
VR0577	Carrots	5	5	5	5	9
VR0589	Potato	7	7	7	7	4
VS	Stalk and stem vegetables	5	5	5	5	9
VS0621	Asparagus	5	5	5	5	9
VS0624	Celery	5	5	5	5	9
WC	Crustacea	300	300	300	300	1
WD	Diadromous fish	600	600	600	600	1
WF0858	Bream	300	300	300	300	1
WR, WS	Other marine fish	231	231	231	231	1
WS0004	Gemfish	200	200	200	200	1
WS0008	Flathead	50	50	50	50	1
WS0010	Snapper	400	400	400	400	1

TABLE 2: CONCENTRATIONS OF IODINE IN FOODS USED IN THE INTAKE ASSESSMENT FOR AUSTRALIAN CHILDREN AGED 2-3 YEARS

Food Code	Food Name	Mean or Median# Iodine Concentration Level (µg/kg)				Baseline Data Source
		Baseline		Scenario 1		
		'National'	'Tasmanian'	'National'	'Tasmanian'	
WS0130	Sardine	100	100	100	100	1
WS0131	Flake	100	100	100	100	1
WS0927	Cod	500	500	500	500	1
WS0943	Mullet	100	100	100	100	1
WS0952	Tuna	150	150	150	150	1
WS0953	Whiting	100	100	100	100	1
WW	Water	2	2	2	2	4
XX0001	Seaweed	14,700	14,700	14,700	14,700	8
XX0002	Dry soup mixes	120	120	120	120	1

(1) unpublished Australian food composition data;
(2) unpublished New Zealand food composition data;
(3) 1997/8 New Zealand Total Diet Survey (Ministry of Health (MOH) 2000);
(4) 2003/4 New Zealand Total Diet Survey (Vannoort 2003; Vannoort 2004a; Vannoort 2004b; Vannoort 2004c);
(5) German Food Composition tables (Souci *et al*., 1994);
(6) A493 Applicant;
(7) derived data;
(8) British food composition data (Holland *et al*., 1991);
(9) 22nd Australian Total Diet Survey (unpublished data);
(10) Personal Communication with Judy Seal (DHHS, 2004).

= median iodine concentration used.

Note: shaded cells indicate a difference between baseline and scenario iodine concentrations or a difference between the iodine concentrations used in 'National' modelling and in the 'Tasmanian' scenario.

TABLE 3: CONCENTRATIONS OF IODINE IN FOODS USED IN THE INTAKE ASSESSMENT FOR AUSTRALIAN CHILDREN AGED 1 YEAR

Food Name	Mean or Median# Iodine Concentration Level (µg/kg)				Baseline Data Source
	Baseline		Scenario 1		
	'National'	'Tasmanian'	'National'	'Tasmanian'	
Almonds	58	58	58	58	1
Apples	5	5	5	5	9
Bacon	14	14	14	14	9
Baked beans	10	10	10	10	9
Bananas	1	1	1	1	4
Beans, green, raw	5	5	5	5	9
Beef, minced	7	7	7	7	9
Biscuits, savoury	8	8	8	8	4
Biscuits, sweet plain	7	7	7	7	4

TABLE 3: CONCENTRATIONS OF IODINE IN FOODS USED IN THE INTAKE ASSESSMENT FOR AUSTRALIAN CHILDREN AGED 1 YEAR

Food Name	Mean or Median[#] Iodine Concentration Level (µg/kg)				Baseline Data Source
	Baseline		Scenario 1		
	'National'	'Tasmanian'	'National'	'Tasmanian'	
Bran, processed wheat	10	10	10	10	4
Bread, multigrain	12	35	12	35	4,10
Bread, white	3	35	3	35	4,10
Breakfast cereal, mixed grain	10	10	10	10	4
Breakfast cereal, single grain	7	7	7	7	4
Broccoli	5	5	5	5	9
Capsicum	1	1	1	1	4
Carrots	5	5	5	5	9
Celery	5	5	5	5	9
Cheese, cheddar	229	229	229	229	9
Chicken breasts	5	5	5	5	9
Coffee, instant	1	1	1	1	9
Dim sim	8	8	8	8	4
Eggs	366	366	366	366	9
Fish fillets, raw, unfrozen	350	350	350	350	9
Fish portion, crumbed, frozen	350	350	350	350	9
FSFYC	169	169	208	208	
Grapes	5	5	5	5	4
Hamburgers	23	23	23	23	4
Infant cereal, mixed	9	9	9	9	9
Infant dessert	72	72	72	72	9
Infant dinner, strained	30	30	30	30	9
Infant formula	77	77	77	77	9
Kiwifruit	1	1	1	1	4
Lamb chops	5	5	5	5	9
Lamington	100	100	100	100	1
Leg Ham	37	37	37	37	4
Lettuce	76	76	76	76	6
Liver pate (chicken)	68	68	68	68	4
Margarine, table spread	5	5	5	5	9
Milk chocolate	158	158	158	158	4
Milk, full fat	133	133	133	133	9,10
Mushrooms	3	3	3	3	4
Nectarines	30	30	30	30	6
Oats, rolled	13	13	13	13	9
Onions	4	4	4	4	4
Orange Juice	9	9	9	9	4

TABLE 3: CONCENTRATIONS OF IODINE IN FOODS USED IN THE INTAKE ASSESSMENT FOR AUSTRALIAN CHILDREN AGED 1 YEAR

Food Name	Mean or Median[#] Iodine Concentration Level (µg/kg)				Baseline Data Source
	Baseline		Scenario 1		
	'National'	'Tasmanian'	'National'	'Tasmanian'	
Oranges	73	73	73	73	6
Pasta, mixed	24	24	24	24	9
Peanut butter	58	58	58	58	1
Peas, frozen	5	5	5	5	9
Potato	7	7	7	7	4
Potato chips	13	13	13	13	4
Prawns	1,050	1,050	1,050	1,050	1
Pumpkin	5	5	5	5	9
Rice, white	3	3	3	3	4
Sausages, meat, thick	80	80	80	80	4
Soft Drink	2	2	2	2	4
Strawberries	2	2	2	2	4
Sugar, white	6	6	6	6	4
Sultanas	17	17	17	17	4
Tomato Sauce	14	14	14	14	4
Tomatoes	6	6	6	6	9
Tuna, canned	130	130	130	130	4
Vanilla Ice cream	213	213	213	213	9
Watermelon	1	1	1	1	4
Wine, white	7	7	7	7	4

(1) unpublished Australian food composition data;
(2) unpublished New Zealand food composition data;
(3) 1997/8 New Zealand Total Diet Survey (Ministry of Health (MOH) 2000);
(4) 2003/4 New Zealand Total Diet Survey (Vannoort 2003; Vannoort 2004a; Vannoort 2004b; Vannoort 2004c);
(5) German Food Composition tables (Souci *et al*., 1994);
(6) A493 Applicant;
(7) derived data;
(8) British food composition data (Holland *et al*., 1991);
(9) 22nd Australian Total Diet Survey (unpublished data);
(10) Personal Communication with Judy Seal (DHHS, 2004).

= median iodine concentration used.

Note: shaded cells indicate a difference between baseline and scenario iodine concentrations or a difference between the iodine concentrations used in 'National' modelling and in the 'Tasmanian' scenario.

The recommended number of serves per day of FSFYC on the package is two, with market research by the Applicant showing that, for consumers of FSFYC, the mean number of serves per day is approximately one. Depending on the brand of FSFYC, one serve per day is equivalent to 174 – 236 g formula per day and 2 serves formula per day to 348 – 472 g per day.

Each of the factors listed above were used to adjust the iodine concentration of 'cattle milk – full fat fluid milk only' to account for the consumption of FSFYC (see Figure 1 below for details).

The Applicant reported that between 7-10% of parents who have children aged 13-36 months are 'regular' users of toddler drinks. The market share of FSFYC in the 1-3 year age group was assumed to be 20% to allow for the consumption of FSFYC by more than one child (1-3 years) per household, for market growth and to allow for the use of FSFYC by children who are not 'regular' consumers of the product.

In the 1995 NNS, there was no consumption of FSFYC recorded. In the dietary intake assessment for 2-3 year old children, it was assumed that 20% of all full fat or unspecified fat content fluid plain and commercially flavoured cow's milks (referred to as 'cattle milk – full fat fluid milk only' hereafter) would be replaced by FSFYC. Cheeses, ice creams and ice confections, yoghurts and reduced and low fat milks were not replaced with FSFYC (see last step in Figure 1).

In the theoretical diet for 1-year old children, it was assumed that 20% of all milks and yoghurts were replaced with FSFYC. The difference in foods substituted with FSFYC between the 2-3 year old assessment and the 1 year old assessment is due to the different methodologies used to estimate the dietary iodine intakes for these two population groups. Since there are differences in methodologies, the estimated dietary iodine intakes for 1-year old children and 2-3 year old children are presented separately within this report.

4.3 Scenarios for Dietary Modelling

Data were received from DHHS on the iodine concentrations of bread and milk available in Tasmania (DHHS, 2004). From the 22nd ATDS, nationally representative milk iodine concentration data that included data for full fat milk sampled from Tasmania and four other states/territories were available. Inter-laboratory check sample analyses were conducted on sub-samples of milk tested in the 22nd ATDS using three different laboratories. These confirmatory analyses suggested that the 'nationally representative' milk iodine concentrations determined as a part of the 22nd ATDS, most accurately reflected iodine concentrations in Tasmanian milk. In Tasmania, bread has higher iodine concentrations due to the use of iodised salt in the place of non-iodised salt by a number of bread manufacturers. To take the higher Tasmanian bread iodine concentration into account, two model types were examined in the Australian dietary iodine intake assessments. These are:

1. 'National' Modelling:
   This model uses nationally representative iodine concentrations for all foods.

2. 'Tasmanian' Modelling
   This model uses Tasmania's bread iodine concentrations in addition to nationally representative iodine concentrations for all other foods. These models are for the Tasmanian population only. For the 'National' models, white bread was assigned an iodine concentration of 3 μg/kg, wholemeal bread 5 μg/kg, and other breads 12 μg/kg. In the 'Tasmanian' models, white, wholemeal and other breads were assigned an iodine concentration of 350 μg/kg.

4.3.1 Baseline

A baseline iodine dietary intake assessment was conducted to estimate dietary iodine intake before permission to increase the maximum permitted iodine quantity in FSFYC from 35 µg/serve to 70 µg/serve was considered. The baseline assessment incorporated the currently permitted maximum quantities of iodine in FSFYC taking account of preparation methods, in addition to the iodine levels in other foods, assuming no products are available with higher iodine levels.

4.3.2 Scenario 1

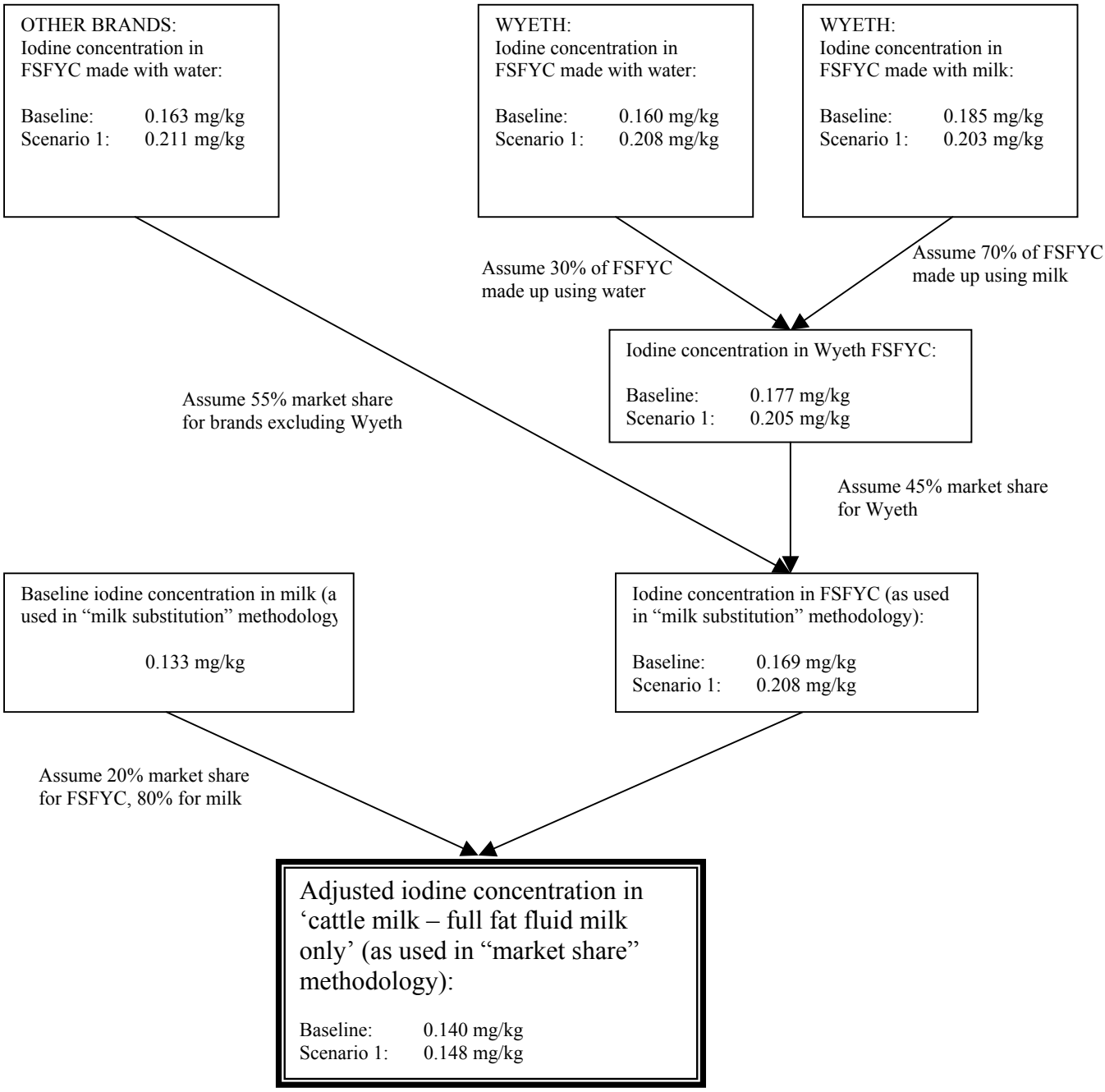
The scenario intake assessment (Scenario 1) takes into account the increase in the maximum permitted iodine quantity in FSFYC from 35 µg/serve to 70 µg/serve, with iodine concentration adjustments for different preparation methods and frequency of current ability to comply with the 35 µg/serve limit, in addition to the iodine levels in other foods.

The Applicant stated that, approximately 30% of the time, the raw ingredients for FSFYC do not allow the FSFYC to meet the current maximum permitted iodine quantity of 35 µg per serve. This Application is requesting an amendment to the Code to allow 70 µg per serve of FSFYC to take into account naturally occurring iodine[31]. For dietary modelling purposes, it was assumed that the average maximum iodine level in FSFYC would be 45.5 µg per serve – this takes into account that 70% of the time, FSFYC will contain a maximum of 35 µg of iodine per serve and that 30% of the time FSFYC will contain a maximum of 70 µg of iodine per serve.

In both the baseline and Scenario 1 dietary intake assessments, the 'cattle milk - full fat fluid milks only' iodine concentrations were weighted to take into account the consumption of FSFYC as discussed under 'Iodine concentration data' and as shown in Figure 1.

[31] In this case 'naturally occurring' refers to the innate iodine content in addition to any adventitious contamination which may occur during the processing of ingredients e.g. iodophors in milk.

Figure 1: Adjustment of the iodine concentration applied to food category 'cattle milk - full fat fluid milks only' for 'National' and 'Tasmanian' modelling



Note: the baseline scenario is based on 35 µg of iodine per serve of FSFYC (if prepared according to directions) and Scenario 1 is based on 45.5 µg of iodine per serve of FSFYC (if prepared according to directions)

4.4 How were the Estimated Dietary Intakes Calculated?

In this Application, a number of dietary intake assessment methodologies were used. These are discussed below and summarised in Table 1.

4.4.1 Market Share Methodology – 2-3 year old Australian children

The DIAMOND program allows iodine concentrations to be assigned to food groups. Each individual's intake of iodine was calculated using their individual food records from the dietary survey. The DIAMOND program multiplies the specified concentration of iodine by the amount of food that an individual consumed from that food group in order to estimate the iodine intake from each food. Once this has been completed for all of the foods specified to contain iodine, the total amount of iodine consumed from all foods is summed for each individual. Population statistics (mean iodine intakes) are then derived from the individuals' ranked intakes.

Where estimated dietary intakes are expressed per kilogram of body weight, each individual's total dietary intake is divided by their own body weight, the results ranked, and population statistics derived. A small number of NNS respondents did not provide a body weight. These respondents are not included in calculations of estimated dietary intakes that are expressed per kilogram of body weight.

Where estimated intakes are expressed as a percentage of the reference health standard (UL), each individual's total intake is calculated as a percentage of the reference health standard (in units per day), the results are then ranked, and population statistics derived.

Food consumption amounts for each individual take into account where each food in a classification code is consumed alone and as an ingredient in mixed foods. For example, raw tomato eaten as a part of a salad, tomato in pasta sauce, and tomato paste are all included in the consumption of tomatoes. Where a higher level food classification code (e.g. FI Tropical fruits – inedible peel) is given an iodine concentration, as well as a sub-category (e.g. FI0326 Avocado), the consumption of the foods in the sub-classification is not included in the higher level classification code.

When a food is classified in two food groups (for example, mixed fruit juice may be entered in the apple and pear groups), and these food groups are assigned different iodine permissions, DIAMOND will assume the food is in the food group with the highest assigned iodine level to assume a worst case scenario. If the food groups have the same permitted iodine level, DIAMOND will assume the food is in the food group that appears first, based alpha-numerically on the DIAMOND food code.

In DIAMOND, all mixed foods have a recipe. Recipes are used to break down mixed foods into their raw commodity components (e.g. bread will be broken down to wheat flour, yeast, water etc). The data for consumption of the raw commodities are then used in models that assign iodine permissions to raw commodity classifications.

In DIAMOND, hydration and raw equivalence factors are applied to some foods to convert the amount of food consumed in the dietary survey to the equivalent amount of the food in the form to which a food chemical permission is given. Factors are only applied to individual foods, and not major food group codes. For example, consumption figures for instant coffee powder are converted into the equivalent quantities of coffee beans and consumption figures for tomato paste are converted into the equivalent quantities of raw tomatoes.

Percentage contributions of each food group to total estimated intakes are calculated by summing the intakes for a food group from each individual in the population group who consumed a food from that group and dividing this by the sum of the intakes of all individuals from all food groups containing iodine, and multiplying this by 100.

In this methodology, the iodine concentration for 'cattle milk – full fat fluid only' was weighted to take into account various preparation methods, market share and that 20% of children are consumers of FSFYC. The dietary intake assessment using this methodology provides information on mean dietary iodine intakes for the population group over a period of time but it does not provide information on dietary iodine intakes for those children who are 'actual' consumers of FSFYC. The methodology for the dietary intake assessment for 'actual' consumers of FSFYC is discussed under 'Milk Substitution Methodology' below.

4.4.2 Milk Substitution Methodology

A different methodology for determining dietary iodine intakes was used for the Final Assessment of this Application - the 'milk substitution' methodology. This methodology was used to determine dietary iodine intakes for children who are 'actual' consumers of FSFYC. Concern was raised in a submission regarding the substitution of the New Zealand guideline quantity of milk (500-600 ml daily for 1-2 year old children) with FSFYC and the impact that this would have on dietary iodine intakes. A 500-600 ml quantity of FSFYC would correspond to 2-3½ serves per day, depending on the brand of FSFYC. Information on the frequency of consumption of FSFYC by children aged 13-36 months that was provided by the Applicant indicated that approximately 70% of children do not consume FSFYC on a daily basis. Approximately 10-15% of children aged 13-36 months consume 2 to 3 serves of FSFYC per day. Using data provided by the Applicant, it was determined that, on average, consumers of FSFYC aged 13-36 months consume one serve of FSFYC per day. This figure has been used in the dietary modelling.

Using the 1995 Australian NNS data, a mean and 95th percentile consumption amount of 'cattle milk - full fat fluid milk only' was derived for 2-3 year old children. The mean 'cattle milk - full fat fluid milk only' consumption was 403 g/day and the 95th percentile was 1,007 g/day. These consumption figures do not take into account the consumption of cheeses, yoghurts, ice creams and ice confections, or reduced fat and low fat milks.

As previously discussed, the recommended number of serves of toddler formula per day on the package is two, with market research by the Applicant showing that consumers of FSFYC have an average of 1 serve per day. From the products that FSANZ has examined, 2 serves of FSFYC corresponds to between 348 grams and 472 grams, depending on the brand of product. The mean consumption of 'cattle milk - full fat fluid milk only' of 403 g for 2-3 year old children corresponds with the weight range for two serves of FSFYC. Consequently, 1 serve of FSFYC was assumed to be equivalent to 50% of the mean 'cattle milk - full fat fluid milk only' consumption amount – 202 g for 2-3 year old children.

In this methodology, only the consumers of FSFYC are considered. A dietary iodine intake was estimated for mean consumers of milk ('mean milk consumers'). It was assumed that children consume 1 serve of FSFYC per day and that 1 serve is equivalent to the 50% of the mean consumption of 'cattle milk – full fat fluid milk only' for 2-3 year old children.

Therefore, the mean consumption of 'cattle milk – full fat fluid milk only' for 2-3 year old children is comprised of 202 g of FSFYC plus 202 g of cow's milk. Using these consumption amounts, the dietary iodine intake from FSFYC and milk was calculated.

The mean dietary iodine intake from all other foods (except 'cattle milk – full fat fluid milk only') was determined using the methodology listed under 'Market Share Methodology'. In order to estimate dietary iodine intake from the total diet for consumers of FSFYC, the dietary iodine intake from FSFYC and milk was added to the mean dietary iodine intake from all other foods (except 'cattle milk – full fat fluid milk only'). The calculation for the estimation of dietary iodine intake for 'mean milk consumers' is listed below:

Dietary iodine intake for 'mean milk consumers'	=	Dietary iodine intake from 1 serve of FSFYC (202 g)	+	Dietary iodine intake from 1 serve of milk (202 g)	+	Mean dietary iodine intake from all other foods (except 'cattle milk – full fat fluid milk only')

A dietary iodine intake was estimated for high consumers of milk ('high milk consumers'). The 95th percentile consumption of 'cattle milk – full fat fluid only' was derived from DIAMOND and it was assumed that, of this quantity, 1 serve of FSFYC would be consumed, with the remainder of this amount being consumed as milk. The dietary iodine intake from FSFYC and milk was then added to the estimated mean dietary iodine intake from all other foods to estimate dietary iodine intake for 'high milk consumers'. The calculation for the estimation of dietary iodine intake for 'high milk consumers' is listed below:

Dietary iodine intake for 'high milk consumers'	=	Dietary iodine intake from 1 serve of FSFYC (202 g)	+	Dietary iodine intake from milk (805 g)	+	Mean dietary iodine intake from all other foods (except 'cattle milk – full fat fluid milk only')

This model is likely to overestimate iodine intakes as no adjustment for the high consumption of milk including FSFYC is made for other foods, whereas in fact it is likely these would be reduced in amount.

4.4.3 Theoretical One Year-Old Diet

As there are no data available from the 1995 Australian NNS for children aged < 2 years, a theoretical diet was constructed to estimate dietary iodine intake for children aged 1 year. The recommended energy intake for a twelve-month-old boy (FAO 2004) at the 50th percentile weight (WHO, 1983) was used as the basis for the theoretical diet. Boys' weights were used because boys tend to be heavier than girls at the same age and therefore have higher energy and food requirements. It was assumed that 35 per cent of energy intake was derived from milk and 65 per cent from solids (Hitchcock *et al*., 1986). The patterns of consumption of a two-year-old child from the 1995 NNS were scaled down and used to determine the solid portion of the 1 year old's diet. Certain foods such as nuts (excluding peanut butter), coffee and alcohol were removed from the diet since nuts can be a choking risk (NHMRC, 2001) and coffee and alcohol are unsuitable foods for infants (ACT Community Care, 2000).

The same type of models were used for 1 year olds as 2-3 year olds (see Table 1). A 'market share' methodology was used in the dietary intake assessment for iodine for 1 year old children.

The 'market share' methodology for 1 year old children differs from that for 2-3 year old children in that no individual dietary records were available for 1 year old children. A theoretical diet with mean food consumption figures for a 1 year old was constructed. The ways that foods were grouped for the purpose of dietary modelling were different for the 1 year old theoretical diet. For 2-3 year old children, it was assumed that 20% of full fat or unspecified fat content fluid plain and commercially flavoured cow's milks would be replaced by FSFYC. Cheeses, ice creams and ice confections, yoghurts and reduced and low fat milks were not replaced with FSFYC. In the theoretical diet for 1 year old children, it was assumed that 20% of all milks and yoghurts were replaced with FSFYC (referred to as 'milk' hereafter). The dietary intake assessment using this methodology provides information on mean dietary iodine intakes for the population group over a period of time but it does not provide information on dietary iodine intakes for those children who are consumers of FSFYC.

Dietary iodine intakes for 1 year old children were also determined using a 'milk substitution' methodology. The mean intake of 'milk' for 1 year old children was determined as being 453 g/day. This consumption amount was assumed to be equivalent to 2 serves of FSFYC.

As previously discussed, the recommended number of serves of toddler formula per day is two, with market research by the Applicant showing that children usually have 1 serve per day. The mean consumption of 'milk' of 453 g by 1 year old children corresponds with the weight range for two serves of FSFYC. It was assumed that 1 year old 'mean milk consumers' are consuming 1 serve of FSFYC per day and that 1 serve is equivalent to the 50% of the mean dietary intake of 'milk'. Therefore, the mean dietary intake of 'milk' for 1 year old children is comprised of 226 g of FSFYC plus 226 g of cow's milk. Using these consumption amounts, the dietary iodine intake from FSFYC and milk was then calculated. The mean dietary iodine intake from all other foods (except 'milk') was also determined. In order to estimate dietary iodine intake for 'mean milk consumers' from the total diet, the following formula was used:

Dietary iodine intake for 'mean milk consumers'	=	Dietary iodine intake from 1 serve of FSFYC (226 g)	+	Dietary iodine intake from 1 serve of milk (226 g)	+	Mean dietary iodine intake from all other foods (except 'milk')

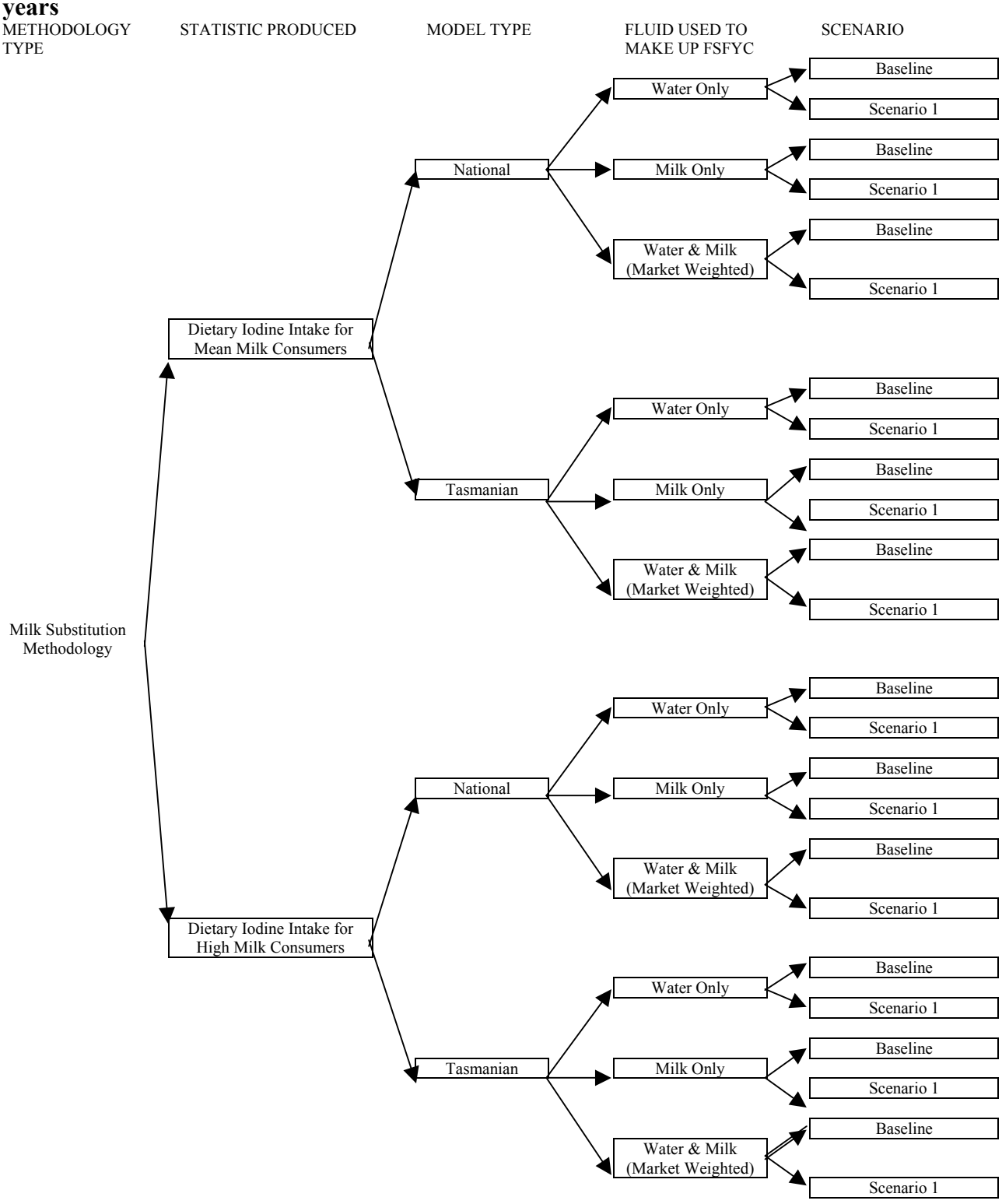
A dietary iodine intake was estimated for high consumers of milk ('high milk consumers'). It was assumed that, of the 95th percentile consumption amount of 'milk', 1 serve of FSFYC would be consumed, with the remainder being consumed as cow's milk. A 95th percentile consumption figure for 1 year old children for 'milk' was derived. As individual dietary records were not available, it was not possible to derive the 95th percentile milk consumption from a distribution. Using the ratio of mean 'cattle milk - full fat fluid milk only' consumption to 95th percentile 'cattle milk - full fat fluid milk only' consumption for 2-3 year old children. The ratio used was 1:2.5, with the 95th percentile 'milk' consumption amount determined as being 1,132 g/day. Similar ratios between mean consumption food amounts and high percentiles have been previously reported (WHO, 1985). The dietary iodine intake from FSFYC and milk was then added to the estimated mean dietary iodine intake from all other foods to estimate dietary iodine intake for 'high milk consumers'. The calculation for the estimation of dietary iodine intake for 'high milk consumers' is listed below:

Dietary iodine intake for 'high milk consumers'	=	Dietary iodine intake from 1 serve of FSFYC (226 g)	+	Dietary iodine intake from milk (906 g)	+	Mean dietary iodine intake from all other foods (except 'milk')

4.4.4 Summary of Dietary Modelling Methodologies

The data produced under each of the methodologies discussed previously are summarised in Table 1 above and Figure 2 below.

Figure 2: Summary of data produced for the 'Milk Substitution' methodology estimation of dietary iodine intakes for Australian children aged 1 year and aged 2-3 years



5. Assumptions in the dietary modelling

The aim of the dietary intake assessment was to make as realistic an estimate of dietary intake as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the dietary intake assessment did not underestimate intake.

Assumptions made in the dietary modelling include:

- since there were no consumption data for New Zealand children aged 1-3 years, the dietary iodine intakes for Australian children aged 1-3 years were taken as being representative of New Zealand children aged 1-3 years. It is likely that the dietary iodine intakes for New Zealand children aged 1-3 years are lower since the mean New Zealand milk iodine concentration is lower than Australian mean milk iodine concentrations;

- for the 1 year old theoretical diet, 35% of energy is derived from milk and 65% from solids;

- where a permission for iodine is given to a food classification, all foods in that group contain iodine;

- all the foods within the group contain iodine at the levels specified in Table 2 for Australian children aged 2-3 years and in Table 3 for Australian children aged 1 year;

- consumption of foods as recorded in the NNS represent current food consumption patterns;

- for 1 year old children, only cow's milk and yoghurts (referred to as 'milk' in this report) are replaced by FSFYC;

- on a population basis, 20% of all 'cattle milk – full fat fluid milk only' (for 2-3 year old children) and 20% of all 'milk' (for 1 year old children) is substituted with FSFYC;

- for 2-3 year old children, only full fat or unspecified fat content fluid cow's milk (referred to as 'cattle milk – full fat fluid milk only' in this report), including plain milk and commercial flavoured full fat and unspecified fat content milk, is replaced by FSFYC;

- for all brands of FSFYC, 70% of the time FSFYC meet the current maximum iodine limit of 35 µg/serve and 30% of the time they meet the requested maximum iodine limit of 70 µg/serve. It is assumed that, over a period of time, children will consume FSFYC products with the above concentrations of iodine and in the specified ratios. Therefore, the Scenario 1 iodine concentration in FSFYC is 45.5 µg/serve over a period of time;

- 70% of all Wyeth FSFYC are made up using milk and 30% using water (as per the Applicant's market research data);

- Wyeth indicate on its FSFYC product label that consumers can use milk to make up the FSFYC. This was not found for other brands of FSFYC. Consequently, it is assumed that only consumers of Wyeth FSFYC use milk to make up FSFYC;

- for FSFYC products made up using milk, consumers always use 2 scoops of dry FSFYC (instead of the 5 scoops used to make the product up with water) in 200 ml of milk;

- the mean consumption amount for 'cattle milk – full fat fluid milk only' for 2-3 year old children and the mean consumption amount for 'milk' for 1 year old children is equivalent to 2 serves of FSFYC. Therefore, 1 serve of FSFYC is equivalent to 50% of the mean consumption amount of 'cattle milk – full fat fluid milk only' or 'milk';

- high consumers of milk have a mean dietary iodine intake from all other foods;

- the maximum iodine limit relates to the amount of iodine in FSFYC products that are made up with water according to label directions – i.e. the iodine contribution from water is incorporated into the maximum iodine limit;

- the mean iodine concentration values determined from the listed data sources are representative of the levels found in foods throughout Australia with no regional, seasonal or natural variation for the 'National' model;

- for the 'Tasmanian' modelling, all plain bread available is manufactured using iodised salt. Plain bread was defined as white, wholemeal, and multigrain breads and rolls for the purpose of assessing this Application. Fancy breads (e.g. focaccia, English muffins) and buns were assumed not to be manufactured using iodised salt;
- since DIAMOND does not identify respondents in the 1995 NNS by geographical location, it was assumed that Tasmanian food consumption patterns are the same as those for the whole of Australia for the 'Tasmanian' modelling (i.e. the 1995 NNS food consumption data set for all Australians was used as a proxy for food consumption patterns for Tasmanians);

- all iodine present in foods is 100% bioavailable, therefore there are no inhibitors to iodine absorption (such as goitrogens) present in the diet;

- where the concentration of iodine in a food was reported as being less than the Limit of Detection (LOD) or Limit of Reporting (LOR), then the iodine concentration of the food was equal to half of the LOD or LOR value. The LOD is the lowest concentration of a chemical that can be qualitatively detected using a specified laboratory method and/or item of laboratory equipment (i.e. its presence can be detected but not quantified). The LOR used in this assessment has been established at the Limit of Quantification (LOQ) which is the lowest concentration of a chemical that can be detected and quantified, with an acceptable degree of certainty, using the specified laboratory method;

- where there were no Australian iodine data for specific food groups, it was assumed that New Zealand data were representative of these food groups;

- where there were no Australian or New Zealand data on iodine concentrations for food groups, it was assumed that overseas data (British and German) were representative of these food groups;

- where a food or food group has a zero concentration of iodine, it was not included in the intake assessment;

- where a food has a specified iodine concentration, this concentration is carried over to mixed foods where the food has been used as an ingredient e.g. milk in custard;

- one or more fruits or vegetables from a classification can be deemed to be representative of the entire classification (e.g. celery is representative of all stalk and stem vegetables);

- there is no consumption of iodine through discretionary salt use (since NNS did not measure discretionary salt use) or supplements;

- there are no reductions in iodine concentrations on cooking; and

- food manufacturers do not use iodised salt in their products, with the exception of bread manufacturers in Tasmania for the 'Tasmanian' models where it is known that some bread manufacturers use iodised salt in the production of bread. In a study by Gunton et al (Gunton *et al*., 1999), three major Australian food manufacturers of processed food were contacted and reported using only non-iodised salt.

These assumptions are likely to lead to a conservative estimate for iodine dietary intake.

6. Limitations of the Dietary Modelling

A limitation of estimating dietary intake over a period of time associated with the dietary modelling is that only 24-hour dietary survey data were available, and these tend to over-estimate habitual food consumption amounts for high consumers. Therefore, predicted high percentile intakes are likely to be higher than actual high percentile intakes over a longer period of time. For second day adjustment figures to be derived there must be an adequate number of consumers in order to derive a result that is statistically robust. Second day adjustments have little impact on estimated mean nutrient intakes (Rutishauser, 2000), but usually reduce estimated daily 95th percentile nutrient intakes. Daily food consumption amounts for occasionally consumed foods based on 24 hour food consumption data would be higher than daily food consumption amounts for those foods based on a longer period of time.

Second day nutrient adjustments were not calculated for iodine since dietary iodine intakes were calculated using a methodology in DIAMOND that does not include a component for adjusting estimated intakes. This is because it only includes food consumption data from the first 24-hour recall.

Over time, there may be changes to the ways in which manufacturers and retailers make and present foods for sale. Since the data were collected for the Australian and New Zealand NNSs, there have been significant changes to the Food Standards Code to allow more innovation in the food industry.

As a consequence, another limitation of the dietary modelling is that some of the foods that are currently available in the food supply were either not available or were not as commonly available in 1995/1997 (e.g. FSFYC). Since the data were collected for the NNSs, there has been an increase in the range of products that are fortified with nutrients. For example, breads manufactured using iodised salt in Tasmania.

Both the Australian and New Zealand NNSs did not measure discretionary salt use, therefore salt could not be included in the dietary intake assessments. Additionally, DIAMOND does not contain data on the use of complementary medicines (Australia) or dietary supplements (New Zealand). Consequently, these could not be included in the dietary intake assessment.

While the results of NNSs can be used to describe the usual intake of groups of people, they cannot be used to describe the usual intake of an individual (Rutishauser, 2000). In particular, they cannot be used to predict how consumers will change their eating patterns as a result of an external influence such as the availability of a new type of food.

FSANZ does not apply statistical population weights to each individual in the NNSs in order to make the data representative of the population. This prevents distortion of actual food consumption amounts that may result in an unrealistic intake estimate.

DIAMOND does not allow the identification of the state/territory in Australia that a NNS respondent lives. As a consequence, a dietary intake assessment could not be conducted using food consumption data for Tasmanians only. To overcome this limitation, it was assumed that the food consumption data set for the 1995 NNS for all Australians was representative of the food consumption patterns of Tasmanians.

7. Results

7.1 Estimated Dietary Intakes of Iodine

7.1.1 'Market Share' methodology

The dietary intakes for iodine as estimated using the 'market share' methodology, are shown in Figures 3 and 4 for Australian children aged 2-3 years and 1 year, respectively (full results in Tables A1.1 and A1.2 in Appendix 1). The results for 1 year old children are presented separately since the results were obtained using a different methodology to that used for 2-3 year old children. The results for 2-3 year old children are presented for all survey respondents in the age group (n=383) because all respondents had an iodine intake due to the nutrient being ubiquitous in the food supply.

At baseline, the estimated mean dietary intakes of iodine were:

- 74-85 μg/day (7.3-8.4 μg/kg bw/day) for 1 year old children; and
- 109-129 μg/day (7.1-8.4 μg/kg bw/day) for 2-3 year old children.

For Scenario 1, the estimated mean dietary intakes of iodine were:

- 78-89 μg/day (7.6-8.7 μg/kg bw/day) for 1 year old children; and
- 112-132 μg/day (7.3-8.6 μg/kg bw/day) for 2-3 year old children.

At baseline and Scenario 1, the range of estimated dietary iodine intakes for 1-3 year old Australian children (74-132 µg/day) is within the range given by the Applicant for British children aged 1½ - 4½ years (87-309 µg/day).

Figure 3: Estimated mean dietary intakes of iodine, in µg/day, for Australian children aged 2-3 years for 'National' and 'Tasmanian' modelling using 'Market share' methodology

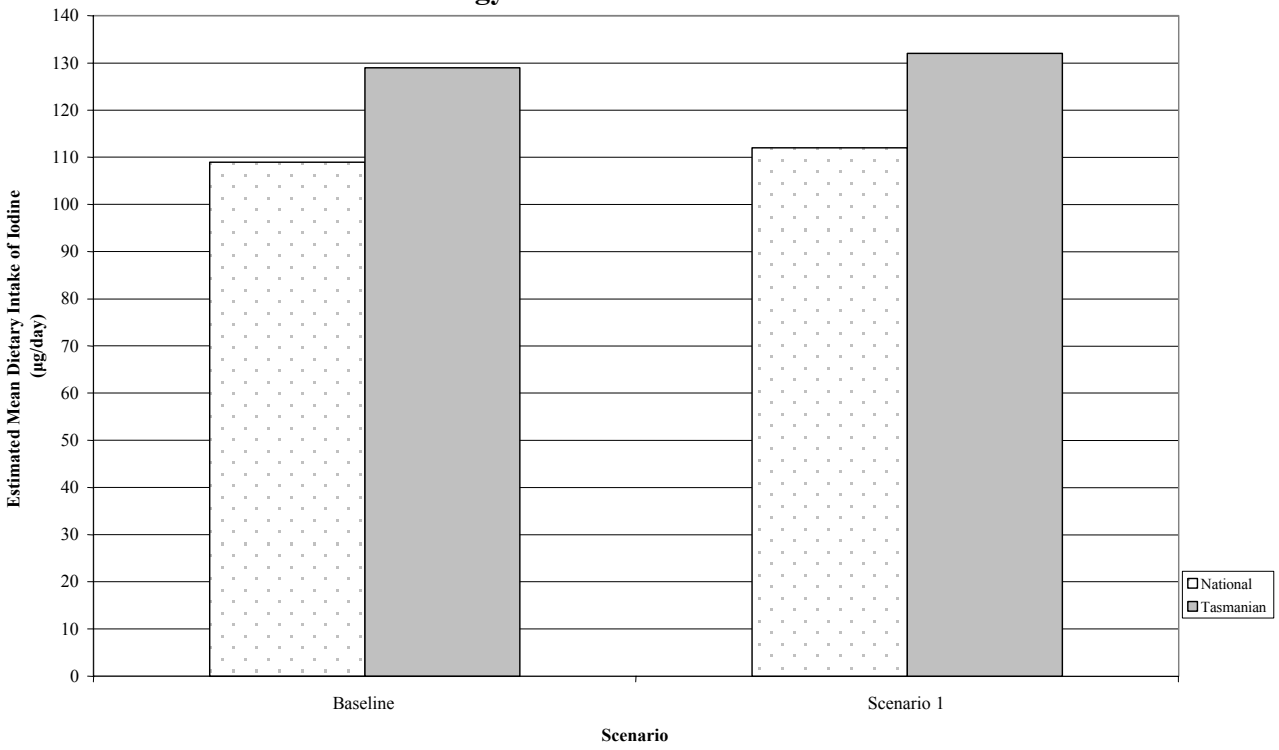
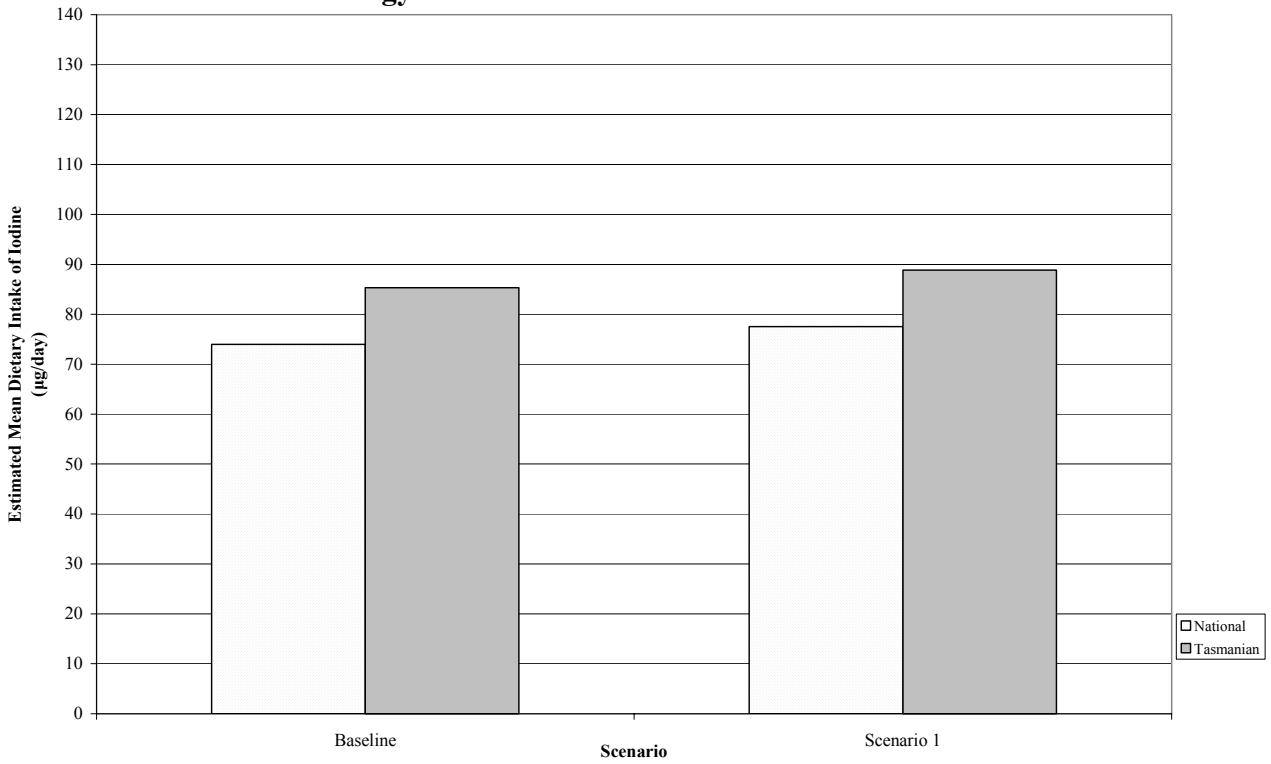


Figure 4: Estimated mean dietary intakes of iodine, in µg/day, for Australian children aged 1 year for 'National' and 'Tasmanian' modelling using 'Market share' methodology



7.1.2 'Milk Substitution' methodology

The dietary intakes for iodine, estimated using the 'milk substitution' methodology, are shown in Figures 5 and 6 for Australian children aged 2-3 years and in Figures 7 and 8 for 1 year old children. The results for 1 year-old children are presented separately since the results were obtained by a different methodology to that used for 2-3 year old children. Full results can be found in Tables A2.1 - A2.4 in Appendix 2.

At baseline, the estimated dietary intakes of iodine for 'mean milk consumers' were:

- 77-94 µg/day (7.6-9.2 µg/kg bw/day) for 1 year old children, depending on the fluid used to make up the FSFYC and on the type of model used; and

- 116-141 µg/day (7.2-8.8 µg/kg bw/day) for 2-3 year old children, depending on the fluid used to make up the FSFYC and on the type of model used.

For Scenario 1, the estimated dietary intakes of iodine for 'mean milk consumers' were:

- 87-100 µg/day (8.5-9.8 µg/kg bw/day) for 1 year old children, depending on the fluid used to make up the FSFYC and on the type of model used; and

- 124-146 µg/day (7.8-9.1 µg/kg bw/day) for 2-3 year old children, depending on the fluid used to make up the FSFYC and on the type of model used.

Mean intakes estimated by using the milk substitution model were therefore very similar to those estimated from the market share methodology.

At baseline, the estimated dietary intakes of iodine for 'high milk consumers' were:

- 168-184 µg/day (16.4-18.0 µg/kg bw/day) for 1 year old children, depending on the fluid used to make up the FSFYC and on the type of model used; and

- 196-221 µg/day (12.3-13.8 µg/kg bw/day) for 2-3 year old children, depending on the fluid used to make up the FSFYC and on the type of model used.

For Scenario 1, the estimated dietary intakes of iodine for 'high milk consumers' were:

- 177-190 µg/day (17.3-18.6 µg/kg bw/day) for 1 year old children, depending on the fluid used to make up the FSFYC and on the type of model used; and

- 205-226 µg/day (12.8-14.1 µg/kg bw/day) for 2-3 year old children, depending on the fluid used to make up the FSFYC and on the type of model used.

Figure 5: Estimated dietary intakes of iodine, in µg/day, for Australian children aged 2-3 years who are 'mean milk consumers' for 'National' and 'Tasmanian' modelling using 'Milk substitution' methodology

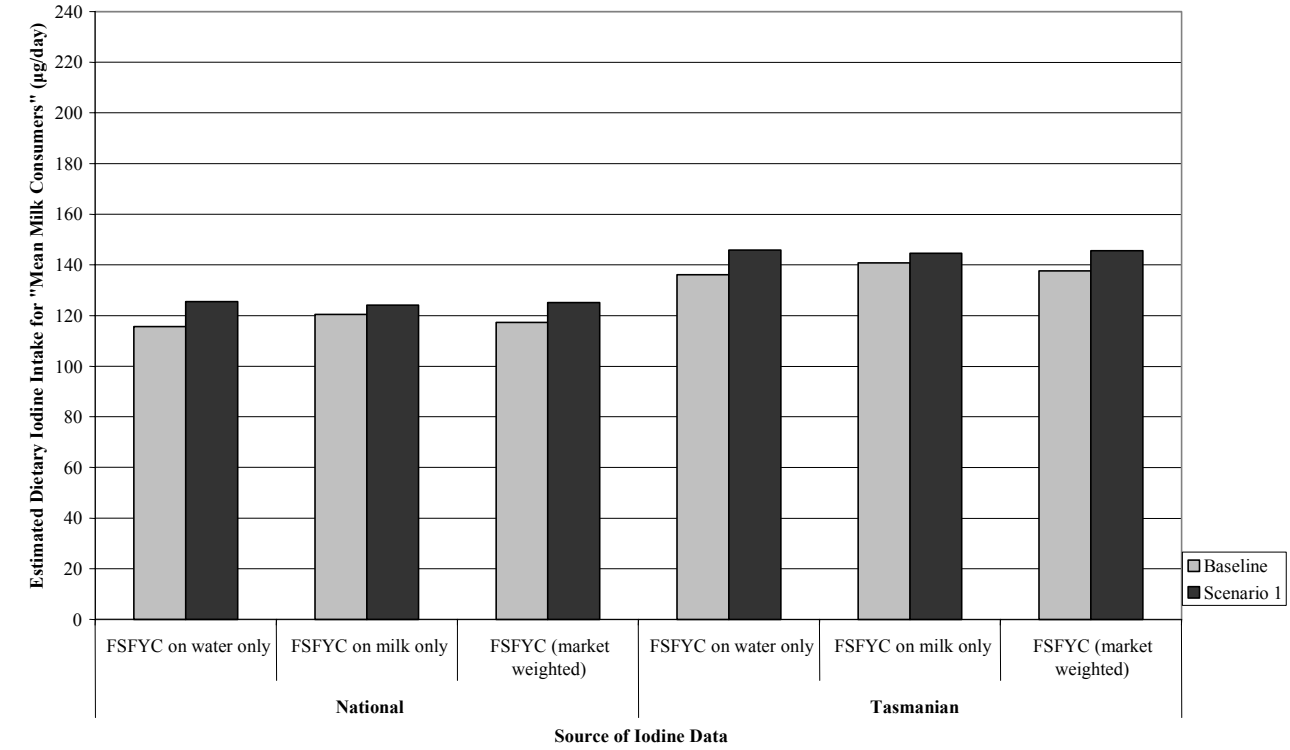


Figure 6: Estimated dietary intakes of iodine, in µg/day, for Australian children aged 2-3 years who are 'high consumers of milk' for 'National' and 'Tasmanian' modelling using 'Milk substitution' methodology

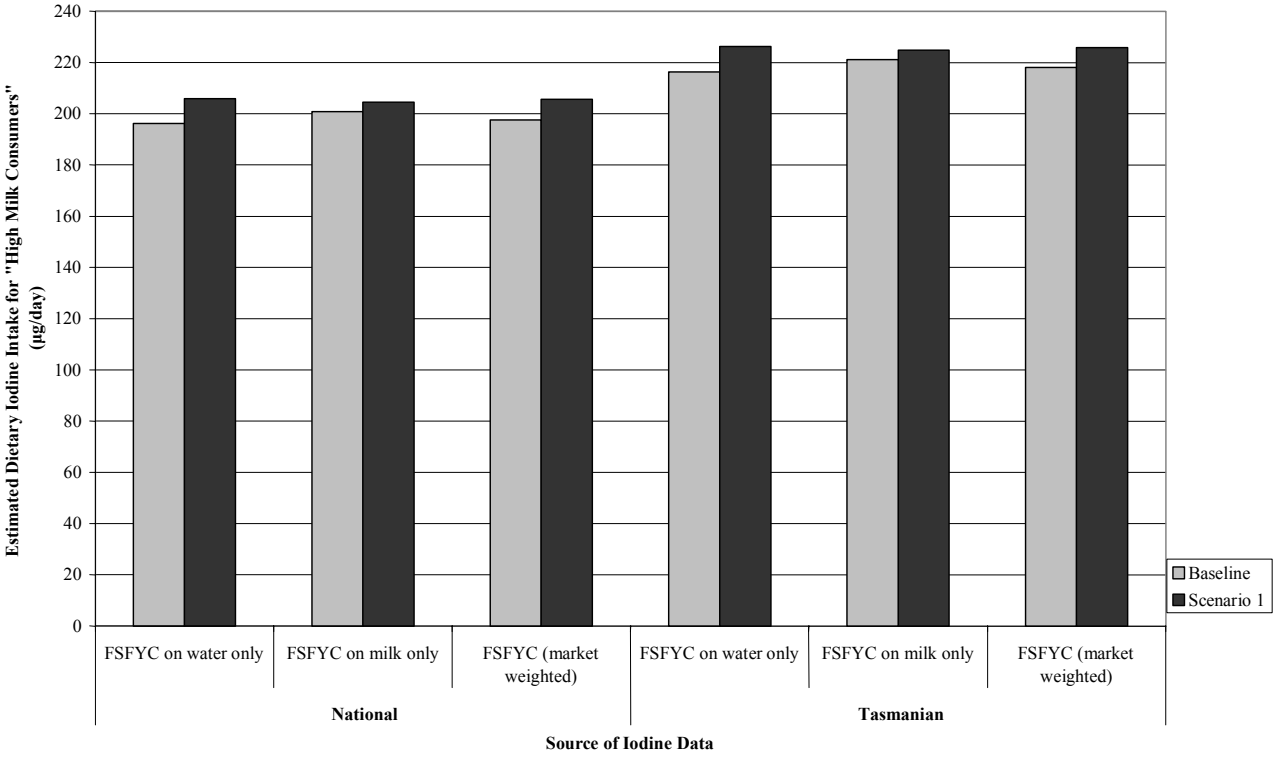


Figure 7: Estimated dietary intakes of iodine, in µg/day, for Australian children aged 1 year who are 'mean milk consumers' for 'National' and 'Tasmanian' modelling using 'Milk substitution' methodology

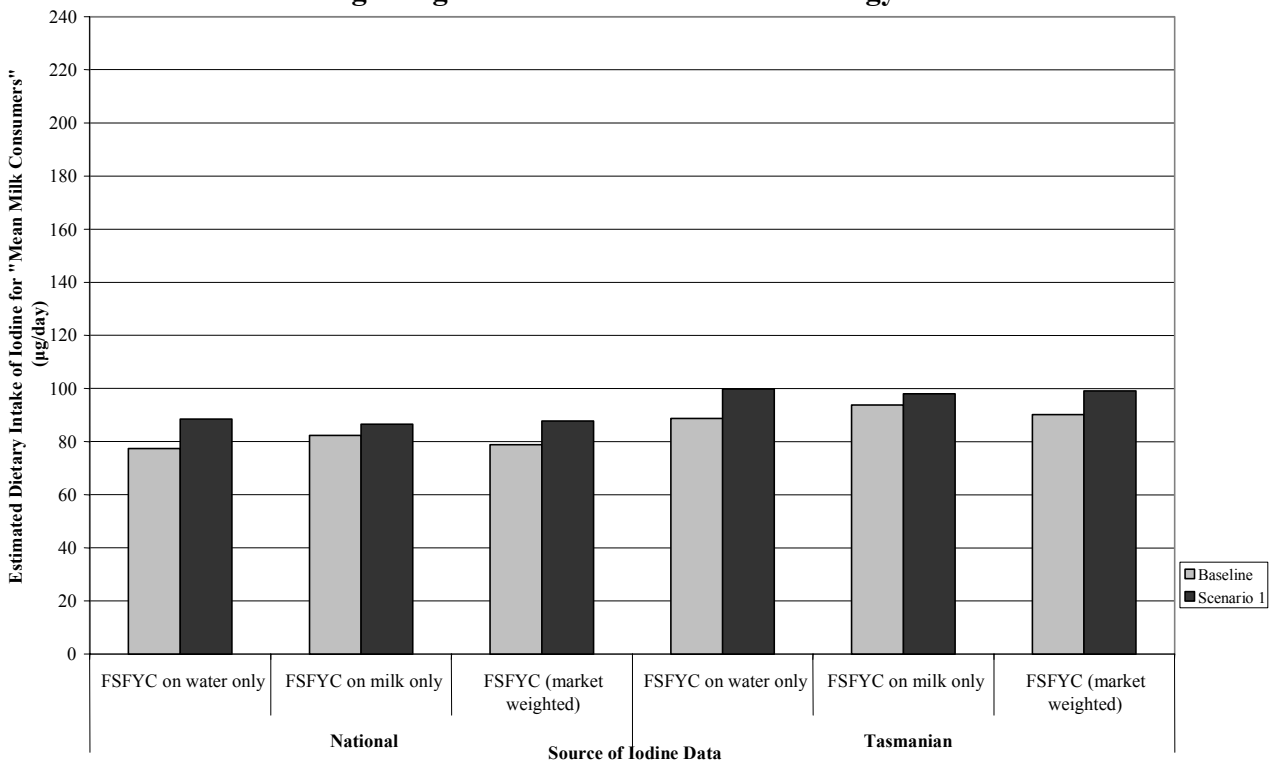
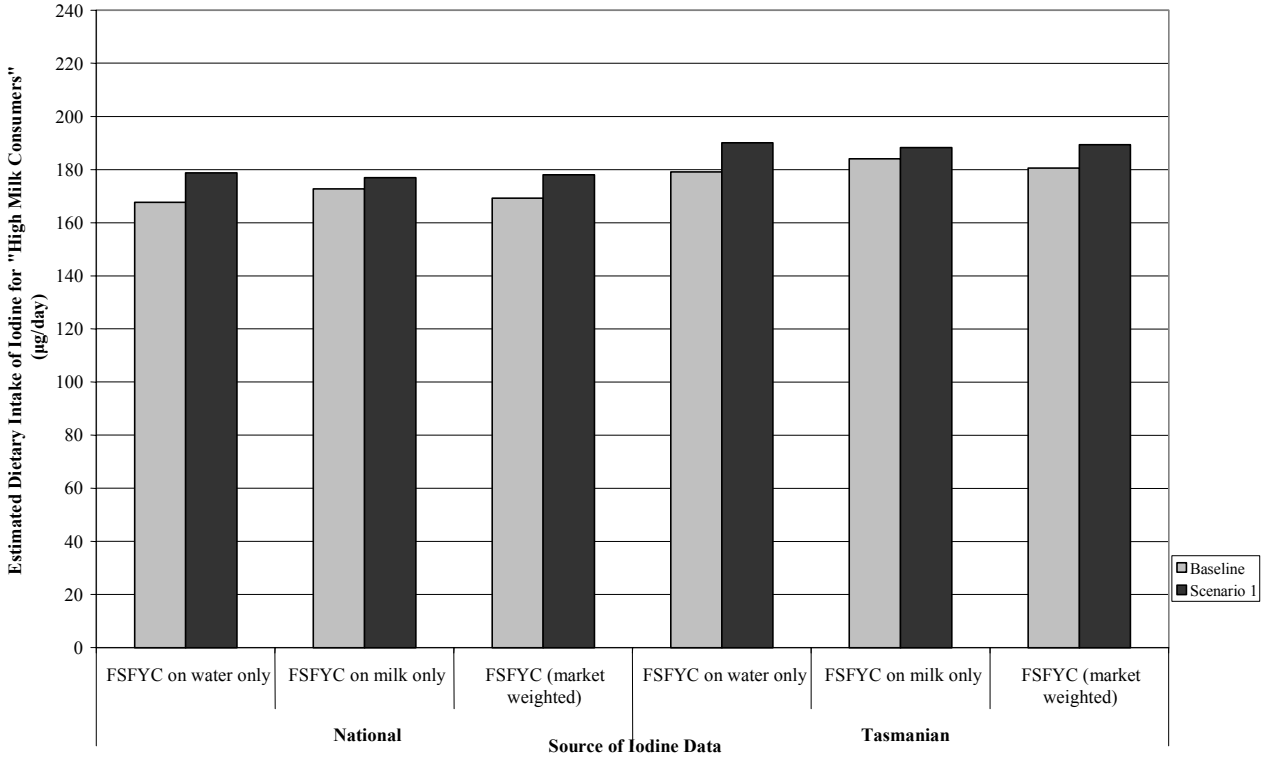


Figure 8: Estimated dietary intakes of iodine, in µg/day, for Australian children aged 1 year who are 'high milk consumers' for 'National' and 'Tasmanian' modelling using 'Milk substitution' methodology



7.2 Major Contributing Foods to Total Estimated Dietary Intakes – 'Market Share' Methodology

The major contributors (>5%) to total iodine dietary intakes for Australian children aged 2-3 years for the 'market share' methodology were dairy products and FSFYC (65-80% for baseline and Scenario 1) and fruits (10% for baseline and Scenario 1). When Tasmanian bread that is produced using iodised salt is considered (i.e. the 'Tasmanian' models), cereal foods were also major contributors (20%) to total estimated iodine intakes. A full list of all the food groups and their contributions can be found in Table A1.3 in Appendix 1 and in Figures 9-12 below.

8. Risk Characterisation

In order to determine if the levels of dietary iodine intakes are likely to be of public health and safety concern, the estimated dietary intakes were compared to an upper level of intake (UL) for iodine for children aged 1-3 years of 200 μg/day (NHMRC, 2004). ULs are the highest average daily nutrient levels likely to pose no adverse health effects to almost all individuals in the general population (NHMRC, 2004).

8.1 Comparison of the estimated dietary intakes with the UL

The estimated dietary intakes of iodine, as compared to the UL are shown in Figures 13-18 (full results in Tables A2.1-2.4 in Appendix 2 and Tables A3.1-3.2 in Appendix 3).

8.1.1 'Market Share' Methodology

For Australian children aged 2-3 years and 1 year, the estimated mean dietary intakes of iodine were below the upper level for iodine of 200 μg/day for all of the scenarios and model types examined. The percentage of 2-3 year old respondents who had estimated dietary iodine intakes that exceeded the UL or who had dietary intakes less than the EAR can be found in Table A1.4 of Appendix 1.

8.1.2 'Milk Substitution' Methodology

For the 'milk substitution' methodology, the estimated dietary iodine intakes for mean milk consumers and high milk consumers aged 1 year were below the UL. The estimated dietary iodine intakes for mean milk consumers aged 2-3 years were also below the UL. For high milk consumers aged 2-3 years, the estimated dietary iodine intakes were at the UL for all National models but exceeded the UL for all Tasmanian models. The 'Tasmanian' – baseline and 'Tasmanian' – Scenario 1 dietary iodine intakes for high milk consumers at 110% of the UL.

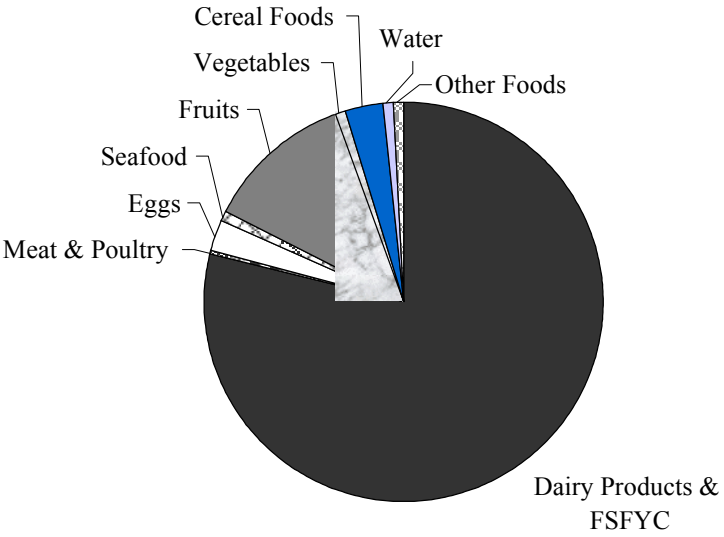


Figure 9: Contributors to Iodine Intake for 2-3 year old children- "National" - Baseline

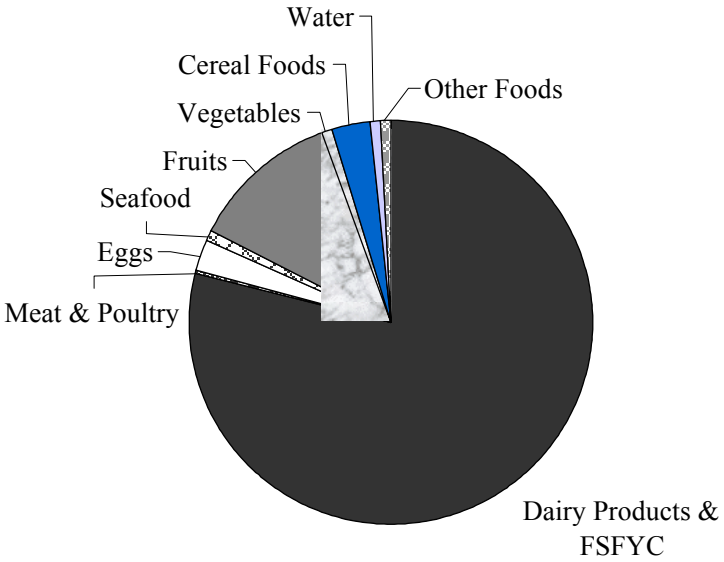


Figure 10: Contributors to Iodine Intake for 2-3 year old children - "National" – Scenario 1

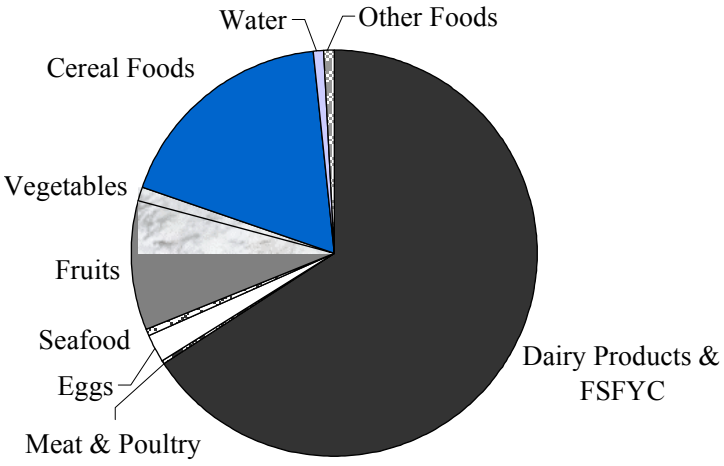


Figure 11: Contributors to Iodine Intake for 2-3 year old children - "Tasmanian" - Baseline

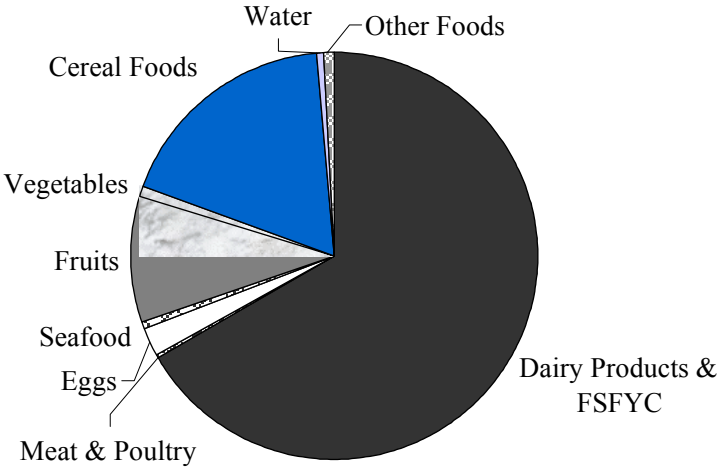


Figure 12: Contributors to Iodine Intake for 2-3 year old children - "Tasmanian" – Scenario 1

Note: The percent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario.

Figure 13: Estimated mean dietary intakes of iodine for Australian children aged 2-3 years, as a percentage of the UL, for 'National' and 'Tasmanian' modelling using 'Market share' methodology

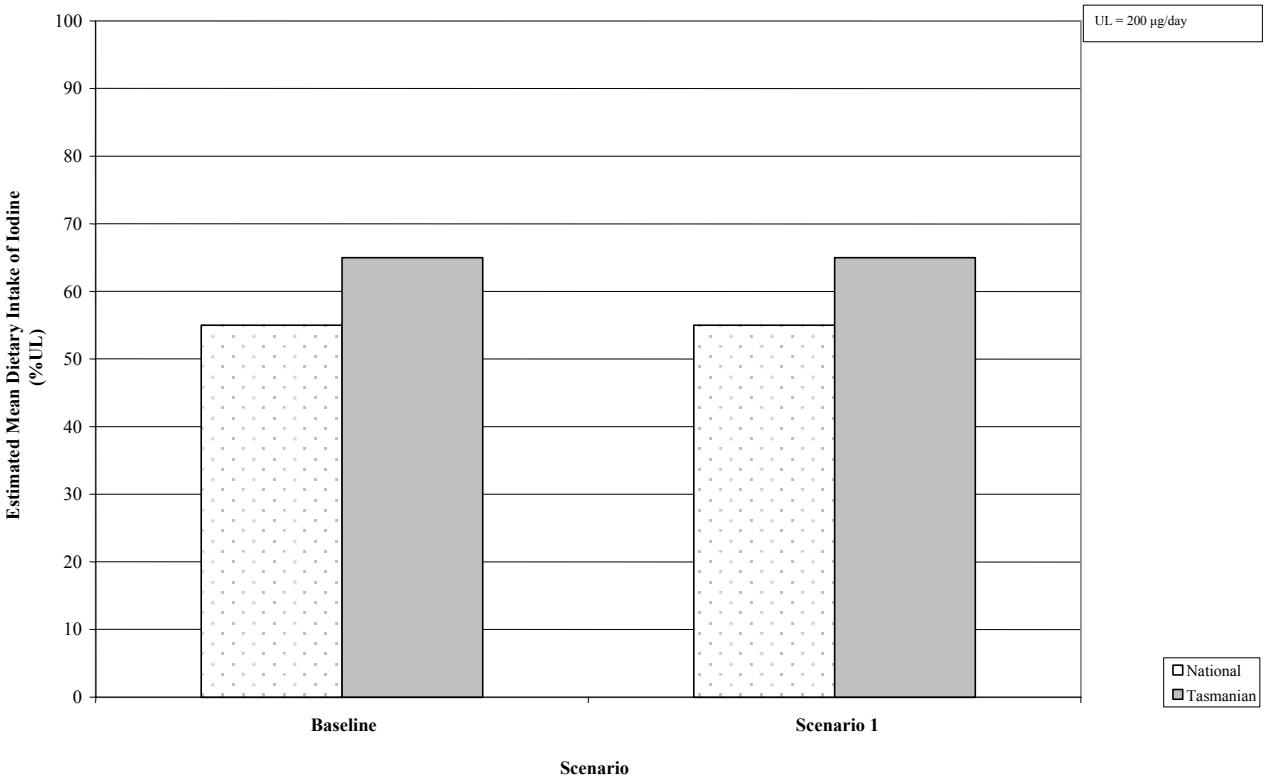


Figure 14: Estimated mean dietary intakes of iodine for Australian children aged 1 year, as a percentage of the UL, for 'National' and 'Tasmanian' modelling using 'Market share' methodology

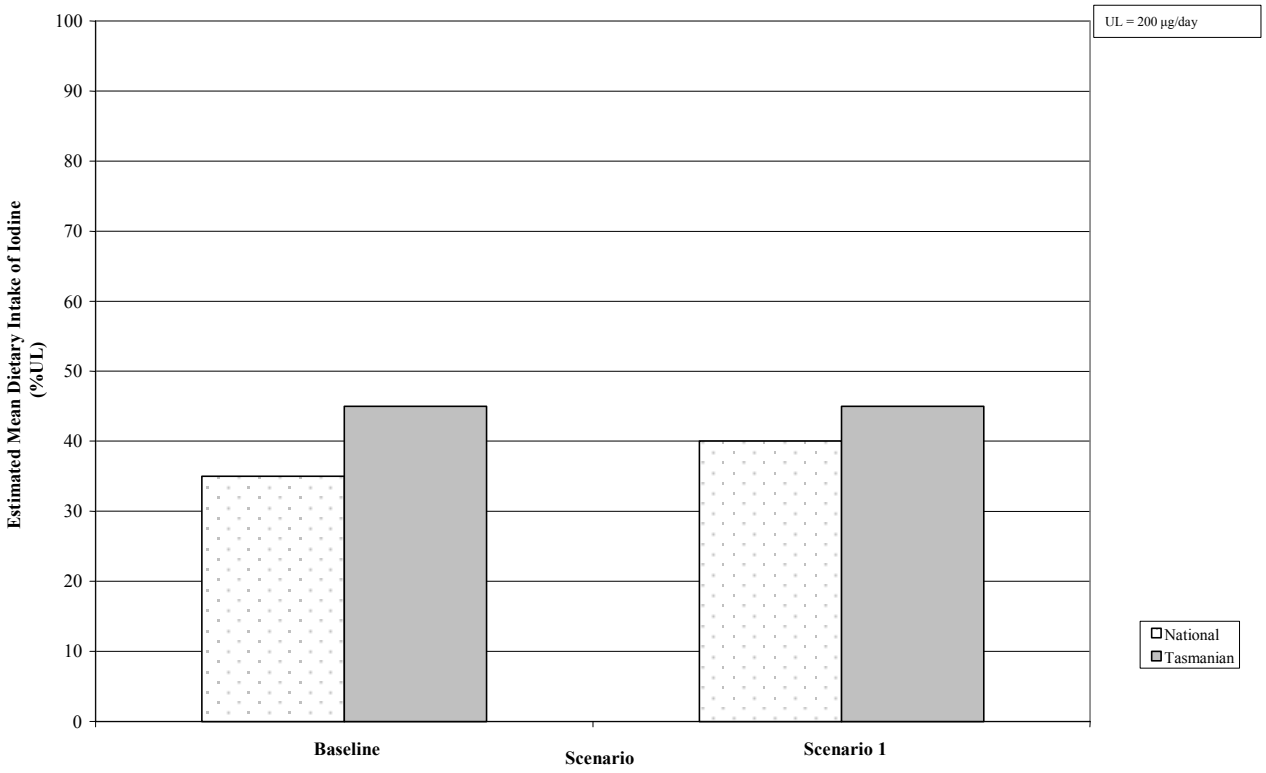


Figure 15: Estimated dietary intakes of iodine, as a percentage of the UL, for Australian children aged 2-3 years who are 'mean milk consumers' for 'National' and 'Tasmanian' and modelling for 'Milk substitution' methodology

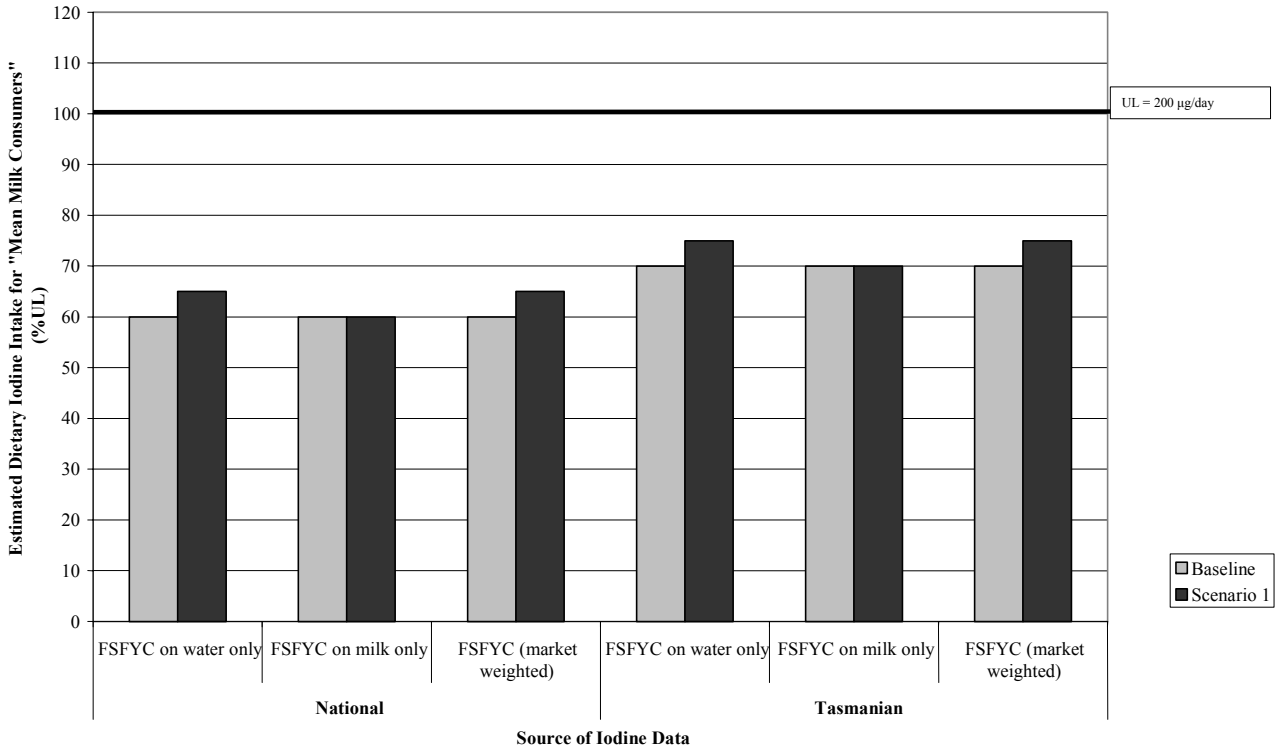


Figure 16: Estimated dietary intakes of iodine, as a percentage of the UL, for Australian children aged 2-3 years who are 'high milk consumers' for 'National' and 'Tasmanian' modelling for 'Milk substitution' methodology

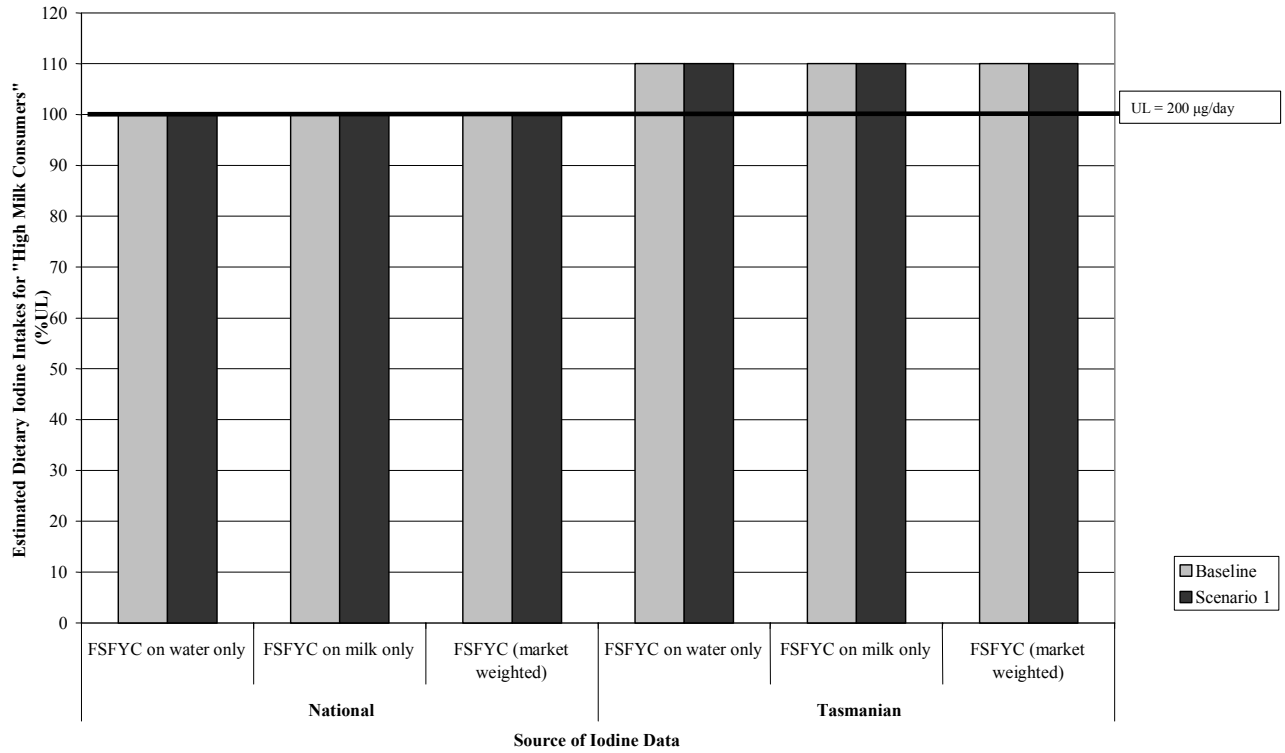


Figure 17: Estimated dietary intakes of iodine, as a percentage of the UL, for Australian children aged 1 year who are 'mean milk consumers' for 'National' and 'Tasmanian modelling for 'Milk substitution' methodology

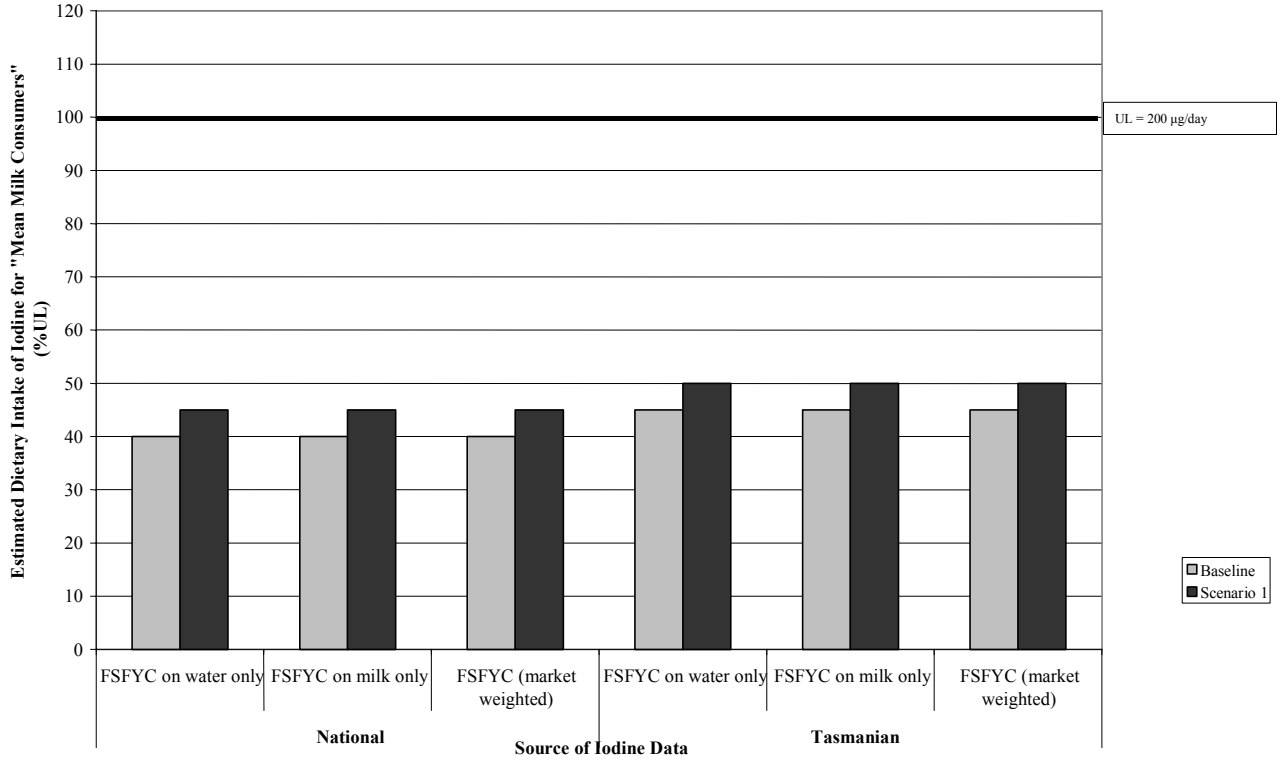
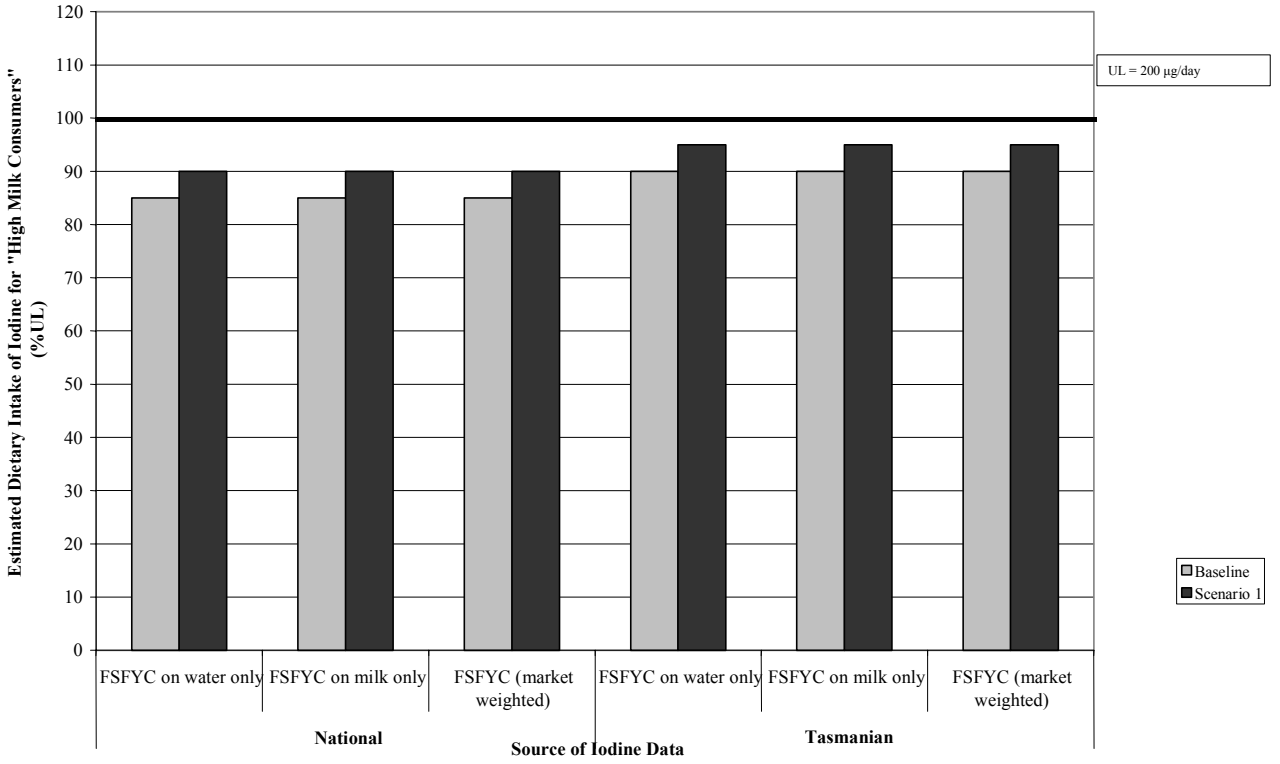


Figure 18: Estimated dietary intakes of iodine, as a percentage of the UL, for Australian children aged 1 year who are 'high milk consumers' for 'National' and 'Tasmanian' modelling for 'Milk substitution' methodology



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COMPLETE INFORMATION ON DIETARY INTAKE ASSESSMENT RESULTS – 'MARKET SHARE' METHODOLOGY

Table A1.1: Estimated mean dietary intakes of iodine for Australian children aged 2-3 years for 'National' and 'Tasmanian' models using 'Market share' methodology

Model Type	Number of consumers of iodine	Consumers♦ as a % of total respondents#	Average body weight (kg)	Mean consumers µg/day (µg/kg bw/day)	
				Baseline	Scenario 1
'National'	383	100	16	109 (7.1)	112 (7.3)
'Tasmanian'	383	100	16	129 (8.4)	132 (8.6)

Total number of respondents for Australia: 2-3 years = 383. Respondents include all members of the survey population whether or not they consumed a food that contains iodine.
♦ Consumers only – This only includes the people who have consumed a food that contain iodine.

Table A1.2: Estimated mean dietary intakes of iodine for Australian children aged 1 year for 'National' and 'Tasmanian' models using 'Market share' methodology

Model Type	Average body weight (kg)	Mean consumers µg/day (µg/kg bw/day)	
		Baseline	Scenario 1
'National'	10.2	74 (7.3)	78 (7.6)
'Tasmanian'	10.2	85 (8.4)	89 (8.7)

Table A1.3: Contribution of each food group to total iodine dietary intakes for Australian children aged 2-3 years for 'National' and 'Tasmanian' models (Market share method)

Food Name	% Contribution to iodine dietary intake			
	Baseline		Scenario 1	
	'National' model	'Tasmanian' model	'National' model	'Tasmanian' model
Dairy products & FSFYC	80	65	80	65
Fruits	10	10	10	10
Cereal foods	3	20	3	20
Eggs	3	2	3	2
Vegetables (including herbs)	1	<1	1	<1
Seafood (including	<1	<1	<1	<1

seaweed)				
Meat & poultry	<1	<1	<1	<1
Water	<1	<1	<1	<1
Other foods	<1	<1	<1	<1

Table A1.4: Percentage of Australian children aged 2-3 years with estimated dietary iodine intakes below the EAR and above the UL for 'National' and 'Tasmanian' models (Market share method)

Model	Scenario	Percentage of Respondent with Dietary Iodine Intakes < EAR (%)	Percentage of Respondent with Dietary Iodine Intakes > UL (%)
'National'	Baseline	25	6
	Scenario 1	25	7
'Tasmanian'	Baseline	15	15
	Scenario 1	15	15

Complete information on dietary intake assessment results – 'Milk substitution' methodology

Table A2.1: Estimated dietary intakes of iodine for 'mean milk consumers' for Australian children aged 2-3 years for 'National' and 'Tasmanian' models using the 'Milk substitution' methodology

Scenario	Units	Estimated Dietary Iodine Intake					
		FSFYC + Nationally representative other foods			FSFYC + Tasmanian bread + Nationally representative other foods		
		FSFYC on water only	FSFYC on milk only	FSFYC (market weighted)	FSFYC on water only	FSFYC on milk only	FSFYC (market weighted)
Baseline	ug/day	116	120	117	136	141	138
	ug/kg bw/day	7.2	7.5	7.3	8.5	8.8	8.6
	%UL	60	60	60	70	70	70
Scenario 1	ug/day	126	124	125	146	145	146
	ug/kg bw/day	7.8	7.8	7.8	9.1	9.0	9.1
	%UL	65	60	65	75	70	75

Table A2.2: Estimated dietary intakes of iodine for 'mean milk consumers' for Australian children aged 1 year for 'National' and 'Tasmanian' models using the 'Milk substitution' methodology

Scenario	Units	Estimated Dietary Iodine Intake					
		FSFYC + Nationally representative other foods			FSFYC + Tasmanian bread + Nationally representative other foods		
		FSFYC on water only	FSFYC on milk only	FSFYC (market weighted)	FSFYC on water only	FSFYC on milk only	FSFYC (market weighted)
Baseline	ug/day	77	82	79	89	94	90
	ug/kg bw/day	7.6	8.1	7.7	8.7	9.2	8.8
	%UL	40	40	40	45	45	45
Scenario 1	ug/day	88	87	88	100	98	99
	ug/kg bw/day	8.7	8.5	8.6	9.8	9.6	9.7
	%UL	45	45	45	50	50	50

Table A2.3: Estimated dietary intakes of iodine for 'high consumers of milk' for Australian children aged 2-3 years for 'National' and 'Tasmanian' models using the 'Milk substitution' methodology

Scenario	Units	Estimated Dietary Iodine Intake					
		FSFYC + Nationally representative other foods			FSFYC + Tasmanian bread + Nationally representative other foods		
		FSFYC on water only	FSFYC on milk only	FSFYC (market weighted)	FSFYC on water only	FSFYC on milk only	FSFYC (market weighted)
Baseline	ug/day	196	201	198	216	221	218
	ug/kg bw/day	12.3	12.5	12.4	13.5	13.8	13.6
	%UL	100	100	100	110	110	110
Scenario 1	ug/day	206	205	206	226	225	226
	ug/kg bw/day	12.9	12.8	12.8	14.1	14.1	14.1
	%UL	100	100	100	110	110	110

Table A2.4: Estimated dietary intakes of iodine for 'high consumers of milk' for Australian children aged 1 year for 'National' and 'Tasmanian' models using the 'Milk substitution' methodology

Scenario	Units	Estimated Dietary Iodine Intake					
		FSFYC + Nationally representative other foods			FSFYC + Tasmanian bread + Nationally representative other foods		
		FSFYC on water only	FSFYC on milk only	FSFYC (market weighted)	FSFYC on water only	FSFYC on milk only	FSFYC (market weighted)
Baseline	ug/day	168	173	169	179	184	181
	ug/kg bw/day	16.4	16.9	16.6	17.6	18.0	17.7
	%UL	85	85	85	90	90	90
Scenario 1	ug/day	179	177	178	190	188	189
	ug/kg bw/day	17.5	17.3	17.5	18.6	18.5	18.6
	%UL	90	90	90	95	95	95

Complete Information on Risk Characterisation

Table A3.1: Estimated mean dietary intakes of iodine for Australian children aged 2-3 years, as a percentage of the UL for 'National' and 'Tasmanian' models using 'Market share' methodology

Model Type	Number of consumers of iodine	Consumers♦ as a % of total respondents#	Average body weight (kg)	Mean consumers (%UL)	
				Baseline	Scenario 1
'National'	383	100	16	55	55
'Tasmanian'	383	100	16	65	65

Total number of respondents for Australia: 2-3 years = 383. Respondents include all members of the survey population whether or not they consumed a food that contains iodine.
♦ Consumers only – This only includes the people who have consumed a food that contains iodine.
* UL = 200 µg/day

Table A3.2: Estimated mean dietary intakes of iodine for Australian children aged 1 year, as a percentage of the UL for 'National' and 'Tasmanian' models using 'Market share' methodology

Model Type	Average body weight (kg)	Mean consumers (%UL)	
		Baseline	Scenario 1
'National'	10.2	35	40
'Tasmanian'	10.2	45	45

ATTACHMENT 4

NUTRITION ASSESSMENT

Contents

Executive Summary

The aim of this nutrition assessment is to consider the nutritional consequences from increasing the maximum permitted iodine content of formulated supplementary foods for young children (FSFYC). These impacts have been assessed by:

- determining the iodine status of 1-3 year old children;
- identifying how iodine intakes impact on other nutrients; and
- determining the health consequences for young children of high iodine intakes.

Iodine status of 1-3 year old children

FSANZ has assessed the current iodine status of the 1-3 year-old target population, by assessing urinary iodine data and dietary iodine intakes. The only data on urinary iodine levels specific to 1-3 year old children is Skeaff *et al.* (2005). This study shows that New Zealand 1-3 year old children are a mildly deficient as an entire group (mean urinary iodine = 59 μg/L), and that 33% of this group is moderately deficient (urinary iodine < 50 μg/L).

No urinary iodine studies have been conducted directly on Australian 1-3 year-old children, although older childhood population studies (Guttikonda *et al.* 2003, Li *et al.* 2001, McDonnell *et al.* 2003, Skeaff *et al.* 2002, Skeaff *et al.* 2005, Ministry of Health 2003)[32] indicate that Australian and New Zealand children have a reduced iodine status. Therefore, it is assumed that Australian 1-3 year old children have an iodine status generally similar to New Zealand 1-3 year old children. Because Australian milk contains higher mean iodine levels than New Zealand milk, the actual iodine status of Australian 1-3 year-old children may be less severe than has been reported in Skeaff *et al.* (2005).

An assessment of baseline dietary iodine intakes against the Estimated Average Requirement (EAR) (a reference for measuring nutritional inadequacy) shows that a substantial proportion (43%) of young children have intakes below the EAR at baseline, although the absence of second day NNS data may mean that the actual level of inadequacy has been overestimated. This level of inadequacy decreases to 37% of 1-3 year old children when the proposed amendments are modelled, showing that the amendments may a beneficial effect on those 1-3 year old children who are not able to obtain sufficient iodine in the diet.

Impact of increased iodine intakes on other nutrients

There is no available scientific literature to suggest that increased iodine intakes inhibit the bioavailability of other nutrients. However, the presence of low selenium intakes in a population (such as in New Zealand) may exacerbate any iodine deficiencies that are currently prevalent amongst children, because of a relationship between the selenium and iodine status of the human body. This effect magnifies the potential for any reduced iodine status that may exist for New Zealand 1-3 year olds.

[32] For full reference listing see Nutrition Risk Assessment at Attachment 4.

Conclusion

There is a significant proportion of 1-3 year old Australian and New Zealand children that do not obtain sufficient quantities of iodine from the diet. As the Dietary Intake Assessment (Attachment 4) has shown, an increase in the maximum permitted iodine limit as sought by Application A528 and in the consumption of FSFYC will increase iodine intakes of 1-3 year old children, albeit by a small margin. Such an increase therefore represents a potential health benefit for a section of the 1-3 year old population.

1. Introduction

The aim of this nutrition assessment is to consider the nutritional consequences for Australian and New Zealand children from increasing the maximum permitted iodine content of formulated supplementary foods for young children (FSFYC). This assessment will be conducted by reviewing the following nutritional issues:

- the current iodine status of Australian and New Zealand young children;
- the interactions between iodine and other nutrients; and
- the likelihood of adverse health outcomes for young children who consume high iodine intakes.

2. Current Iodine Status of Australian and New Zealand Children

The International Council for the Control of Iodine Deficiency Disorders (ICCIDD) and the World Health Organization (WHO) have established median urinary iodine concentration criteria for determining a population's iodine status (see Table 1) (ICCIDD 2001). A median of 100 μg/L or greater is recommended by the WHO as being indicative of iodine sufficiency.

Table 1: Epidemiological Criteria for Assessing Iodine Nutrition Based on Median Urinary Iodine Concentrations in School-Aged Children (ICCIDD 2001)

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
200 – 299	More than adequate	Risk of iodine-induced hyperthyroidism (populations with long-standing iodine deficiency only)
≥300	Excessive	Risk of thyroiditis, goiter, hypothyroidism, autoimmune thyroid diseases, and iodine sensitivity reactions; and in iodine deficient populations, the additional risk of iodine-induced hyperthyroidism.

1.1 Population Iodine Data

In the early 1990s it was reported that there was no evidence of iodine deficiency in Australia (Stanbury 1996). A downward trend in iodine status has been noted in more recent years (Thomson 2002), and has been identified in several Australian and New Zealand urinary iodine studies that specifically focus on children (see Table 2).

While this information is significant, it should be noted that only one of the studies includes the FSFYC target group of 1-3 year old children (Skeaff *et al.* 2005), and can be used only as a direct measurement of iodine status for New Zealand children.

Table 2: Results from Australian and New Zealand Urinary Iodine Studies on Children

Author	Study Design	Subject Type and Numbers		Urinary Iodine Results		
				% Subjects with < 50 μg/L	% Subjects with < 100 μg/L	Median concentration (μg/L)
Australian Studies						
Guttikonda *et al* (2003)	Prospective cross-sectional study, conducted at NSW Central Coast primary school. Urine collected as 1st morning spot samples.	301 children 5 -13 years (133 females, 168 males)		14	69	82
Li *et al* (2001)	Randomised cross-sectional study within Sydney. Urine collected as spot samples.	School children 6 - 13 years		13.8	-	84
McDonnell *et al* (2003)	Prospective cross-sectional study within Melbourne. Urine collected as 1st morning spot samples.	577 school children aged 11-18 years.	Male (n=167)	17	68	82
			Female (n=410)	31	79	64
			Total	27	76	70
New Zealand Studies						
Skeaff *et al* (2002)	Randomised cross-sectional study, undertaken across two New Zealand cities.	300 Children aged 8 - 10 years.		31.4	79.7	66
Skeaff *et al.* (2005)	Randomised cross-sectional survey undertaken across several South-island NZ cities.	230 children aged 6 to 24 months. Results are given only for those not formula or breast fed (n=119).		39.5	66.4	59
Ministry of Health (2003)	Randomised sampling from representative schools. Urine collected as spot samples.	3275 Children 5 -14 years	Male	25	-	68
			Female	31	-	62
			Total	28	-	66

- = not assessed as part of the study.

Both the WHO and the ICCIDD have established that more than 50% of a population must have a urinary iodine concentration above 100 μg/L before it can be considered iodine replete, and that no more than 20 percent of a population should have urinary iodine levels less than 50 μg/L (ICCIDD 2001). However, as shown in Table 2, Skeaff *et al.* (2005) has indicated that less than 50% of New Zealand children aged 1-3 years have a urinary iodine concentration above 100 μg/L, and more than 20% have a urinary iodine concentration less than 50 μg/L. According to the WHO and ICCIDD criteria, the median urinary iodine concentration of 59 μg/L for 1-3 year old New Zealand children also indicates that this population is mildly iodine deficient.

No studies were identified on Australian children aged 1-3 years. The results from older Australian children presented in Table 2 can be used as an indicator of iodine status for 1-3 year-old children, or alternatively the results of Skeaff *et al.* (2005) can be extrapolated to Australian children. When older child data is used, it is recognised that the iodine intakes may be typically lower in these age groups as a result of their reduced milk consumption. When using New Zealand data, the lower mean iodine content of New Zealand milk (~80 μg/L) is seen as a potential downward factor on 1-3 year old iodine intakes in comparison to Australia (a mean milk iodine content ~130μg/L). Notwithstanding these uncertainties, the data presented in Table 2, particularly that of Skeaff *et al.* (2005), suggests that iodine intakes of 1-3 year-old Australian children might not meet the iodine-replete criteria established by WHO and ICCIDD.

Overall, the information presented in Table 2 indicates that a proportion of Australian and New Zealand 1-3 year old children may not be consuming iodine at sufficient levels to meet their requirements.

1.2 Iodine Intake Compared to Estimated Average Requirements

An Estimated Average Requirement (EAR) is a value representative of a population's median requirement for the dietary intake of a particular nutrient (in this case iodine). The adequacy of nutrient intakes can therefore be assessed according to the percentage of the population with an intake below the EAR. Where a proportion of the population has an intake less than the EAR, it can be concluded that their distribution of intakes has shifted below the distribution of requirements (IOM 2001).

FSANZ has assessed the dietary iodine status of children by comparing dietary iodine intake data for 2-3 year olds against the EAR. The US EAR (IOM 2001) for 1-3 year old children of 65 μg/day was used for this assessment, which is consistent with the Australia and New Zealand 1-3 year old draft EAR proposed by the National Health and Medical Research Council (NHMRC 2004).

The assessment against the iodine EAR was undertaken using 1995 Australian National Nutrition Survey information only, as New Zealand dietary information on young children is unavailable. The first 24-hour recall data of the Australian National Nutrition Survey was only used, as second day data was not available for 1-3 year-old children. The absence of second day data may therefore produce an overestimated proportion of inadequate 1-3 year old iodine intakes, as adjustments cannot be made for atypical dietary patterns.

The results of this assessment are provided in Table 3 below, and show that 25% of 2-3 year olds consumed iodine below the EAR and thus are likely to have an inadequate iodine intake. The absence of second day NNS data means that the actual percentage of 1-3 year olds with intakes below the EAR may be smaller than these figures.

Table 3: Percentage of Australian children aged 2-3 years with estimated dietary iodine intakes below the EAR and above the UL for 'National' and 'Tasmanian' models (Market share method)

Model	Scenario	Percentage of Respondent with Dietary Iodine Intakes < EAR (%)
National#	Baseline*	25
	Scenario 1	25
Tasmanian#	Baseline*	15
	Scenario 1	15

* This scenario is based on the Australian National Nutrition Survey 1995, which does not include data on FSFYC use by 1-3 year olds.

\# These models and scenarios have been developed from NNS data by applying assumptions on the use of FSFYC by 1-3 year olds. Full details of the methodology behind the modelling are located in Attachment 3.

1.3 Conclusion

The data on urinary iodine data indicates that New Zealand 1-3 year old children are mildly iodine deficient. In extrapolating the data on New Zealand children, and using data on older children, it is assumed that 1-3 year old Australian children are experiencing a similar level of iodine deficiency. Dietary iodine intake data for 1-3 year old children in both Australia and New Zealand reinforces these conclusions.

2. Nutrient Interactions

2.1 Bioavailability

Some nutrients are known to compete with each other for absorption and bioavailability when they are consumed together in the same meal. There is no literature to suggest that iodine inhibits the bioavailability of any other nutrient, however the absorption of dietary iodine can be reduced by the calcium, magnesium and iron content in food and water (SCF 2002). Goitrogens (found in the vegetables of the *Brassica* genus, *Cruciferae* family: cabbage, broccoli, turnips, and Brussels sprouts) can affect the utilisation of dietary iodine in the body by interfering with the biosynthesis of the hormones T3 and T4. Heat from cooking will inactivate most of the goitrogens present in these vegetables.

Of particular importance for Application A528 is that iodine bioavailability can also be compromised by the consumption of soy flour. The digestive by-products of soy flour block the enterohepatic circulation of thyroxine (T_4) (ESCF 2002), and therefore soy-based FSFYC may inadvertently have the potential to affect iodine status. However, this effect is expected to be negligible as it is only the exclusive use of soy products (e.g. feeding of soy-based formulas to infants, who cannot receive nutrition from other sources) that has been known to adversely impact on iodine status, and not supplementary feeding as occurs with FSFYC.

2.2 Selenium and Iodine Interactions

Iodine status is also influenced by selenium intakes. Although iodine is essential for the synthesis of thyroid hormones, selenium-dependent enzymes (iodothyronine deiodinases) are also required for the conversion of T_4 to the biologically active thyroid hormone triiodothyronine (T_3) (Goyens 1987, Vanderpas 1990).

Selenium deficiency can thus exacerbate the thyroid complications of iodine toxicity, as the uptake of iodide by the thyroid gland increases in compensation to a reduced T_3 production (ATDSR 2001). The selenium/iodine interaction is particularly important for New Zealand children, as the New Zealand population has a reduced selenium status compared to other countries, and may even border on insufficiency (Thompson 2004).

2.3 Conclusion

The bioavailability of iodine or other nutrients is not likely to be affected as a result of this Application. However, the potential for selenium deficiency to exacerbate iodine deficiency is of importance, as it could impact on the iodine status of young children especially in New Zealand.

3. Overall Conclusion

There is a significant proportion of 1-3 year old Australian and New Zealand children that do not obtain sufficient quantities of iodine from the diet. As the Dietary Intake Assessment (Attachment 3) has shown, an increase in the maximum permitted iodine limit as sought by Application A528 and in the consumption of FSFYC will increase iodine intakes of 1-3 year old children, albeit by a small margin. Such an increase therefore represents a potential health benefit for a section of the 1-3 year old population.

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ATTACHMENT 5

Summary of Submissions at Final Assessment

FSANZ received 9 submissions (2 being student assignments), in response to public consultation on Application A528 – Maximum Iodine Limit in Formulated Supplementary Foods for Young Children (FSFYC), during the 7-week public consultation period of 4 August to 22 September 2004. A summary of submitter comments is provided in the table below.

Two regulatory options were presented at Draft Assessment. These were:

Option 1 – Maintaining the *status quo* by not increasing the permitted maximum iodine limit in FSFYC; or

Option 2 – Amending Standard 2.9.3 to increase the permitted maximum level of iodine in FSFYC from 35μg to 70 μg per serve.

No.	Submitter	Submission Comments
1	ACT Health Melissa Langhorne	**Supports Option 2** No additional comments
2	Australian Food and Grocery Council Tony Downer	**Supports Option 2** Considers that, within the bounds of safety, maintaining a maximum permitted level of iodine, which cannot be achieved consistently due to varying levels of naturally occurring iodine in milk, militates against an efficient and internationally competitive food industry.
3	Food Technology Association of Victoria Inc (FTAV) David Gill	**Supports Option 2** No additional comments
4	Nestlé Robyn Banks	**Supports Option 2** No additional comments
5	New South Wales (NSW) Food Authority Bill Porter	**Supports Option 2** Note the concerns raised by Tasmania Health (relates to the absence of available data) and the potential impact of A493 – Iodine as a Processing Aid. Urges FSANZ to monitor iodine levels in relevant foods over the next few years to determine the impact of these Applications and to consider if necessary the need to re-evaluate FSANZ's assessment**.**

6	New Zealand Food Safety Authority (NZFSA) Carole Inkster	**Supports Option 1** Cannot agree to the proposed draft variation, at this time, as considers the dietary intake assessment report underestimates the potential iodine intake for the following reasons: No food consumption data for children aged 1 -2 years. Would like some intake calculations for 1 year olds as this age group is just as likely (if not more), to consume FSFYC (Toddler Milk) as 2 –3 year olds. Therefore proposes that a lower weight of 10 kg could be used for dietary modelling equating to a 'safe intake level' of 170 micrograms/day. A 10 kg child would only need to consume 2.5 serves of toddler milk (at the new proposed level of 70 micrograms per serve) to reach the safe upper limit. The NZFSA does not believe that this is enough safety margin; Disagrees with using the assumption that FSFYC are not made up to directions when calculating iodine concentrations in FSFYC. States that dietary modelling should be performed in the first instance using the values obtained when FSFYC are prepared to manufacturers directions. The baseline figure of 0.1628 mg/kg is an underestimate and does not reflect the iodine concentration in FSFYC made up as directed; and Guidelines for 1 – 2 years old in New Zealand recommend consumption of 500 –600 ml of milk per day. Carers providing Toddler milk instead of cows' milk would in some cases provide up to 3 serves per day (at 200 ml per serve), further increasing the risk of exceeding the PTDI for iodine. Suggests that another product (a sliced luncheon product) available in New Zealand and made to Standard 2.9.3, Division 4 could be of interest for comparative purposes. Is unclear why the Applicant cannot take steps to comply with the current standard, when infant formula made to Standard 2.9.1 must comply with an upper limit for iodine. Suggests that this could be achieved by sourcing milk powder with known, lower levels of iodine, or blending batches of milk powder with varying iodine levels.
7	Queensland Health Gary Bielby	**Supports Option 2** Notes the lack of available data for dietary modelling (i.e. the National Nutrition Survey (NNS) data for Australia does not included consumption data below 2 years of age and for New Zealand data for 1-3 years of age). Acknowledges the difficult task in conducting dietary exposure assessments based on out-of-date data. Requests that the matter be reconsidered when new information (i.e. NNS data) becomes available.
8	University of Auckland Ngan King Chok	**Supports Option 2**
9	University of Auckland Qiong Chen	**Supports Option 2**