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

2-05
23 March 2005

FINAL ASSESSMENT REPORT

APPLICATION A493

IODINE AS A PROCESSING AID

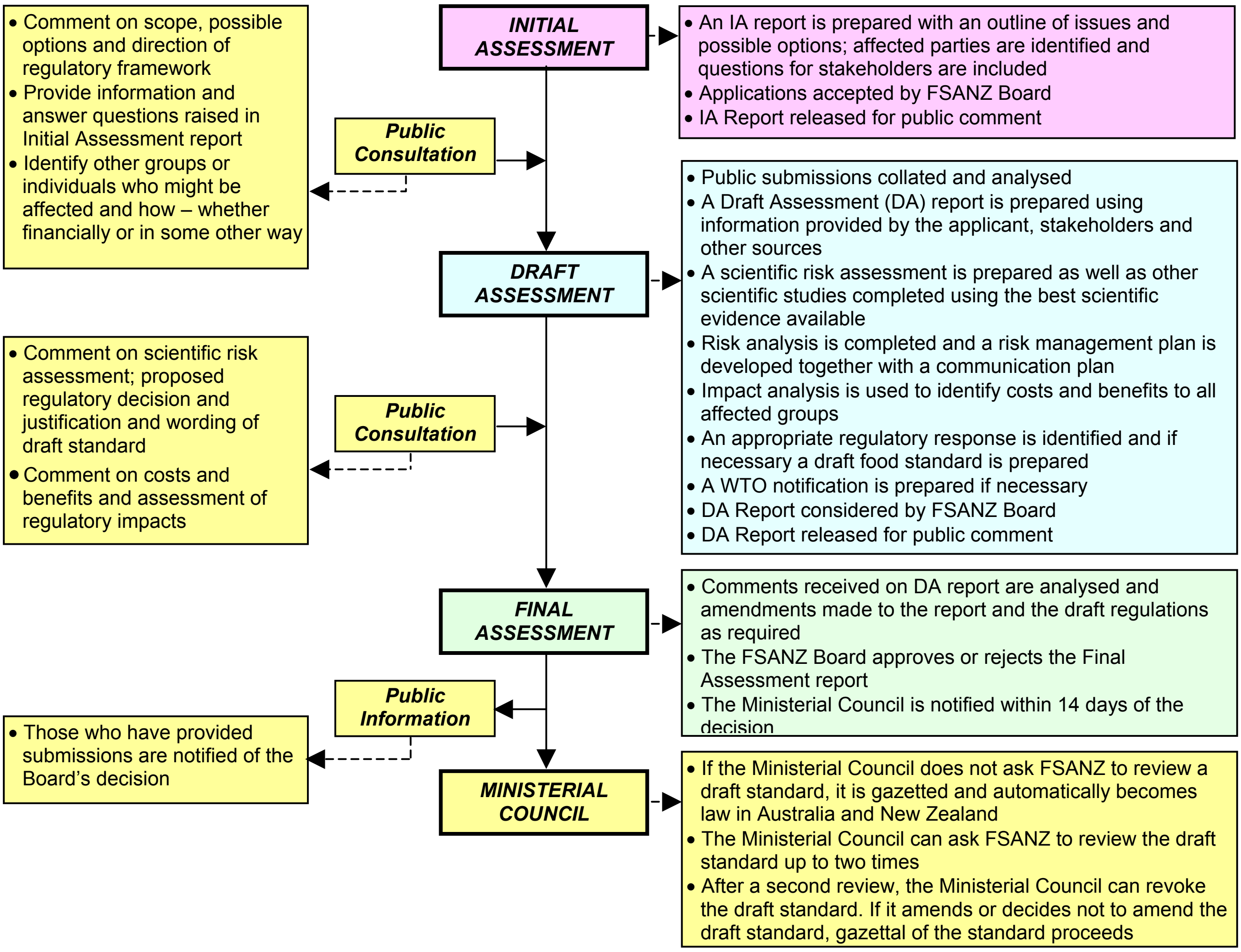
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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.



INITIAL ASSESSMENT

- An IA report is prepared with an outline of issues and possible options; affected parties are identified and questions for stakeholders are included
- Applications accepted by FSANZ Board
- IA Report released for public comment

Public Consultation

- Comment on scope, possible options and direction of regulatory framework
- Provide information and answer questions raised in Initial Assessment report
- Identify other groups or individuals who might be affected and how – whether financially or in some other way

DRAFT ASSESSMENT

- Public submissions collated and analysed
- A Draft Assessment (DA) report is prepared using information provided by the applicant, stakeholders and other sources
- A scientific risk assessment is prepared as well as other scientific studies completed using the best scientific evidence available
- Risk analysis is completed and a risk management plan is developed together with a communication plan
- Impact analysis is used to identify costs and benefits to all affected groups
- An appropriate regulatory response is identified and if necessary a draft food standard is prepared
- A WTO notification is prepared if necessary
- DA Report considered by FSANZ Board
- DA Report released for public comment

Public Consultation

- Comment on scientific risk assessment; proposed regulatory decision and justification and wording of draft standard
- Comment on costs and benefits and assessment of regulatory impacts

FINAL ASSESSMENT

- Comments received on DA report are analysed and amendments made to the report and the draft regulations as required
- The FSANZ Board approves or rejects the Final Assessment report
- The Ministerial Council is notified within 14 days of the decision

Public Information

- Those who have provided submissions are notified of the Board's decision

MINISTERIAL COUNCIL

- If the Ministerial Council does not ask FSANZ to review a draft standard, it is gazetted and automatically becomes law in Australia and New Zealand
- The Ministerial Council can ask FSANZ to review the draft standard up to two times
- After a second review, the Ministerial Council can revoke the draft standard. If it amends or decides not to amend the draft standard, gazettal of the standard proceeds

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.

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:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
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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 on 21 February 2003 from Ioteq Limited (formerly Iodine Technologies Australia Pty Ltd) to approve the use of iodine as a processing aid under Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code).

Iodine has a long history of use as a water disinfectant, and is also used as a sanitising compound (in iodophors) by the dairy industry. The purpose of this Application is to seek approval for the use of iodine for the surface sanitisation of foods, specifically fruit, vegetables, nuts and eggs.

Sanitising agents are used at all levels during food manufacture and processing to reduce the levels of pathogens and spoilage organisms on the surface of foods. Chlorine-based washing systems are by far the most commonly used but are said to possess a number of disadvantages. The Applicant has developed an iodine-based washing system as an alternative to chlorine-based systems.

Under Standard 1.3.3, processing aids are required to undergo pre-market approval in Australia and New Zealand. There is currently no approval for the use of iodine as a processing aid in the Code, although the Australian Pesticides and Veterinary Medicines Authority (APVMA) have registered iodine for use in the Applicant's proprietary system for the post harvest sanitisation of whole fruits and vegetables. This Application, if successful, will broaden this use to eggs as well as minimally processed fruits and vegetables, such as fresh cut produce.

The objective of this assessment is to determine whether it is appropriate to amend the Code to permit the use of iodine as a washing agent for fruit, vegetables, nuts and eggs at good manufacturing practice levels. A range of issues was considered during the assessment, including the technological justification for the use of iodine and the potential impact on public health and safety.

The food technology assessment concluded that the use of iodine as a washing agent for fruits, vegetables, nuts and eggs is technologically justified. Iodine is superior to chlorine at equivalent concentrations in reducing the number of surface organisms on food and a technological need exists for suitable alternatives to the currently available sanitisers.

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

Two regulatory options were identified in the assessment – to either approve or not approve the use of iodine as a processing aid. Following an assessment of the potential impact of each of the options on the affected parties (consumers, the food industry and government), and taking into account the outcome of the risk assessment, the preferred option would be to approve the use of iodine as a processing aid.

This option potentially offers significant benefits to the food industry and consumers with very little associated negative impact. The proposed variation to the Code is therefore considered necessary, cost effective and of net benefit to both the food industry and consumers.

- The Draft Assessment Report for this Application was circulated for public comment on 4 August 2003 for a period of six weeks. A total of eleven submissions were subsequently received and the issues raised by these submissions are addressed in this report.
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Statement of Reasons

The variation to Standard 1.3.3 – Processing Aids of the Code (**Attachment 1**), approving the use of iodine as a processing aid, is agreed for the following reasons:

- the use of iodine as a washing agent for fruit, vegetables, nuts and eggs is technologically justified – the efficacy of iodine as a sanitising agent for foods has been demonstrated and a technological need exists for alternative food sanitizers;
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- the use of iodine as proposed may result in a small increase in iodine intake but not to a level that would raise safety concerns for the vast majority of the population or pose any adverse nutritional risks. The proposed use of iodine is also considered unlikely to pose any additional risk for vulnerable individuals;
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- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act. In particular, FSANZ has addressed the protection of public health and safety by undertaking a risk assessment based on the best available scientific data.
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- The regulation impact assessment has concluded that the benefits of permitting use of iodine as a washing agent outweigh any costs associated with its use.
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- The variation to the Code will come into effect on the date of gazettal. FSANZ proposes to review the extent of use of iodine as a processing aid three years from the date of gazettal.
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1. Introduction

FSANZ received an Application on 21 February 2003 from Ioteq Limited (formerly Iodine Technologies Australia Pty Ltd) to approve the use of iodine as a processing aid under Standard 1.3.3 Processing Aids of the Code. It is proposed to use iodine as a washing/sanitising agent for foods.

2. Regulatory Problem

Under Standard 1.3.3, processing aids are required to undergo pre-market approval in Australia and New Zealand. According to Standard 1.3.3, processing aid means:

> a substance listed in clauses 3 to 18, where –
>
> (a) the substance is used in the processing of raw materials, foods or ingredients, to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food; and
> (b) the substance is used in the course of manufacture of a food at the lowest level necessary to achieve a function in the processing of that food, irrespective of any maximum permitted level specified.

There is currently no approval for the use of iodine as a processing aid in the Code, therefore the Applicant has applied to have permission for iodine as a washing agent inserted in the Table to clause 12 of Standard 1.3.3. The substances listed in this Table may be used as bleaching agents, washing and peeling agents in the course of manufacture of the corresponding foods specified in the Table provided the final food contains no more than the corresponding maximum permitted level specified in the Table.

The Applicant requested an amendment to Standard 1.3.3 to allow iodine to be used as a washing agent for fruit, vegetables (which includes herbs and nuts)[1] and eggs at good manufacturing practice (GMP)[2] levels.

3. Objective

The purpose of this assessment is to determine whether it is appropriate to amend Standard 1.3.3 of the Code to permit the use of iodine as a processing aid.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives, which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
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[1] Standard 2.3.1 Fruit and Vegetables of the Code defines fruit and vegetables as meaning fruit, vegetables, nuts, spices, herbs, fungi, legumes and seeds.

[2] Under GMP, the amount of iodine used should be the minimum amount necessary to have the intended effect (i.e. sanitisation).

- the provision of adequate information relating to food to enable consumers to make informed choices; and
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- the prevention of misleading or deceptive conduct.

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

- the need for standards to be based on risk analysis using the best available scientific evidence;
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- the promotion of consistency between domestic and international food standards;
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- the desirability of an efficient and internationally competitive food industry;
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- the promotion of fair trading in food; and
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- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Iodine as a Sanitising Agent

Iodine is a member of the halogen family of chemical elements. Like other halogens, such as chlorine and bromine, it has strong anti-microbial activity. Chlorine is the more commonly used halogen and various forms of compounds that deliver chlorine (including hypochlorite) have been used for many years as sanitising agents by the food industry. Elemental iodine has a long history of use as a water disinfectant, and is also used as a sanitising compound (in iodophors) by the dairy industry.

Sanitising agents are used at all levels during food manufacture and processing to reduce the levels of pathogens and spoilage organisms on the surface of foods. The use of sanitising agents is therefore important for improving the safety of food as well as keeping quality and shelf life. Sanitising agents typically do not kill all bacteria (so they are not sterilising agents) but tend to inhibit the growth of the bacteria to acceptable levels.

The Applicant has developed a fully automated and enclosed post harvest sanitising system – the Iodoclean™ System – which uses elemental iodine as the active ingredient to reduce the levels of bacteria and fungi on the surface of food, particularly fresh produce. The sanitising system delivers iodine in treatment water at a controlled concentration, which can be set within the range of 3 to 30 ppm.

The iodine concentration used depends on the contact time and the microbial load on the product to be treated. This system is being promoted as a viable alternative to chlorine for the sanitation of food and is said to offer several advantages over chlorine.

4.2 Relevant Projects

4.2.1 Formulated Supplementary Foods for Young Children

FSANZ is currently assessing Application A528 – Maximum Iodine Limit in Formulated Supplementary Foods for Young Children. This Application is seeking to increase the maximum permitted quantity of iodine in formulated supplementary foods for young children (FSFYC) from 35 µg to 70 µg per serving. A combined dietary exposure assessment was undertaken at Draft Assessment for Application A528, which examined the effect on iodine intake in 2-3 year olds from increasing the maximum iodine limit in FSFYC in combination with using iodine as a washing agent. This combined assessment was presented in the Draft Assessment Report for Application A493.

During Final Assessment, a number of issues have arisen in relation to FSANZ's consideration of Application A528, and as a consequence it will take longer than originally anticipated to complete assessment of that Application. As finalisation of Application A493 is not contingent on the finalisation of Application A528, a decision has been taken to progress Application A493 in advance of Application A528. The impact of Application A493 on iodine intake in young children consuming FSFYC with an increased iodine intake will be considered in the Final Assessment report for Application A528 and is not presented in this report.

4.2.2 Iodine Fortification

While not relevant to consideration of this Application, the Ministerial Council recently agreed to a new policy guideline for the fortification of foods with vitamins and minerals[3]. This guideline recognises particular circumstances in which mandatory fortification to meet public health need is appropriate. FSANZ has raised a separate proposal (P230 Iodine Fortification) to investigate the need for increased iodine content in the Australia New Zealand food supply.

4.3 Other Regulatory Approvals

4.3.1 National Approvals

The APVMA registered iodine, under the product name of Biomaxa Iodine Granules Post Harvest Sanitiser, on 6 November 2002. The iodine granules are to be used only with the Iodoclean™ System, a fully automated post harvest sanitising system to assist in the control of bacterial and fungi on a range of whole fruits and vegetables.

Under this registration, the APVMA have granted a Table 5 exemption for iodine, which means iodine is permitted as a post harvest sanitiser without the necessity for the setting of a Maximum Residue Limit (MRL). This covers situations where residues do not or should not occur in foods or animal feeds; or where the residues are identical to or indistinguishable from natural food components; or are otherwise of no toxicological significance.

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[3] http://www.foodsecretariat.health.gov.au/policydocs.htm

Notwithstanding that, in this instance, the Applicant has an Application pending with FSANZ for the use of iodine as a processing aid, this is not inconsistent with the registration and Table 5 exemption provided by the APVMA. Nor does the registration and Table 5 exemption impact on consideration of this Application by FSANZ.

The fact there is currently no permission for the use of iodine as a processing aid under the Code is not actually contradictory to the APVMA registration. It is not necessary, in all cases, where there is registration with the APVMA for there to be a corresponding permission in the Code. A number of post harvest sanitisers are in use with APVMA registration for which there is no corresponding permission in the Code. The use of these chemicals pursuant to the APVMA registration would not amount to a breach of the Code. This also applies in the case of the Iodoclean™ system.

In addition to the above, a variety of iodine-based compounds are approved in both Australia and New Zealand for use as teat/udder sanitisers, general equipment sanitisers and for food contact surfaces.

4.3.2 Overseas Approvals

Overseas legislation for the use of iodine as a sanitising agent for foods primarily relates to its use on food contact surfaces. The relevant regulations are:

- United States Code of Federal Regulations Title 21, 178.1010 – Sanitising Solutions (food contact surfaces and utensils only).
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- United Kingdom Statutory Instrument 1999 No 919, Schedule 2 – Approved Disinfectants (sanitisation of dairies).

A range of provisions also exists for the short-term use of iodine to treat water supplies in emergency situations.

The Applicant has also advised FSANZ that they are currently seeking registration of iodine, as used in the Iodoclean™ System, as a biochemical pesticide by the United States Environment Protection Agency.

5. Relevant Issues

5.1 Technological Justification

The assessment of technological justification considered the technological function and efficacy of iodine as a sanitising agent and evidence of technological need. The full report is at **Attachment 2**.

Overall it was concluded that the use of iodine as a sanitising agent for foods is technologically justified. Iodine is superior to equivalent concentrations of chlorine in reducing the number of surface organisms on food. There is a technological need for safe and effective sanitisers for use on food, and iodine would appear to be a useful alternative to the chlorine-based wash systems currently available.

A number of submissions (Sydney Postharvest Laboratory, Food Science Australia and Department of Crop Sciences, University of Sydney) also raised the issue of technological need, commenting on the shortage of effective sanitisers. The approval of iodine as a washing agent for foods would be considered by them to be a very useful addition to the available sanitisers.

5.2 Risk Assessment

5.2.1 Safety of Iodine

Iodine is an essential component of the diet, however, as with many other essential nutrients, intakes in excess of physiological requirements may produce adverse effects. In the case of iodine, it is thyroid gland function and the regulation of thyroid hormone production and secretion that may be adversely affected.

FSANZ has undertaken a review of the toxic effects associated with excess dietary iodine, the full report of which is at **Attachment 3.** The findings of this assessment are briefly summarised below.

Excess iodine can produce an enlargement of the thyroid 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.

The human response to excess iodine can be quite variable. Some individuals can tolerate quite 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 typically have an underlying thyroid disorder or have a long history of iodine deficiency.

For the majority of healthy individuals, the most sensitive endpoint for iodine toxicity is sub-clinical hypothyroidism. Sub-clinical hypothyroidism is defined as an elevation in thyroid stimulating hormone concentration while serum thyroid hormone concentration is maintained within the normal range of values for healthy individuals. While not clinically adverse, such an effect, if persistent, could lead to clinical hypothyroidism. In healthy adults, such an effect has been associated with acute iodine intakes of 1700 µg/day (24 µg/kg body weight/day for a 71 kg person), and for children, has been associated with chronic intakes of 1150 µg/day (29 µg/kg/day for a 40 kg child).

Iodine intakes of approximately 1000 µg/day however appear to be well tolerated by healthy adults. This level has been used by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to establish a provisional maximum tolerable daily intake (PTDI)[4] for iodine of 17 µg/kg bw from all sources. FSANZ has adopted this level as a safe intake level for the purpose of risk assessment for the general healthy population.

For those individuals with thyroid disorders or a long history of iodine deficiency, this PTDI is not applicable since these individuals may respond adversely at levels of intake below the PTDI. It has been reported that intakes in the range 3-7 µg/kg/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.

5.2.2 Dietary Exposure Assessment

A dietary exposure assessment was done to estimate current and potential exposure to iodine from the diet if approval for the use of iodine as a processing aid for fruit, vegetables, nuts and eggs is granted.

Since Draft Assessment, the dietary exposure assessment has been completely revised to take into account new information that became available. This included:

- new analytical iodine concentration data for New Zealand and Australian foods, which became available through the 2003/2004 New Zealand Total Diet Survey (NZTDS) and the 22nd Australian Total Diet Survey (ATDS);

- data on the iodine concentration in bread and milk available in Tasmania, supplied by the Department of Health and Human Services, Tasmania (DHHS). These data differ from those that are nationally representative for these foods;

- data provided by the Applicant on the estimated market share that an elemental iodine wash will have for a number of individual commodities. Market share data had not previously been incorporated in the dietary exposure assessment.

The revised dietary exposure assessment report is at **Attachment 4** and is summarised below.

Estimated dietary intakes of iodine were calculated for the Australian and New Zealand populations, and for the population sub-group of Australian children aged 2-3 and 2-6 years. This was to ensure that iodine intakes would not exceed the PTDI if approval to use elemental iodine as a washing agent were granted.

As iodine is also an essential micronutrient, dietary intakes were also assessed for a range of age-gender categories for the purpose of comparison with the Estimated Average Requirements (EARs)[5] for iodine. The results of these comparisons are discussed in the nutrition risk assessment report at **Attachment 5** and below in Section 5.2.3.

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[4] PTDIs represent the permissible human exposure to those contaminants unavoidably associated with the consumption of otherwise wholesome and nutritious food, and is a level of intake that is considered safe over a life time.

[5] The EAR is defined as the level below which 50 per cent of the population may be at risk of having inadequate dietary intake and is used to estimate the prevalence of inadequate intakes in a population.

Baseline intakes of iodine were calculated using the iodine concentrations in untreated foods. Two post-treatment scenarios were examined in each dietary intake assessment: Scenario 1 applied a peeling factor to those fruits and vegetables washed with iodine that may be consumed with the peel either on or off (e.g. apples); and Scenario 2 assumed that fruits and vegetables washed with iodine that may be consumed with the peel on or off were always consumed unpeeled. Scenario 1 is considered to represent a more accurate estimate of the likely extent to which an elemental iodine wash will impact on dietary iodine intakes for Australian and New Zealand population groups. Scenario 2 is a worst-case scenario. In each of the post-treatment scenarios, iodine concentrations were weighted to take into account the estimated market share for an iodine wash for each commodity.

Data were received from DHHS on the iodine concentrations of bread and milk available in Tasmania. 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 confirmatory analysis of these samples suggested that the nationally representative milk iodine concentrations determined as part of the 22nd ATDS, most accurately reflect 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. This model is for the Tasmanian population only.

The dietary intake assessments conducted for New Zealand use the 'National' modelling type only.

In general, young children (2-3 years and 2-6 years) had the highest dietary intakes of iodine (on a µg/kg bw/day basis) for all of the population groups examined. The dietary iodine intakes of all Australian aged 2 years and above were higher than the dietary intakes of New Zealanders aged 15 years and above. The higher dietary iodine intake by Australians may be due to the higher iodine content of Australian milk (133 µg/kg) in comparison to New Zealand milk (86 µg/kg), especially given that milk is a major contributor to dietary iodine intake.

Estimated mean dietary intakes of iodine were below the PTDI of 17 µg/kg bw/day for all population groups, all scenarios and all model types examined. For all of the 'National' models, estimated 95th percentile dietary intakes of iodine were below the PTDI for all population groups and all scenarios. For the 'Tasmanian' model, the estimated 95th percentile dietary intakes of iodine were below the PTDI except for 2-3 year old children for Scenario 2 (102% of the PTDI).

5.2.3 Nutrition Assessment

A nutrition assessment was undertaken to consider the current iodine status of the Australian and New Zealand populations, and to compare this with the results of the dietary exposure assessment (**Attachment 4**) in order to subsequently determine the nutritional risks, if any, to Australian and New Zealand populations from the proposed amendments to the Code. The full nutrition risk assessment report is at **Attachment 5**. A brief summary of the findings is given below.

Several published studies, measuring urinary iodine concentration, have investigated the iodine status of various populations in Australia and New Zealand. Urinary iodine measures are more indicative of population iodine status than measures of dietary iodine intake. The general conclusion from these studies is that a sizeable proportion of Australians and New Zealanders suffer from iodine deficiency to varying extents.

In addition to examining studies of urinary iodine concentration, dietary modelling has been conducted to determine the percentage of Australian and New Zealand populations not meeting the Estimated Average Requirement (EAR) for iodine intake (baseline intake data). Current estimates of dietary intake, based on Australian and New Zealand National Nutrition Surveys (NNS), suggest that between 26 and 52 per cent of mainland Australians, 12 to 35 per cent of Tasmanians and about 65 per cent of New Zealanders are not meeting the EAR for dietary iodine intake.

Although not directly comparable, the general inference from both types of data is that a considerable proportion of Australians and New Zealanders are mildly iodine deficient. Data on the median urinary iodine levels in Australian and New Zealand populations suggests the baseline levels of iodine intake used in the dietary modelling for this Application may be slightly higher than in reality, which would mean the percentages of those not meeting the EAR may in fact be higher than calculated.

In terms of interactions with other nutrients, there is no literature to suggest that iodine competes with, or inhibits the bioavailability of any other nutrient. This suggests that increasing the levels of dietary iodine intake will not have an adverse consequential effect on the nutritional status of consumers.

5.2.4 Risk Characterisation

5.2.4.1 Safety

Healthy population

The data support the safety of iodine as a washing agent for the specified foods for the normal healthy population.

Dietary modelling using the ‘National’ model indicates that exposure for all population groups is predicted to be below the PTDI even at the 95th percentile (high consumer) exposure level and applying the worst-case scenario (Scenario 2).

In Tasmania, where modelling was undertaken to take account of the fortification of bread with iodine, all population groups, with the exception of 2-3 year olds, are estimated to have 95th percentile dietary intakes of iodine below the PTDI. Estimated 95th percentile exposure for 2-3 year olds is estimated to only marginally exceed the PTDI (102%) and only if the worst-case scenario (Scenario 2) is applied. If a more realistic scenario (Scenario 1) is applied, the 95th percentile exposure level is below the PTDI (98%).

Due to use of 24-hour dietary survey data, which tends to over-estimate habitual food consumption amounts for high consumers, it is likely that the 95th percentile dietary intake is an over-estimate. In addition, a number of conservative assumptions were used in the dietary modelling which may further add to the overestimation. These conservative assumptions include:

- all fruits, vegetables, nuts and eggs will not be rinsed after the iodine wash, or prior to preparation and consumption in the home;

  (Fruit and vegetables are often washed prior to consumption and this will most likely reduce the actual exposure to iodine.)

- there are no reductions in iodine concentrations on cooking.

  (In the case of some vegetables, cooking will certainly reduce the concentration of iodine.)

The PTDI represents a level of intake that is considered safe over a lifetime, therefore short-term excursions above the PTDI, particularly when these are of small magnitude (e.g. 102%), generally do not raise any safety concerns as the PTDI is not itself a threshold for toxicity. In this case, the predicted 95th percentile intake for 2-3 year olds is still well below a level at which adverse effects might be observed. The ‘all population’ models are a good indicator of the likely dietary exposures for the population over a lifetime and these predict 95th percentile dietary intakes that are well below the PTDI, with the higher intakes predicted for 2-3 year olds not being sustained in the older age groups (e.g. 2-6 year olds).

Overall, the potential to exceed the PTDI, even for 2-3 year olds, is considered to be low.

Vulnerable individuals

In relation to the vulnerable individuals identified in the safety assessment, further consideration is necessary. Under certain circumstances these individuals may respond to excess iodine in the diet by developing thyrotoxicosis (also referred to as iodine-induce hyperthyroidism) (discussed in detail in **Attachment 3**). Symptoms include rapid heartbeat, nervousness, weakness, heat intolerance, and weight loss. The most vulnerable are those over 40 years of age who have a long history of iodine deficiency, although individuals with underlying thyroid disorders may also be affected.

Comparison of estimated intakes with the PTDI is not appropriate when considering the health risk for these individuals, as typically they respond adversely to levels of intake that fall below the PTDI and, in some cases, at levels that approximate normal dietary intakes. Such individuals may therefore potentially be at risk even from natural fluctuations in the iodine levels in foods.

In the case of individuals with underlying thyroid disease, such as Graves' disease, the risk is considered low. Such individuals will typically be under the care of a medical professional, therefore should there be any exacerbation of the condition, this should be detected quickly and remedial action taken. In the case of individuals with a long history of iodine deficiency, there may be cause for greater concern as such individuals may not be aware of their condition. Typically however, iodine-induced hyperthyroidism is mild and self-limiting and readily treated. In addition, although there is evidence of iodine deficiency in the Australian and New Zealand populations, the deficiency is believed to be relatively mild. For this reason very few individuals would be expected to be vulnerable to the occurrence of iodine-induced hyperthyroidism.

The proposed use of iodine as a sanitising agent is therefore not considered to pose any increased risk to these individuals – it is not expected to increase dietary iodine intake to any significant extent and very few vulnerable individuals would exist in the Australian and New Zealand populations.

Conclusion

For the vast majority of the population, there are no safety concerns associated with the use of iodine as a washing agent for fruit, vegetables, nuts and eggs. Also, because the proposed use of iodine is expected to have only a relatively small impact on dietary iodine intake, it is not considered to pose any additional risks to vulnerable individuals, in particular those with a long history of iodine deficiency.

5.2.4.2 Nutrition Considerations

As with the use of iodophors, the use of iodine as a processing aid may result in adventitious contamination of the food supply. It is very unlikely that the observed increase in iodine intake as a result of the use of iodine as a processing aid will cause imbalances with other nutrients; to the contrary, it may have the beneficial outcome of helping to replete populations with poor iodine status. There are no identified adverse nutritional risks created by the proposed amendment to the *Food Standards Code.* The use of iodine as a processing aid, and its contribution to iodine intake, would need to be taken into account should any iodine fortification programs be contemplated in the future.

5.2.4.3 Overall conclusion

The use of iodine as a washing agent for fruit, vegetables, nuts and eggs is likely to result in a small increase in iodine intake but not to a level that would raise any safety concerns or pose any nutritional risks for the vast majority of the population, or pose any additional risks for vulnerable groups.

5.3 Issues Raised in First Round Public Submissions

5.3.1 Classification of Iodine as a Processing Aid.

The Western Australian Food Advisory Committee, of the WA Department of Health noted that iodine residues are more likely to remain on food surfaces and reach the final consumer, and that this raises the issue of the appropriateness of classifying iodine as a processing aid.

The New Zealand Food Safety Authority (NZFSA) submitted that as part of the assessment of the Application, FSANZ should consider the function of iodine when used as a sanitising agent to determine if it is solely acting as a processing aid, or is there also a food additive function.

5.3.1.1 Response

To be classified as a processing aid a substance must fulfil a technological purpose relating to treatment or processing, but should not perform a technological function in the final food. Substances performing a technological function in the final food would generally be classed as a food additive.

It is correct that residues may remain on the surface of foods that have been washed with iodine. However, the iodine remaining on these foods will largely be in the form of iodide, which has virtually no biocidal activity. Any iodine remaining in the final food is therefore unlikely to be performing a technological function related to sanitisation. Sanitisation occurs exclusively during the washing process, which is optimised to ensure the greatest contact with the most biocidally active forms of iodine – elemental iodine (I_2) and hypoiodous acid (which forms from the reaction of I_2 with water).

5.3.2 Iodine Deficiency

Two submissions were made that commented on the issue of iodine deficiency. The Dietitians Association of Australia (DAA) submitted that the reintroduction of iodine as a sanitising agent may be a suitable replacement for chlorine-based sanitising agents, but should not be seen as a way of correcting nutritional inadequacies. The Australian Food and Grocery Council (AFGC) noted recent concerns expressed by others suggesting that iodine consumption in Australia may be below optimum levels, and stated that mandatory iodine fortification should be considered for certain foods. The AFGC mentioned that this outcome was a point in favour of approving this Application.

5.3.2.1 Response

The Dietary Exposure Assessment (**Attachment 4**) has shown that the use of iodine as a washing agent for fruit, vegetables, nuts and eggs may increase the dietary iodine intake of Australian and New Zealand populations to some extent.

Further clarification of the population iodine status is required, however current evidence indicates that some level of iodine deficiency exists among Australian and New Zealand populations. A positive public health benefit may therefore occur if iodine is approved as a washing agent. Even so, FSANZ agrees that it would not be appropriate to rely on an iodine wash as a means of addressing iodine deficiency, particularly as its only likely to result in small increases in iodine intake. Instead, any strategies to address iodine deficiency should be developed through work on food fortification. FSANZ has received policy guidance on fortification from Australian and New Zealand Health Ministers, and has recently commenced work on a Proposal (P230) to consider the fortification of foods with iodine.

5.3.3 Bioavailability of Iodine

NZFSA submitted that as part of the assessment of the Application, FSANZ should consider the bioavailability of iodine from this source.

5.3.3.1 Response

The majority of the iodine remaining on the surface of the food following treatment will be in the form of iodide, which is nearly 100% bioavailable. Other chemical forms of iodine, such as elemental iodine and iodate, if they were present, would tend to undergo reduction to iodide in the small intestine before absorption.

A conservative approach is taken in the dietary exposure assessment where it is assumed all iodine present in foods is 100% bioavailable, and there are no inhibitors to iodine absorption (such as goitrogens) present in the diet.

5.4 Issues raised in Second Round Public Submissions

5.4.1 Assessing the potential health impact

The Tasmanian Department of Health and Human Services (DHHS) expressed concern about Australia's capacity to assess the potential health impact of applications of this nature in the absence of food consumption and food composition data, comprehensive data on the nutritional status of the population and Australian nutrient reference values (such as RDIs). While they acknowledge that the responsibility for these issues lies outside the control of FSANZ, they argue that these information gaps limit the scientific credibility of the assessment report.

5.4.1.1 Response

Risk assessment will always contain elements of uncertainty because it depends on the quality of scientific information available and the assumptions used during assessment. FSANZ tries to limit the degree of uncertainty by using the most up to date information available, and by updating assessments when relevant new information comes to hand. Some degree of uncertainty however cannot be avoided and FSANZ deals with this by adopting a cautious approach both in the assumptions made during risk assessment and in any risk management measures adopted.

For this assessment FSANZ considers that sufficient information of good quality is available to enable an evaluation of the potential health impact. The assessment has focussed mainly on determining whether estimated iodine intakes are likely to exceed safe levels (the PTDI). As the processing aid is also an important nutrient, however, a nutrition assessment was also undertaken, although in considering whether to approve or not approve iodine as a processing aid, the relevant question is whether its use is likely to raise safety concerns, not whether iodine intakes are nutritionally adequate. Most of the analysis has therefore involved estimating the potential dietary exposure to iodine, should the Application be approved. To do this, FSANZ has used the most up to date food consumption and concentration data available.

The dietary modelling was revised following Draft Assessment to take account of new data on the iodine concentrations in foods in Australia and New Zealand, incorporating results from the 2003/2004 New Zealand Total Diet Survey (TDS) (quarters 1-4) and the unpublished results from the 22nd Australian TDS.

As FSANZ is also currently examining the need for the iodine fortification of foods (Proposal P230), there will be further and possibly ongoing assessment of iodine intake and on the population iodine status. FSANZ is also proposing to review the extent of use of iodine as a processing aid three years from the date of its approval.

5.4.2 Tasmanian population

The Tasmanian DHHS submitted that the milk iodine levels in Tasmania (~ 200 µg/L) are higher than the levels used in the modelling (83 µg/L). In addition, in October 2001, Tasmania introduced an Iodine Supplementation Program, asking that bread manufacturers switch to iodised salt in place of regular salt. It is understood that a significant number of Tasmanian bread manufacturers are now using iodised salt, with the levels of iodine in bread ranging between 25 and 70 µg/100 g bread. It has therefore been requested that FSANZ incorporate an additional scenario in the dietary modelling which takes account of the potentially higher baseline exposure to iodine in Tasmania.

5.4.2.1 Response

The milk iodine level used in the dietary modelling conducted at Draft Assessment of 82.7 µg/kg was obtained from the Australian Dairy Corporation and was the best information on milk iodine levels for Australia that was available at the time. Since then, FSANZ has received information on milk iodine levels in Australia, which were collected for the next (22nd) Australian Total Diet Survey (ATDS). Sampling was undertaken of full fat milk in New South Wales, Australian Capital Territory, Tasmania, Queensland and Victoria. A mean iodine concentration of 133 µg/kg was obtained. Inter-laboratory confirmatory analysis of these samples suggested that the nationally representative milk iodine concentrations determined as part of the 22nd ATDS, most accurately reflect iodine concentrations in Tasmanian milk. FSANZ has used this nationally representative figure for the revised dietary modelling undertaken at Final Assessment.

In relation to the use of iodised salt in bread manufacture in Tasmania, FSANZ have included a separate model for Tasmania, which takes account of this practice and the resultant higher baseline intakes.

5.4.3 Overlap with potential introduction of iodine fortification

The Tasmanian DHHS are concerned that with the effects of iodine fortification, combined with higher milk levels in Tasmania, and increased iodine residues in fruits, vegetables, nuts and eggs, there may be potential for iodine intakes to exceed the PTDI. If the Application is approved they argue it would make it difficult to predict the level of iodine intake, because the levels of iodine in fruit and vegetables would vary depending on whether the processing aid was used or not, and this will make the make the management of public health measures to maintain adequate population iodine status very difficult.

5.4.3.1 Response

While it is reasonable to conclude that the level of iodine on fruits and vegetables might fluctuate in the first instance when the processing aid technology is being introduced, FSANZ expects that this will probably stabilise in a few years time.

The results of the dietary modelling reflect a worst-case situation, that is, they are an estimate of the maximum iodine intake that could potentially result from the use of iodine as a processing aid. Realistically, intakes are more likely to fall below the predicted levels. In the case of Tasmania, the model applied already takes account of a fortification scenario therefore its unlikely that actual intakes will exceed those already estimated, should mandatory fortification be introduced at a future date. The risk assessment indicates that the potential to exceed the PTDI, even in the case of the Tasmanian situation, is low.

In relation to the possible introduction of mandatory iodine fortification, this is being considered under Proposal P230 – Iodine Fortification. FSANZ anticipates there should be useful information available on the iodine status of the population prior to or coincident with the introduction of iodine as a processing aid:

- in Australia, no national surveys have been undertaken to assess the iodine status of Australians, although national data collection in a National Iodine Nutrition Study (NINS) is currently in progress with results expected in early 2005;

- New Zealand has regularly monitored national iodine status due to the low iodine content of its soils with the most recent results available from the National Children's Nutrition Survey; and

- routine monitoring of iodine status in children also occurs in Tasmania.

If it is determined under proposal P230 that mandatory fortification is necessary then it's likely some form of monitoring will be undertaken after the fortification programme has been introduced. Irrespective of what happens in relation to iodine fortification, FSANZ is proposing to review the extent of use of iodine as a processing aid some three years after its approval.

5.4.4 Impact analysis

The AFGC suggest including in the Impact Analysis that Option 1 may disadvantage consumers by denying them potentially safer food and Option 2 may be an advantage to consumers in the potential increased safety of certain foods.

5.4.4.1 Response

The Food Technology Report explains the efficacy of washing foods with iodine solutions. The trial indicated that iodine, under the conditions of the test, was superior to the equivalent concentrations of chlorine. This indicates a technological need, however, the data are too limited to be able to extrapolate this trial to the regulatory impact analysis to state that not approving the product may disadvantage consumers by denying them potentially safer foods. Therefore, the Regulatory Impact Analysis has not been altered.

5.4.5 Monitoring

The NSW Food Authority and the Tasmanian DHHS both strongly recommended there should be a system for monitoring the use of iodine as a processing aid, who is using it, on what products, the level of iodine in the final product, and how widely the products are distributed and consumed.

5.4.5.1 Response

The Applicant has submitted that out of all the fruit and vegetables produced in Australia, only about 32% are subject to any kind of sanitation process. Under the current APVMA registration, the Applicant estimates that less than 0.5% of the total fruit and vegetable tonnage is being sanitised using their technology. The Applicant predicts that, once this Application is approved, the market penetration for this technology will increase to approximately 10-13% of total production. Therefore, out of the fruits and vegetables that are subject to sanitisation, the Applicant expects to capture approximately one third of the market, as a best case, and predicts this could take up to four years to achieve.

FSANZ has incorporated this market share data into the dietary modelling and proposes to undertake a review of this information three years after the date of gazettal to confirm that these original market share assumptions were valid. This should allow sufficient time for the technology to become established. Both industry surveys and food composition analysis could be used to inform such a review.

5.4.6 Residue data

Queensland Health submitted that the iodine levels used to estimate dietary intake appear to be calculated values and that no data on measured levels of iodine have been included.

5.4.6.1 Response

Although not presented in the Draft Assessment Report, comprehensive residue data were provided by the Applicant for nuts, eggs, and a representative range of fruits and vegetables (e.g. potato, oranges, tomatoes, peaches, rock melon, nectarines, melons, butter lettuce and cos lettuce). Using this residue data, the Applicant was able to demonstrate there is a consistent relationship between the magnitude of the increase in iodine level after disinfection and the surface area to volume ratio of the particular fruit or vegetable. The various fruits and vegetables were then classified according to their surface area to volume ratio and a set residue increase applied according to the category. So for medium sized smooth skinned produce dipped in 30 mg/kg iodine, an iodine increase of 0.15 mg/kg was applied; for rougher skinned produce, an iodine increase of 0.3 mg/kg was applied; and for very high surface area produce, an iodine increase of 3 mg/kg was applied. Table 3 of the dietary exposure assessment report (**Attachment 4**), shows the baseline concentration level of iodine used for each food or food group, as well as the post-disinfection level for each modelling scenario.

For example, for the dietary modelling, potatoes were classed as rougher skinned produce; therefore a residue increase of 0.3 mg/kg (300 ppb) was applied in the case of Scenario 2 (which assumes potatoes would always be eaten unpeeled). This compares to the actual measured increase in iodine levels for potatoes after disinfection, which was 149 ppb.

In general, the calculated increases in iodine levels applied in the dietary modelling were equivalent to or higher than the actual measured levels, where these were available.

5.4.7 Food technology report

Queensland Health raised concerns with the referencing used in the Food Technology Report, submitting that some claims were not referenced, and other claims cited website articles which appeared to be no longer accessible. Queensland Health noted that most of the references in the Food Technology Report are to website articles, in contrast to the more appropriate use of primary referencing which is used in the Toxicology Report.

5.4.7.1 Response

The Food Technology Report (**Attachment 2**) has been revised and greater effort has been made to use primary referencing, where these are available. While there is a large amount of peer-reviewed scientific information on the toxicity of iodine, much less published information is available in relation to the use of iodine as a sanitising agent, which is a more recent area of development. As a result, there is a paucity of primary reference sources for such work, which is often the case when it comes to justifying the technological use of new processing aids. Safety evaluation data is usually published, whereas product development related studies are usually regarded as Commercial-in-Confidence.

5.4.8 Disinfection by-products

Queensland Health noted the statement in the Food Technology Report that chlorine-based sanitisers may produce disinfection by-products (e.g. trihalomethanes) which are potentially carcinogenic and asked whether any iodinated compounds are formed during the sanitation process that may be considered harmful. In further correspondence with Queensland Health, particular concern was expressed about the potential for iodine to react with the organic constituents of the food itself. They wish to know if this has been investigated and whether the reaction products are considered safe at the levels of dietary intake anticipated. It was stated that similar considerations would also apply to chlorine-based disinfection systems.

5.4.8.1 Response

Most disinfectants or sanitising agents that are used will produce by-products during the disinfection process. The risk posed by the potential formation of disinfection by-products must be balanced against the benefit derived from the disinfection process. In the case of the surface sanitisation of fruits and vegetables, disinfection is useful for reducing the level of pathogens on the surface of the food, therefore there is potential for substantial benefit to be obtained.

When halogens are used for disinfection, the most common by-products formed are trihalomethanes, although a number of other halogenated compounds may also be produced. In the case of water disinfection, by-products are usually formed as a result of the reaction between the disinfectant and naturally occurring organic substances present in water. These organic substances result from the decay of vegetable and animal matter and are present to varying levels in most water supplies. Removal of these organic chemicals from the water prior to its disinfection limits the potential for the formation of disinfection by-products. Most municipal water treatment plants routinely remove these organic substances from the water supply prior to disinfection, which is usually the final step in water treatment.

In relation to the use of chlorine as a disinfecting agent it has been recognised that active chlorine can react both with the organic matter in water as well as food itself[6]. The same types of by-products found following water disinfection may also be found following the surface disinfection of fruits and vegetables, with the most frequently encountered product being the trihalomethanes, although a number of other chlorinated compounds may also be produced. In the case of iodine, most of what is known about by-product formation relates to its use as a water disinfectant. However, as with chlorine, it is anticipated that the types of by-products formed on the surface of fruits and vegetables will be similar to those formed in water. In water disinfection systems using iodine, iodoform is the most commonly found disinfection by-product[7]. The formation of iodoform and other by-products in water is slow (days to months).

Iodoform has been used in the past as a topical antiseptic where it was used extensively in wound dressings but has now largely been replaced by more effective antiseptics. The toxicity of iodoform has not been extensively studied, with only limited information being available on acute oral toxicity in some animal species, and no human data. However, because of its structural similarity to methyl iodide and chloroform, both of which are potential carcinogens, the carcinogenicity of iodoform has been extensively studied in rats[8]. These studies do not indicate any potential for carcinogenicity.

The types of by-product that will form are dependent on the characteristics of the organic constituent, the halogen species and the reaction conditions. Most of these organic chemical reactions have been investigated under conditions that involve molar concentrations of reactants that should favour product formation. This will not normally be the case in the disinfection situation where the organic reactants are expected to be at low concentrations.

Of the halogens (fluorine, chlorine, bromine, iodine), iodine is the least reactive and as such is regarded as a mild oxidising agent. Because of this, generally only very low levels of product will be formed with iodine compared to other halogens[9].

Overall, FSANZ considers the risk posed by any iodine disinfection by-products will be low. Given their slow rate of formation in water disinfection systems its unclear if they will be present at all on the surface of fruits and vegetables given the relatively short contact time with elemental iodine. Should by-product formation occur, the levels are expected to be much lower than what would occur following chlorine disinfection. The presence of trace amounts of iodoform would not raise any safety concerns.

5.4.9 Iodate residues

Queensland Health noted the statement in the Food Technology Report that ‘It is best to keep the water pH below 8.5 to limit iodate production’ and asked whether iodate ends up as a residue in food and whether this would be of concern.

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[6] CCFAC (2002). Discussion paper on the use of active chlorine. Codex Committee on Food Additives and Contaminants, Thirty-fifth Session, Arusha, Tanzania, 17-21 March 2003, CX/FAC 03/11

[7] Peters-Dodd, J. (1997). Chemical identification and organoleptic evaluation of iodine and iodinated disinfection by-products associated with treated spacecraft drinking water. Masters Thesis, Virginia Polytechnic Institute and State University, Virginia.

[8] National Institutes of Health (1978). Bioassay of iodoform for possible carcinogenicity. National Cancer Institutes Technical Report Series, No. 110.

[9] March, J. (1977). *Advanced Organic Chemistry: Reactions, Mechanisms and Structure*, Second Edition. McGraw-Hill Book Company, New York.

5.4.9.1 Response

Iodate formation in water is primarily dependent on time, iodine concentration and pH. At low iodine concentrations (<1 ppm) and neutral pH, iodate formation will be negligible over a short period of time. At higher iodine concentrations (>10 ppm) and pH however, significant iodate formation can occur in a relatively short period of time. As iodate has no biocidal activity[10] it is important for the efficacy of the disinfection process to limit its formation, and instead use reaction conditions that favour more biocidally active forms of iodine, these being I_2 and hypoiodous acid (HIO). As disinfection requires the use of iodine concentrations >10 ppm, the best way to limit iodate formation is by controlling the pH of the wash water. Aqueous iodine solutions are however less sensitive to pH than chlorine solutions. The Applicant advises that the effective pH range for iodine disinfection is between pH 3.0 and 8.0. At this pH range, the majority of iodine will be in the form of I_2 and HOI. If more alkaline wash water were used then pH adjustment would be necessary to limit iodate formation. According to the Applicant however this is typically not required as the occurrence of water with pH > 8.2 is rare.

Notwithstanding that significant iodate formation would not be expected in the disinfection process used by the Applicant, the presence of low levels of iodate on food would not raise a toxicological concern. When ingested, iodate is reduced to iodide by non-enzymatic reactions in the gut prior to absorption[11]. Therefore from a toxicological perspective, iodate can be considered equivalent to iodide. There is widespread experience with the use of iodate-fortified salt and there is no evidence from the scientific literature to indicate that the long-term consumption of low levels of iodate is toxic or carcinogenic to humans[12].

5.4.10 Analytical methods

Queensland Health noted the statement that the Applicant provided a more detailed specification of the moist iodine crystals used in their sanitation system and asked whether analytical methods are available.

5.4.10.1 Response

The Application refers to the 'Recommended Method of Analysis for the Determination of Total Iodine in Foods Other Than Milk' Method 8.14, Appendix XI, p93-95, June 1986, National Health and Medical Research Council (NHMRC). The Application states that this method measures not only iodine but also all of its breakdown products containing iodine.

Iodine levels in water can be measured spectrophotometrically and the Australian Drinking Water Guidelines (1996) also contains an analytical method for the determination of iodine or iodide in drinking water.

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[10] Chang, S.L. (1958). The use of active iodine as a water disinfectant. *J. Amer. Pharm. Assoc.* **47**: 417-423.

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

[12] Bürgi, H., Shaffner, T. and Seiki, J.P. (2001). The toxicology of iodate: a review of the literature. *Thyroid* **11**: 449-456.

5.4.11 Potential for reaction with pesticide residues

In separate correspondence with Queensland Health, the issue was raised about the potential for iodine to react with pesticide residues converting them to oxygen analogues that may potentially be more toxic. An example given was the potential reaction of iodine with the widely used insecticide dimethoate to oxidise it to omethoate, which is claimed to be ten times more toxic.

5.4.11.1 Response

This issue is not specific to the use of iodine as a processing aid, but rather may arise with any oxidant used as a sanitising agent. Most of the approved sanitising agents are oxidants. The potential for reaction with pesticides would be the same irrespective of which oxidant is used. FSANZ does not consider that the use of iodine poses any additional risk, compared to the sanitisers already in use.

In the case of dimethoate, this is an insecticide, which is used in Queensland to control fruit fly and is applied at relatively high concentrations as a post harvest treatment. The potential for iodine to react with dimethoate would depend on the timing of the iodine treatment. If sanitisation were undertaken following treatment with dimethoate, there would be potential for reaction, as the dimethoate residues would be exposed to elemental iodine. However, FSANZ is advised that it has become normal commercial/agricultural practice that the combination of sanitisation and other postharvest treatments be done in the recommended order of first the oxidation (sanitisation) treatment, and then the fungicide or pesticide treatment, after removal of all excess oxidising treatment. If this practice is applied in the case of dimethoate for the control of fruit fly, the potential for reaction with iodine would be extremely low as any iodine remaining on the surface of the fruit and vegetables would be in the form of iodide.

In Australia, control over the use of agricultural chemicals rests with the APVMA and the States and Territories, and is not part of FSANZ's responsibility.

6. Regulatory Options

The following two regulatory options have been considered:

Option 1. Maintain the *status quo* and not approve the use of iodine as a food processing aid.

Option 2. Amend the Code and approve the use of iodine as a food processing aid.

7. Impact Analysis

7.1 Affected Parties

The affected parties to this Application include:

- consumers;
-

- those sectors of the food industry wishing to produce and market food products that have been washed with sanitising agents; and
-
- Australian Government, State, Territory and New Zealand Government enforcement agencies.

7.2 Impact of Regulatory Options

In the course of developing food regulatory measures suitable for adoption in Australia and New Zealand, FSANZ is required to consider the impact of all options on all sectors of the community, including consumers, the food industry and governments.

7.2.1 Option 1

There are no perceived benefits to the food industry, consumers or government agencies if this option is taken. Parties potentially disadvantaged by not permitting iodine to be used as a washing agent on foods are those sectors of the food industry, including the Applicant, who wish to use iodine as an alternative to existing washing agents and who have invested in the development in the Iodoclean™ System.

7.2.2 Option 2

This option is likely to deliver a benefit to the food industry in that it will provide a cost-effective alternative to the chlorine compounds that are currently been used as washing agents. Consumers may also benefit from the potential increased iodine intake that may result if widespread use of iodine as a washing agent occurs.

There would be little or no direct impact on government.

7.2.3 Conclusion

Option 2 is the preferred option. This option potentially provides benefits to both the food industry and consumers with very little associated negative impact on any sector.

8. Consultation

8.1 Public Consultation

The Initial Assessment Report for this Application was circulated for public comment on 21 May 2003 for a period of six weeks. A total of twelve submissions were received and these are summarised at **Attachment 6** to this Report.

Following the first round of public consultation, FSANZ carried out an assessment of the Application, taking into account the public comments received. The specific issues raised by these comments were addressed in the Draft Assessment Report.

The Draft Assessment Report was circulated for public comment on 4 August 2004 for a period of six weeks. A total of eleven submissions were received and these are summarised at **Attachment 6** to this Report. Six submissions supported the Application; three did not support the Application, and two did not state a position.

8.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are not any relevant international standards and amending the Code to allow the use of iodine as a washing agent for certain foods is unlikely to have a significant impact on international trade as suppliers of food products are not required to take up permissions granted through amendments to the Code therefore this matter was not notified under either the TBT or SPS Agreements.

9. Conclusion and Recommendation

It is concluded that approval of iodine as a washing agent for fruit, vegetables and eggs is technologically justified and would not pose a risk to the health and safety of the general population, or any additional risk to vulnerable individuals.

The variation to Standard 1.3.3 – Processing Aids of the Code (**Attachment 1**), approving the use of iodine as a processing aid, is agreed for the following reasons:

- the use of iodine as a washing agent for fruit, vegetables, nuts and eggs is technologically justified – the efficacy of iodine as a sanitising agent for foods has been demonstrated and a technological need exists for alternative food sanitisers;
-
- the use of iodine as proposed may result in a small increase in iodine intake but not to a level that would raise safety concerns for the vast majority of the population or pose any adverse nutritional risks. The proposed use of iodine is also considered unlikely to pose any additional risk for vulnerable individuals;

- the proposed draft variation to the Code is consistent with the section 10 objectives of the FSANZ Act. In particular, FSANZ has addressed the protection of public health and safety by undertaking a risk assessment based on the best available scientific data.
-
- The regulation impact assessment has concluded that the benefits of permitting use of iodine as a washing agent outweigh any costs associated with its use.

10. Implementation and review

The variation to the Code is to come into effect on the date of gazettal.

FSANZ proposes to review the extent of use of iodine as a processing aid three years from the date of gazettal.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Food Technology Report
3. Toxicology Report
4. Dietary Exposure Assessment Report
5. Nutrition Risk Assessment Report
6. Summary of Public Comments

ATTACHMENT 1

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

To commence: On gazettal

[1] **Standard 1.3.3** of the Australia New Zealand Food Standards Code is varied by –

[1.1] *inserting in the* Table to clause 12 –

Iodine	Fruits, vegetables and eggs	GMP

[1.2] *inserting after the* Table to clause 12 –

Editorial note:

FSANZ will prepare a proposal to review the extent of the use of Iodine as a processing aid three years from the date of the inclusion of Iodine as a processing aid in the Table to clause 12.

ATTACHMENT 2

FOOD TECHNOLOGY REPORT

Introduction

FSANZ received an Application from Iodine Technologies Australia Pty. Ltd. to amend Standard 1.3.3 – Processing Aids of the *Australia New Zealand Food Standards Code* (the Code) to allow the use of iodine as a processing aid, specifically as a washing agent for fruit, vegetables, nuts and eggs at GMP.

Background

The food industry uses a number of primary sanitising agents, at all levels during food manufacture and processing, to reduce the levels of bacteria and fungi which can cause food safety concerns as well as reduce keeping quality and shelf life of products. Such bacteria include *E. coli*, Listeria and Salmonella and non-pathogenic spoilage organisms including yeasts and moulds. These sanitising agents, also called disinfecting agents, do not kill all bacteria so they are not sterilising agents but tend to inhibit the growth of the bacteria to acceptable levels.

Halogens are a family of elements with a high affinity for electrons. They belong to group VII of the periodic table. The affinity for electrons makes the elements very reactive with biological molecules. The halogen elements chlorine and iodine have been used as terminal disinfectants for many years[1]. Halogens are very reactive towards biological molecules and are strong oxidising agents that can disrupt enzyme activity and membrane structure.

Chlorine is used extensively in the food industry as a sanitising agent. An alternative food sanitiser is iodine, which has a history of use in the dairy industry and offers a number of advantages over chlorine.

Chemical Details

Elemental iodine (I_2) has a molecular weight of 253.809 g/mol and a CAS number of 7553-56-2. Iodine exists as blue violet to black crystals, which melt at 114°C and boil at 184°C. Iodine is poorly soluble in water but soluble in many organic solvents. Iodine readily sublimes at room temperature to form a violet corrosive vapour.

Because elemental iodine is rather poorly soluble in water, iodine has been added to other various solvents and carriers or solubilising agents. Such compounds are commonly referred to as iodophors and are widely used as disinfecting agents. Such products have advantages in often enhancing the bactericidal activity of iodine, reducing vapour pressure, odour and staining as well as increasing water solubility. A number of iodophors are approved and used as sanitisers for food contact surfaces and equipment in the food industry.

Specification

Iodine is listed in the Merck Index[2], which is one of the secondary sources listed in clause 3 of Standard 1.3.4 – Identity and Purity, for specifications. The Applicant has provided a more detailed specification of the moist iodine crystals used in their process with lists of various trace impurities. There is nothing atypical in the specification for the iodine used by the Applicant. Analytical methods for the determination of residual iodine would be identical to current methods used.

The Application referred to the 'Recommended Method of Analysis for the Determination of Total Iodine in Foods Other Than Milk' Method 8.14, Appendix XI, p93-95, June 1986, National Health and Medical Research Council (NHMRC). The Application states that this method measures not only iodine but also all of its breakdown products containing iodine.

Iodine levels in water can be measured by a spectrophotometric method mentioned in the Application. The Australian Drinking Water Guidelines 1996, also contains an analytical method for the determination of iodine or iodide in drinking water[3].

Technological Function

Halogens such as chlorine, iodine and bromine have strong antimicrobial activities. Chlorine is the more commonly used element and various forms of compounds that deliver chlorine (including hypochlorite) have been used for many years as sanitising agents in the food industry (as well as many other industries).

Iodine is able to act as a sanitising agent or microbiological control agent for treated food by destroying or limiting the numbers of pathogens or food spoilage organisms. Iodine (as iodophors) has a broad spectrum of antimicrobial acitivity[4]. Specifically, in terms of the Application, this means inactivating and limiting the numbers of such bacteria and other microorganisms on the surface of treated foods, such as vegetables and fruit.

Chemical reactions of iodine dissolved in water

The various important chemical reactions of iodine dissolved in water are listed below[5].

$I_2 + H_2O \leftrightarrow HIO + I^- + H^+$ (hydrolysis, formation of HIO (hypoiodous acid))

$HIO \leftrightarrow OI^- + H^+$ (hypoiodous acid dissociation)

$3HIO \leftrightarrow IO_3^- + 2I^- + 3H^+$ (disproportionation of HIO)

$3I_2 + H_2O \leftrightarrow IO_3^- + 5I^- + 6H^+$ (iodate formation)

$I_2 + I^- \leftrightarrow I_3^-$ (triiodide formation)

All the above reactions, except for those that form iodate, are very rapid and reach equilibrium quickly. Iodate has no activity as a sanitiser so it is important to understand the conditions (predominately time and pH) that favour its formation, since this diminishes the sanitising activity of the iodine solution.

At neutral pH and up to 30 minutes after adding iodine (1-25 ppm) to water the predominate iodine species are iodine (I_2) and hypoiodous acid (HIO).

For normal levels of iodine used for sanitation (10-25 ppm) it is best to keep the water pH below 8.5 to limit the iodate production (which is an inactive form but not a safety concern). Iodate is preferred as the form of iodine that is added to fortify salt to correct for iodine deficiency since it is more stable than iodide[5] so is a quite food safe form of iodine.

The Applicant's system uses iodine specific electrodes to measure the iodine concentration in the treatment water and automatically adjusts the concentration to maintain the pre-set iodine concentration. The Applicant states that their system does not need to regularly monitor and adjust wash solution pH as is required for a chlorine dosing system since iodine is active over a broad pH range (4 to 8.5 for iodine compared to 7-7.5 for chlorine). A broad usage pH range of 4-8.5 should not require any pH adjustment during processing. It has also been reported, over the use concentrations proposed by the Applicant, over 80% of the iodine is present in biocidal active forms, I_2 and HIO, from pH 3.0 to 8.0.

Hypoiodous acid (HIO) is the most effective iodine compound for effectiveness against bacteria. Removal of the iodide ion (I^-) is important to help maintain the iodine sanitation effectiveness by limiting the formation of the less reactive triiodide species.

In the present Application the Applicant is intending to use elemental iodine in a closed system where the iodide that is formed is removed from the process stream using resins, and then regenerated to produce iodine, which is then reused.

Using iodine as a food surface sanitiser has a number of advantages over various chlorine sources. These are summarised below.

Advantages[4,7,10]

- It is highly reactive, meaning less iodine has the same effect as higher concentrations of chlorine.
- It is not as readily inactivated as chlorine by organic matter, which includes dirt.
- Chlorine reacts with organic matter (decomposition of vegetative matter that produces humic and fulvic acids) in treated water to produce unpleasant by-products (trihalomethanes (THMs) such as chloroform) that are suspected carcinogens[8].
- Chlorine is also involved in the formation of the very potent flavour contaminants (such as trichloroanisole) which are known to cause flavour taints in food[9].
- Iodine is less corrosive than chlorine on metals and other surfaces.

Disadvantages[4,7,10]

- Iodine compounds may stain plant including metal and plastic surfaces.
- Sanitiser activity is also reduced through contact with organic matter.
- Iodine has unpleasant and toxic odours and vapours.
- Elemental iodine has limited solubility in water, which is why iodophors have often been used since they have better solubility.
- Iodine has a relatively high cost.

Some of the disadvantages of using iodine are overcome by using an automated, sealed system for iodine delivery and by regenerating iodine from the spent iodide.

Efficacy of washing food with iodine solutions

The Application (as well as other supporting documentation subsequently supplied by the Applicant) provides trial data indicating the efficacy of treating freshly harvested vegetables and fruit with iodine washing systems. These trial results were performed using simple dipping solutions of iodine concentrations ranging from 3-30 ppm compared to the same chlorine concentrations, as well as the Applicant's own enclosed recycled system. Treatment times were 1, 2 and 4 minutes. Results were compared with the reduction in total bacteria and fungi post treatment on the treated produce. Trials were also performed to assess the effect of dirt, which is a problem with freshly harvested produce, and is known to decrease the efficacy of chlorine wash solutions.

The results indicated that iodine was superior to the equivalent concentration of chlorine. This was also the case when dirt was a factor. Some of the fruits and vegetables tested were orange, nectarine, peach, apple, strawberry, rock melon, avocado, potato, tomato, lettuce and bean sprouts. It was generally found that a treatment of 30 ppm or less of iodine caused a 30 fold reduction (1.5 $\log_{10}$) in bacteria and fungi concentrations on the treated produce. It was also reported that increasing the contact time by a factor of four (dip time) was equivalent in effectiveness to doubling the iodine concentration.

Trials were also performed evaluating the efficacy of iodine washing on reducing pathogen concentrations (*Salmonella spp*. and *Listeria monocytogenes*) on three food types, lettuce, fish and meat. The $\log_{10}$ reductions for treatment with 30 ppm iodine for *Listeria* for lettuce, fish and meat are 1.4, 0.8 and 0.9 and for *Salmonella* for the same products, 1.1, 0.7 and 0.6 respectively.

Evidence of Technological Need

There is a technological need to improve the keeping quality and safety of fresh food, primarily fresh fruit and vegetables. These are usually contaminated with soil and various microbiological contaminants, which need to be removed or at least controlled for both food safety and shelf life reasons. The food industry does this by various means such as washing and bleaching the foods. Approved washing and bleaching agents and their restrictions on use are listed in the Table to clause 12 of Standard 1.3.3 – Processing Aids. These agents comprise various compounds that produce active chlorine (various hypochlorites, chlorine itself and chlorine dioxide), hydrogen peroxide, peracetic acid and metabisulphite.

The present Application is another proposed sanitiser that can be used as an alternative to the other approved processing aids listed in the Table to clause 12 of Standard 1.3.3. If the Application is successful the proposed generic approval within this Table will be for 'iodine', which is broader than the Applicant's specific technology.

Conclusion

The use of iodine as a sanitising agent for foods is technologically justified.

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ATTACHMENT 3

TOXICOLOGY REPORT FOR IODINE

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.

The human response to excess iodine can be quite variable. Some individuals can tolerate quite 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 typically have an underlying thyroid disorder or have a long history of iodine deficiency.

For the majority of healthy individuals, the most sensitive endpoint for iodine toxicity is sub-clinical hypothyroidism. Sub-clinical hypothyroidism is defined as an elevation in TSH concentration while serum thyroid hormone concentration is maintained within the normal range of values for healthy individuals. While not clinically adverse, such an effect, if persistent, could lead to clinical hypothyroidism. In healthy adults, such an effect has been associated with acute intakes of 1700 µg/day (24 µg/kg body weight/day for a 71 kg person), and for children, has been associated with chronic intakes of 1150 µg/day (29 µg/kg/day for a 40 kg child).

Iodine intakes of approximately 1000 µg/day however appear to be well tolerated by healthy adults. This level has been used by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) to establish a provisional maximum tolerable daily intake (PTDI) for iodine of 17 µg/kg bw from all sources. FSANZ has adopted this level as a safe intake level for the purpose of risk assessment for the general healthy population.

For those individuals with thyroid disorders or a long history of iodine deficiency, this PTDI is not applicable since these individuals may respond adversely at levels of intake below the PTDI. It has been reported that intakes in the range 3-7 µg/kg/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

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 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, iodophore-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).

5. Toxicokinetics

5.1 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).

5.2 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 and Bender 1997).

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

5.3 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).

5.4 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.

6. 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).

6.1 Disturbance of Thyroid Function

The primary effects of excessive 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 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.

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.

6.1.1 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. Most individuals are therefore able to adapt to excess iodine.

Some individuals who fail to escape from the Wolff-Chaikoff effect typically develop goitre and may also become hypothyroid. Susceptible individuals include: foetuses and newborn infants; 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. Iodine-induced hypothyroidism is also reported to be more common in women.

Excessive intake of iodine by pregnant women is of particular concern as the foetal thyroid is less able to escape the inhibitory effects of iodine on thyroid hormone formation. Iodine-induced goitres and/or hypothyroidism have occurred 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 (WHO 1989).

A number of studies have examined the acute effects of increased intakes of iodine on the thyroid hormone status of adults (Chow et al 1991, 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 an elevation in serum TSH concentration, 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 suppressing effect on thyroid hormone production that, if persistent, could result in thyroid gland enlargement and other clinically significant complications. In the case of elderly adults, subclinical hypothyroidism has been induced by an acute increase of 500 µg/day (7 µg/kg/day) (Chow et al 1991), possibly suggesting that the elderly may be less tolerant of excess iodide than younger adults. 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 subclinical 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 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.

The level of 1700 μg/day for subclinical hypothyroidism has been used by the Institute of Medicine as a lowest-observable-adverse-effect level (LOAEL) to which an uncertainty factor of 1.5 was applied to derive a Tolerable Upper Intake Level (UL) for iodine in adults of 1100 μg/day (Institute of Medicine 2001). By adjusting this level on the basis of bodyweight, the ULs for other age groups were derived. Thus, a UL of 900 μg/day was established 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.

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).

Results from a number of epidemiological studies (Li et al 1987; Laurberg et al 1998) suggest that chronic exposure to excess iodine can result in or contribute to subclinical hypothyroidism in children (1150 μg/day, 29 μg/kg/day) and elderly adults (160-800 μg/day, 4-12 μg/kg/day). The study in children 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[1] 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 subclinical hypothyroidism in healthy human children (ATSDR 2004).

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).

Very high doses of iodine exceeding 200 mg/day (2.8 mg/kg/day) given during pregnancy have been shown to result in congenital goitre and hypothyroidism in the newborn infant (Iancu et al 1974).

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[1] Where TSH levels are in the normal range and the thyroid is neither hypothyroid nor hyperthyroid and considered ‘normal’.

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 (Momotani et al 1992, Pedersen et al 1993, Liesenkötter et al 1996).

6.1.3 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 and 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 and 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 and 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 and 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 and 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 and Williams 1995).

6.2 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 and Aber 1982, Horn and 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.

6.3 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.

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

7. Safe Limits for Oral Intake

A number of safe intake levels have been recommended as a result of reviews on the toxicity of excess iodine. The highest level of intake that has been found to be safe for the majority of the population is about 1000 µg iodine/day. This level was used by JECFA to establish a PTDI for iodine of 17 µg/kg bw from all sources (WHO 1989). It is recommended this level be adopted for the purpose of risk assessment for the general health population.

For those individuals with thyroid disorders or a long history of iodine deficiency, this PTDI is not applicable since these individuals may respond adversely at levels of intake below the PTDI. It has been reported that intakes in the range 3-7 µg/kg/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.

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ATTACHMENT 4

DIETARY EXPOSURE ASSESSMENT

An application was received by FSANZ requesting amendment of Standard 1.3.3 ‘Processing Aids’ – Clause 12 ‘Permitted bleaching agents, washing and peeling agents to allow the use of elemental iodine as a washing agent for fruits, vegetables (including herbs), nuts and eggs at good manufacturing practice (GMP) levels.

A dietary intake assessment was deemed necessary in order to determine the potential impact of granting permission for the use of elemental iodine as a washing agent for fruits, vegetables (including herbs), nuts and eggs on the iodine intake of the population. Iodine intakes, based on residues of iodine on treated foods and the iodine present in untreated foods, were assessed to determine if iodine intakes exceeded health standards.

Since the Draft Assessment report was written for this Application, new analytical iodine concentration data has become available for both New Zealand and Australian foods through the 2003/4 New Zealand Total Diet Survey (NZTDS) and the 22nd Australian Total Diet Survey (ATDS) respectively. Additionally, the Department of Health and Human Services (DHHS), Tasmania supplied FSANZ with data on the iodine concentration in bread and milk available in Tasmania via a submission. Due to the new data available, it was deemed necessary to completely review the iodine concentration data sets to ensure that the most up-to-date iodine concentration data were used in the dietary intake assessment. For these reasons, the dietary intake assessment has been reviewed at Final Assessment.

The Applicant provided FSANZ with details on the estimated market share that an elemental iodine wash will have for a number of individual commodities. These data were incorporated into the dietary modelling at 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 since variation in the results (e.g. the natural variation in the iodine concentrations in foods) has not been presented in the estimates of dietary iodine intake. The dietary modelling results should be used to guide risk management decisions.

Summary

Estimated dietary intakes of iodine were calculated for the Australian and New Zealand populations and for the population sub-group of Australian children aged 2-6 years. This was to ensure that iodine intakes would not exceed the Provisional Tolerable Daily Intake (PTDI) if approval to use elemental iodine as a washing agent was granted. Provisional Tolerable Daily Intakes (PTDI) are upper limits that are set for substances that do not accumulate in animals and humans (WHO 2001) and are estimates of the amount of a chemical that can be ingested daily over a lifetime without appreciable risk to health.

While an upper intake level has been set for iodine, iodine is also an essential micronutrient. Consequently, dietary intakes were also assessed for a range of age-gender categories (as detailed in Table 1) for the purpose of comparison with the Estimated Average Requirements (EARs) for iodine.

The EAR is defined as the level below which 50 per cent of the population may be at risk of having inadequate intake. Further details regarding the results of the comparison of dietary intake with EARs can be found in the Nutrition Report at Attachment 5.

Baseline intakes of iodine were calculated using the iodine concentrations in untreated foods. Two post-treatment scenarios were examined in each dietary intake assessment: Scenario 1 applied a peeling factor to those fruits and vegetables washed with iodine that may be consumed with the peel either on or off (e.g. apples); and Scenario 2 assumed that fruits and vegetables washed with iodine that may be consumed with the peel either on or off were always consumed unpeeled, in order to assume a worst-case scenario where iodine residues from the wash are still on the skin and are consumed. The fruits and vegetables that had peeling factors applied in Scenario 1 are listed in Table 2. In each of the post-treatment scenarios, iodine concentrations were weighted to take into account the estimated market share for an iodine wash for each commodity.

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.

The dietary intake assessments conducted for New Zealand use the 'National' modelling type only.

Results summary

In general, young children (2-3 years and 2-6 years) had the highest dietary intakes of iodine (on a µg/kg bw/day basis) for all of the population groups examined. The dietary iodine intakes of all Australians aged 2 years and above were higher than the dietary iodine intakes of New Zealanders aged 15 years and above.

For all Australians aged 2 years and above, the mean dietary intake of iodine increased above baseline by approximately:

- 30 µg/person/day for Scenario 1; and
- 40 µg/person/day for Scenario 2.

For Australian children aged 2-6 years, the mean dietary intake of iodine increased above baseline by approximately:

- 20 µg/person/day for Scenario 1; and
- 25 µg/person/day for Scenario 2.

For all New Zealanders aged 15 years and above, the mean dietary intake of iodine increased above baseline by approximately:

- 30 µg/person/day for Scenario 1; and
- 50 µg/person/day for Scenario 2.

For all Australians aged 2 years and above, the 95th percentile dietary intake of iodine increased above baseline by approximately:

- 50 µg/person/day for Scenario 1; and
- 65 µg/person/day for Scenario 2.

For Australian children aged 2-6 years, the 95th percentile dietary intakes of iodine increased above baseline by approximately:

- 25 µg/person/day for Scenario 1; and
- 35 µg/person/day for Scenario 2.

For all New Zealanders aged 15 years and above, the 95th percentile dietary intakes of iodine increased above baseline by approximately:

- 45 µg/person/day for Scenario 1; and
- 75 µg/person/day for Scenario 2.

Estimated mean dietary intakes of iodine were below the PTDI of 17 µg/kg body weight (WHO 1989) for all population groups, all scenarios and all model types examined. For all of the 'National' models, estimated 95th percentile dietary intakes of iodine were below the PTDI for all population groups and all scenarios. For the 'Tasmanian' model, the estimated 95th percentile dietary intakes of iodine were below the PTDI except for 2-3 year old children for Scenario 2 (102% of the PTDI).

Due to the conservative assumptions made in this calculation and that the use of 24-hour dietary survey data tends to over-estimate habitual food consumption amounts for high consumers, it is likely that the 95th percentile dietary intake is an over-estimate. The estimated dietary iodine intakes have not been adjusted to take into account iodine intakes over a longer period of time.

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 amendment of Standard 1.3.3 ‘Processing Aids’ – Clause 12 ‘Permitted bleaching agents, washing and peeling agents’ to allow the use of elemental iodine as a washing agent for fruits, vegetables (including herbs), nuts and eggs at GMP levels. The Applicant has developed a system, the Iodoclean™ system, for delivering active iodine in treatment water at a concentration of 3-30 ppm[13]. This treatment is performed for sanitising purposes.

Dietary Intake Assessment provided by the Applicant

The Applicant stated that fruits and vegetables contribute to approximately 5% of the average iodine intake and that a slight increase in iodine intake from treated fruits and vegetables would be beneficial since the typical Western diet and also the typical Australian diet is substantially deficient in iodine. It was also stated that the Iodoclean™ System increases the existing iodine levels in fruit and vegetables twofold. The data for fruit and vegetable contribution to total iodine intakes were obtained from a paper by Lee et al (1994) and related to iodine intake in the British diet. The dietary intake assessment submitted by the Applicant was not detailed enough to allow FSANZ to determine a conclusion about potential dietary intake of iodine if permission to use iodine as a washing agent is granted. Therefore FSANZ conducted its own dietary intake assessment.

Dietary Modelling

Dietary modelling was conducted by FSANZ to estimate potential dietary intakes of iodine for Australia and New Zealand when fruits, vegetables (including herbs), nuts and eggs are washed with elemental iodine in water. The dietary intake assessments include iodine from other food sources in the diet, but not from supplements or discretionary use of iodised salt. Information on iodine intake from supplements was not available therefore was not included in the dietary intake assessment. Discretionary salt use was not measured in the 1995 Australian National Nutrition Survey (1995 NNS) nor the 1997 New Zealand National Nutrition Survey (1997 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 and 1997 NNSs, with iodine concentration data to estimate the iodine intake from the diet. The dietary intake assessment was conducted using FSANZ’s dietary modelling computer program, DIAMOND.

Dietary intake = food chemical concentration x food consumption

The potential dietary intake of iodine was estimated by combining:

- usual patterns of food consumption, as derived from NNS data;
- the levels of iodine in untreated foods;
- estimated market share for an iodine wash for each commodity as indicated by the Applicant; and

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[13] 1 part per million (ppm) is equal to 1 mg/kg.

- the iodine residues in fruits, vegetables (including herbs), nuts and eggs resulting from an elemental iodine wash, as indicated by the Applicant.

Dietary Survey Data

DIAMOND contains dietary survey data for both Australia and New Zealand; the 1995 NNS from Australia that surveyed 13 858 people aged 2 years and above, and the 1997 New Zealand NNS that surveyed 4 636 people aged 15 years and above. Both of these surveys used a 24-hour food recall methodology to collect food consumption data.

The dietary intake assessment was conducted for both Australian and New Zealand populations. Dietary intakes were assessed for a range of age-gender categories for the purpose of comparison with the PTDI and EARs. Further details regarding EARs can be found in the Nutrition Report at Attachment 5. The population groups assessed against each reference health standard are listed in Table 1 below:

Table 1: Population Groups Assessed Against Each Reference Health Standard

Reference Health Standard	Country	Population Group Assessed
PTDI	Australia	2-6 years 2 years and above
	New Zealand	15 years and above
EAR	Australia	2-3 years 4-8 years 9-13 years 14-18 years 19 years and above
	New Zealand	15-18 years 19 years and above

A dietary intake assessment could not be conducted for New Zealand children aged below 15 years since there are no food consumption data available in DIAMOND for this population group at the current time. A dietary intake assessment for comparison with the PTDI was conducted for Australian children, particularly those aged between 2 and 6 years, because children generally have higher intakes due to their smaller body weight, and they consume more food per kilogram of body weight compared to adults.

Scenarios for dietary modelling

Data were received from DHHS on the iodine concentration in bread available in Tasmania (DHHS 2004) and these data indicated higher iodine concentrations in bread in comparison to the nationally representative data for these foods. As a consequence, a number of 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.

The dietary intake assessments conducted for New Zealand use the 'National' modelling type only.

Within each of these model types, a baseline intake and two post-treatment scenarios were examined: Scenario 1 applied a peeling factor to those fruits and vegetables that may be consumed with the peel either on or off (e.g. apples); and Scenario 2 assumed that fruits and vegetables that may be consumed with the peel either on or off are always consumed unpeeled. The fruits and vegetables that had peeling factors applied in Scenario 1 are listed in Table 2.

Baseline

A baseline iodine dietary intake model was conducted to estimate current iodine dietary intake before permission to use iodine as a washing agent was considered.

Scenario 1

The Applicant stated that all of the iodine from the iodine wash, remains on the surface or within a few millimetres of the surface of the produce. Therefore, removal of the peel from fruits and vegetables, and the shell from nuts, results in the removal of additional iodine residues resulting from the elemental iodine wash. Given this information, the first scenario (Scenario 1) applies a peeling factor to the iodine concentrations of those fruits and vegetables that may be consumed either peeled or unpeeled (e.g. apples). These peeling data were derived from the 1995 NNS for Australia and the 1997 NNS for New Zealand from the proportion of each commodity reported as consumed peeled, unpeeled, juiced and canned. These data are listed in Table 2. This scenario reflects a more accurate estimate of the likely extent to which an elemental iodine wash will impact on the iodine dietary intakes for Australian and New Zealand population groups.

Scenario 2

The second scenario (Scenario 2) assumes that fruits and vegetables that may be consumed either peeled or unpeeled (e.g. apples) are always eaten unpeeled. Scenario 2 is a worst-case scenario where iodine residues from the wash are still on the skin and are consumed.

Table 2: Peeling factors applied to fruits and vegetables that may be consumed either peeled or unpeeled for Scenario 1

Commodity	Percentage Consumed Unpeeled (%)	
	Australia	**New Zealand**
Apples	61	68
Apricots	95	94
Nectarines	91	92
Peaches	44	29
Pears	66	69
Peas, green	7	1
Potatoes	22	16
Tomatoes	81	68

Iodine Concentration Levels

The levels of iodine in foods that were used to establish the baseline level of estimated dietary intake of iodine were derived from a number of sources including Australian, New Zealand, British, and German food composition data, the 1997/8 and 2003/4 NZTDSs, unpublished data from the 22nd ATDS, DHHS, and the Applicant. The Applicant provided data on the increases in iodine concentrations in foods in parts per billion[14] (ppb). These were converted to mg/kg concentrations for use in the DIAMOND program.

Data on the increase in iodine levels for a number of specific fruit and vegetable commodities were provided by the Applicant, with the increase in iodine levels being related to the surface area to volume ratio of the produce. For medium sized smooth skinned produce (e.g. tomatoes) dipped in 30 mg/kg iodine, iodine increases in the produce by 0.100-0.150 mg/kg; for rougher skinned produce (e.g. peaches), iodine increases in the produce by 0.200-0.300 mg/kg; and for very high surface area produce (e.g. leaf lettuce), iodine increases in the produce by approximately 3.000 mg/kg. The increase in iodine residues in raw liquid egg following a 30 mg/kg iodine wash is 0.074 mg/kg.

The foods and their iodine concentrations for baseline, Scenario 1 and Scenario 2, and for ‘National’ and ‘Tasmanian’ models are shown below in Tables 3 and 4 for Australia and New Zealand, respectively. The shaded cells in each of the tables indicate that there is either a difference between baseline and scenario iodine concentrations or that there is a difference between the iodine concentrations used in ‘National’ modelling and in the ‘Tasmanian’ scenario.

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[14] One part per billion (ppb) is equal to 0.001 mg/kg (1 μg/kg)

Table 3: Iodine levels in foods available in Australia before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine for 'National' and 'Tasmanian' models

Food Code	Food Name	Mean or Median# Iodine Concentration Level (µg/kg)						Baseline Data Source
		Baseline		Scenario 1		Scenario 2		
		'National'	'Tasmanian'	'National'	'Tasmanian'	'National'	'Tasmanian'	
AP0001	Honey	6	6	6	6	6	6	4
DM, GS	Sugars	6	6	6	6	6	6	4
CF, GC	Cereal foods	73	73	73	73	73	73	9
CF0081, CF0600, CF0654, CM	Bran	10	10	10	10	10	10	4
CF0645, CF1255, GC0656	Maize/Corn	7	7	7	7	7	7	4
CF1210	Germ	20	20	20	20	20	20	2
CF1266, CM1205, GC0649	Rice	9	9	9	9	9	9	4
CP	Breads	12	350#	12	350#	12	350#	4,10
CP1211	Bread, white	3	350#	3	350#	3	350#	4,10
CP1212	Bread, wholemeal	5	350#	5	350#	5	350#	4,10
DF	Dried fruits	13	13	13	13	13	13	2,3,4
DF0014	Dried prunes	8	8	8	8	8	8	4
DF0269	Dried grapes	17	17	17	17	17	17	4
DF0295	Dried dates	15	15	15	15	15	15	2,3
DT	Teas	63	63	63	63	63	63	4
DV	Dried vegetables	931	931	931	931	931	931	7
FB	Berries and other small fruits	4	4	34	34	34	34	4
FB0269	Grapes	5	5	5	5	5	5	4
FB02691	Wine	7	7	7	7	7	7	4
FB0275	Strawberries	2	2	62	62	62	62	4
FC	Citrus fruits	73	73	73	73	73	73	6

Table 3: Iodine levels in foods available in Australia before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine for 'National' and 'Tasmanian' models

Food Code	Food Name	Mean or Median# Iodine Concentration Level (µg/kg)						Baseline Data Source
		Baseline		Scenario 1		Scenario 2		
		'National'	'Tasmanian'	'National'	'Tasmanian'	'National'	'Tasmanian'	
FI	Tropical fruits – inedible peel (smooth skinned)	1	1	1	1	1	1	4
FI0326	Avocado	5	5	5	5	5	5	9
FI0341	Kiwifruit	1	1	1	1	1	1	4
FI0353	Pineapple	10	10	10	10	10	10	2
FI0332, FI0338, FI0343, FI0358	Tropical fruits – inedible peel (rough skinned)	3	3	3	3	3	3	4,9
FP	Pome fruits	5	5	65	65	65	65	9
FP0226	Apples	5	5	42	42	65	65	9
FP0230	Pears	1	1	26	26	39	39	4
FS	Stone fruits (smooth skinned)	30	30	82	82	82	82	6
FS0240	Apricots	85	85	142	142	145	145	2
FS0245	Nectarines	30	30	78	78	82	82	6
FS0247	Peaches	51	51	103	103	171	171	6
FT, DM0305	Tropical fruit – edible peel	15	15	165	165	165	165	5
GC0647	Oats	75	75	75	75	75	75	9
HH	Herbs	76	76	3,076	3,076	3,076	3,076	7
HS	Spices	76	76	76	76	76	76	7
IM	Molluscs	1,050	1,050	1,050	1,050	1,050	1,050	1
IM1004	Oysters	1,600	1,600	1,600	1,600	1,600	1,600	1
IM1005	Scallops	1,500	1,500	1,500	1,500	1,500	1,500	1
MF	Other mammalian fats (not cattle, pig or sheep)	38	38	38	38	38	38	1,2

Table 3: Iodine levels in foods available in Australia before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine for 'National' and 'Tasmanian' models

Food Code	Food Name	Mean or Median[#] Iodine Concentration Level (µg/kg)						Baseline Data Source
		Baseline		Scenario 1		Scenario 2		
		'National'	'Tasmanian'	'National'	'Tasmanian'	'National'	'Tasmanian'	
MF0812	Cattle fat	100	100	100	100	100	100	1
MF0818	Pig fat	16	16	16	16	16	16	2
MF0822	Sheep fat	20	20	20	20	20	20	2
ML	Dairy products	133	133	133	133	133	133	9
MM0812	Cattle meat	7	7	7	7	7	7	9
MM0818	Pig meat	10	10	10	10	10	10	9
MM0822	Sheep meat	4	4	4	4	4	4	9
MO	Mammalian offal	49	49	49	49	49	49	4
OC, OR	Fats and oils	5	5	5	5	5	5	9
PE	Eggs	366	366	440	440	440	440	9
PF, PM, PO	Chicken meat and offal	4	4	4	4	4	4	9
SB	Coffee, cocoa, cola	56	56	56	56	56	56	4
SO, CO0691, TN	Oilseeds and nuts	58	58	58	58	58	58	1
SO0697	Peanuts	38	38	38	38	38	38	1
TN0663	Cashews	100	100	100	100	100	100	1
VA	Bulb vegetables	4	4	34	34	34	34	4
VA0386	Onions	4	4	55	55	55	55	4
VB	Brassica vegetables	4	4	143	143	143	143	2,4
VB0041	Cabbage	5	5	5	5	5	5	9
VB0400	Broccoli	5	5	449	449	449	449	9
VB0404	Cauliflower	1	1	141	141	141	141	4
VC	Cucurbit vegetables	3	3	33	33	33	33	4,6,9
VC0046	Melons, except watermelon	27	27	27	27	27	27	6
VC0424	Cucumber	1	1	31	31	31	31	4
VC0429	Pumpkin	5	5	5	5	5	5	9
VC0431	Zucchini	2	2	32	32	32	32	4
VC0432	Watermelon	1	1	1	1	1	1	4

Table 3: Iodine levels in foods available in Australia before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine for 'National' and 'Tasmanian' models

Food Code	Food Name	Mean or Median# Iodine Concentration Level (µg/kg)						Baseline Data Source
		Baseline		Scenario 1		Scenario 2		
		'National'	'Tasmanian'	'National'	'Tasmanian'	'National'	'Tasmanian'	
VD	Pulses	10	10	10	10	10	10	9
VL	Leafy vegetables	76	76	210	210	210	210	6
VL0482	Lettuce	76	76	565	565	565	565	6
VO	Other fruiting vegetables (smooth skinned)	4	4	56	56	56	56	4,9
VO0051	Capsicum	1	1	54	54	54	54	4
VO0448	Tomato	6	6	79	79	96	96	9
VO0442, VO0446	Other fruiting vegetables (rough skinned)	7	7	112	112	112	112	2,4
VO0447	Sweetcorn	40	40	145	145	145	145	2
VO449, VO0450	Mushrooms	3	3	77	77	77	77	4
VP	Legume vegetables	5	5	170	170	170	170	9
VP00611	Beans, green	5	5	170	170	170	170	9
VP0529	Peas, garden	5	5	11	11	94	94	9
VR	Root and tuber vegetables	7	7	7	7	7	7	4,9
VR0508	Sweet potato	3	3	3	3	3	3	4
VR0574	Beetroot	16	16	16	16	16	16	9
VR0577	Carrots	5	5	187	187	187	187	9
VR0589	Potato	7	7	40	40	157	157	4
VS	Stalk and stem vegetables	5	5	152	152	152	152	9
VS0621	Asparagus	5	5	107	107	107	107	9
VS0624	Celery	5	5	122	122	122	122	9
WC	Crustacea	300	300	300	300	300	300	1
WD	Diadromous fish	600	600	600	600	600	600	1

Table 3: Iodine levels in foods available in Australia before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine for 'National' and 'Tasmanian' models

Food Code	Food Name	Mean or Median# Iodine Concentration Level (µg/kg)						Baseline Data Source
		Baseline		Scenario 1		Scenario 2		
		'National'	'Tasmanian'	'National'	'Tasmanian'	'National'	'Tasmanian'	
WF0858	Bream	300	300	300	300	300	300	1
WR, WS	Other marine fish	231	231	231	231	231	231	1
WS0004	Gemfish	200	200	200	200	200	200	1
WS0008	Flathead	50	50	50	50	50	50	1
WS0010	Snapper	400	400	400	400	400	400	1
WS0130	Sardine	100	100	100	100	100	100	1
WS0131	Flake	100	100	100	100	100	100	1
WS0927	Cod	500	500	500	500	500	500	1
WS0943	Mullet	100	100	100	100	100	100	1
WS0952	Tuna	150	150	150	150	150	150	1
WS0953	Whiting	100	100	100	100	100	100	1
WW	Water	2	2	2	2	2	2	4
XX0001	Seaweed	14,700	14,700	14,700	14,700	14,700	14,700	8
XX0002	Dry soup mixes	120	120	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 2000); (4) 2003/4 New Zealand Total Diet Survey (Vannoort 2003, Vannoort 2004a-c); (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 level.

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

Table 4: Iodine levels in foods available in New Zealand before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine

Food Code	Food Name	Mean Iodine Concentration (µg/kg)			Source of Baseline Data
		Baseline	Scenario 1	Scenario 2	
AP0001	Honey	6	6	6	4
DM, GS	Sugars	6	6	6	4
CF, GC	Cereal foods	45	45	45	4
CF0081, CF0600, CF0654, CM	Bran	10	10	10	4
CF0645, CF1255, GC0656	Maize/Corn	7	7	7	4
CF1210	Germ	20	20	20	2
CF1211, GC0654	Wheat	45	45	45	4
CF1212	Wheat, wholemeal	5	5	5	4
CF1266, CM1205, GC0649	Rice	9	9	9	4
CP	Breads	12	12	12	4
CP1211	Bread, white	3	3	3	4
CP1212	Bread, wholemeal	5	5	5	4
DF	Dried fruits	13	13	13	2,3
DF0014	Dried prunes	8	8	8	4
DF0269	Dried grapes	17	17	17	4
DF0295	Dried dates	15	15	15	2,3
DT	Teas	63	63	63	4
DV	Dried vegetables	140	140	140	7
FB	Berries and other small fruits	4	34	34	4
FB0269	Grapes	5	5	5	4
FB02691	Wine	7	7	7	4
FB0275	Strawberries	2	62	62	4
FC	Citrus fruits	2	2	2	4
FI	Tropical fruits – inedible peel (smooth skinned)	1	1	1	4
FI0326	Avocado	1	1	1	4
FI0341	Kiwifruit	1	1	1	4
FI0353	Pineapple	10	10	10	2

Table 4: Iodine levels in foods available in New Zealand before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine

Food Code	Food Name	Mean Iodine Concentration (µg/kg)			Source of Baseline Data
		Baseline	Scenario 1	Scenario 2	
FI0331, FI0332, FI0334, FI0338, FI0342, FI0343, FI0356, FI0358	Tropical fruits – inedible peel (rough skinned)	1	1	1	4
FP	Pome fruits	2	62	62	4
FP0226	Apples	2	43	62	4
FP0230	Pears	1	27	39	4
FS	Stone fruits (smooth skinned)	1	54	54	4
FS0240	Apricots	85	141	145	2
FS0245	Nectarines	1	49	54	4
FS0247	Peaches	51	85	171	6
FT, DM0305	Tropical fruit – edible peel	15	165	165	5
GC0647	Oats	11	11	11	4
HH	Herbs	17	3,017	3,017	7
HS	Spices	17	17	17	7
IM	Molluscs	1,251	1,251	1,251	4
IM1003	Mussels	1,533	1,533	1,533	4
IM1004	Oysters	970	970	970	4
MF	Other mammalian fats (not cattle, sheep or pig)	18	18	18	2
MF0812	Cattle fat	20	20	20	2
MF0818	Pig fat	16	16	16	2
MF0822	Sheep fat	20	20	20	2
ML	Dairy products	86	86	86	4
MM	Other mammalian meats (not cattle, pig or sheep)	13	13	13	4
MM0812	Cattle meat	6	6	6	4
MM0818	Pig meat	13	13	13	4
MM0822	Sheep meat	25	25	25	4
MO	Mammalian offal	49	49	49	4
OC, OR	Fats and oils	5	5	5	4
PE	Eggs	519	593	593	4

Table 4: Iodine levels in foods available in New Zealand before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine

Food Code	Food Name	Mean Iodine Concentration (µg/kg)			Source of Baseline Data
		Baseline	Scenario 1	Scenario 2	
PF, PM, PO	Chicken meat and offal	12	12	12	4
SB	Coffee, cocoa, cola	56	56	56	4
SO, CO0691, TN	Oilseeds and nuts	11	11	11	4
VA	Bulb vegetables	4	34	34	4
VA0386	Onions	4	55	55	4
VB	Brassica vegetables	1	140	140	4
VB0041	Cabbage	1	1	1	4
VB0400	Broccoli	1	445	445	4
VB0404	Cauliflower	1	141	141	4
VC	Cucurbit vegetables	2	32	32	4
VC0046	Melons, except watermelon	1	1	1	4
VC0424	Cucumber	1	31	31	4
VC0429	Pumpkin	4	4	4	4
VC0431	Zucchini	2	32	32	4
VC0432	Watermelon	1	1	1	4
VD	Pulses	8	8	8	4
VD05411	Tofu	5	5	5	2,3
VL	Leafy vegetables	17	151	151	4
VL0464	Silverbeet	27	161	161	4
VL0482	Lettuce	7	496	496	4
VO	Other fruiting vegetables (smooth skinned)	1	54	54	2,4
VO0051	Capsicum	1	54	54	4
VO0448	Tomato	1	62	91	4
VO0442, VO0446	Other fruiting vegetables (rough skinned)	7	112	112	2,4
VO0447	Sweetcorn	40	145	145	2
VO449, VO0450	Mushrooms	3	77	77	4
VP	Legume vegetables	1	166	166	4
VP00611	Beans, green	1	166	166	4

Table 4: Iodine levels in foods available in New Zealand before and after washing fruits, vegetables (including herbs), nuts and eggs with elemental iodine

Food Code	Food Name	Mean Iodine Concentration (µg/kg)			Source of Baseline Data
		Baseline	Scenario 1	Scenario 2	
VP0529	Peas, garden	1	2	90	4
VR	Root and tuber vegetables	8	8	8	4
VR0505	Taro	6	6	6	4
VR0508	Sweet potato	3	63	63	4
VR0574	Beetroot	23	23	23	4
VR0577	Carrots	4	186	186	4
VR0589	Potato	7	31	157	4
VS	Stalk and stem vegetables	10	157	157	4
VS0621	Asparagus	10	111	111	4
VS0624	Celery	10	126	126	4
WC	Crustacea	300	300	300	1
WD	Diadromous fish	130	130	130	4
WR, WS	Other marine fish	166	166	166	4
WS0006	Orange roughy	10	10	10	2
WS0010	Snapper	166	166	166	4
WS0014	Hoki	166	166	166	4
WS0952	Tuna	130	130	130	4
WW	Water	2	2	2	4
XX0001	Seaweed	14,700	14,700	14,700	8
XX0002	Dry soup mixes	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 2000); (4) 2003/4 New Zealand Total Diet Survey (Vannoort 2003, Vannoort 2004a-c); (5) German Food Composition tables (Souci et al 1994); (6) A493 Applicant; (7) derived data; (8) British food composition data (Holland et al 1991).

Median iodine concentration level.

Note: the shaded cells indicate that there is a difference between baseline and scenario iodine concentrations.

How were the estimated dietary intakes calculated?

The DIAMOND program allows iodine concentrations to be assigned to food groups. Intake of iodine was calculated for each individual in the NNSs 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 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 and high percentile 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.

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

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.

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.

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

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 concentration is assigned. Factors are only applied to individual foods, and not major food group codes. For example, consumption figures for brewed coffee are converted into the equivalent quantities of a coffee beans; consumption figures for tomato paste are converted into the equivalent quantity 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.

Assumptions in the dietary modelling

Assumptions made in the dietary modelling include:

- where a permission for an iodine wash is given to a food classification code, all foods in that group contain iodine;
-
- all the foods within the group contain iodine at the levels specified in Table 3 for Australia and Table 4 for New Zealand;
-
- consumption of foods as recorded in the NNSs represent current food consumption patterns;
-
- the mean/median iodine concentration values determined from the listed data sources are representative of the levels found in foods throughout Australia and New Zealand for the ‘National’ modelling;
-
- 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 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, and vice versa for New Zealand;

- where there were no Australian or New Zealand data on iodine concentrations of food groups, it was assumed that overseas data 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;
-
- the data provided by the Applicant on estimated market share for an elemental iodine wash system on those fruit, vegetable, herb, nut and egg commodities that are able to be washed with an elemental iodine wash system gives a ‘worst-case’ scenario;
-
- 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. apples in apple pie;
-
- the iodine concentration of 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;
- all fruits, vegetables (including herbs), nuts and eggs will be washed with the maximum concentration of iodine (i.e. 30 mg/kg iodine) and will not be rinsed after the iodine wash;
-
- fruits and vegetables are not washed with water prior to preparation and consumption in the home;
-
- there are no reductions in iodine concentrations on cooking;
-
- where a range of increases in iodine concentrations after washing with Iodoclean™ was specified for a fruit, vegetable or herb in the Application, the upper end of the range was used for the intake assessment as a ‘worst-case’ scenario;
-
- all herbs are fresh herbs;
-
- the Australian and New Zealand populations remove the outer leaves from head lettuce and cabbages prior to use, thereby removing the additional iodine residues resulting from the elemental iodine wash;
-
- there are no increases in iodine residues for nuts, beetroot, sweet potatoes (Australia only), parsnips, citrus fruits, bananas, kiwifruit, pineapple, other fruits with inedible peel, and onions (except for fresh cut onions) since these products are assumed to be always eaten peeled; and
-
- food manufacturers do not use iodised salt in their products, with the exception of bread manufacturers in Tasmania for the ‘Tasmanian’ model where it is known that some bread manufacturers use iodised salt in the production of bread. In a study by 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.

Other information used in the dietary modelling

The other information used in conducting the dietary intake assessment was sourced from the Applicant and includes:

- grapes are never washed prior to use for technological reasons;
- an iodine wash system will never be used on fruits and vegetables that are dried; and
- all of the iodine stays on the surface of the produce, essentially remaining on the surface or within a few millimetres of the surface. Therefore, removal of the peel from fruits and vegetables and the shell from nuts results in the removal of additional iodine residues from the elemental iodine wash system.

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 lifetime.

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, the NNSs did not collect data on the use of complementary medicines (Australia) or dietary supplements (New Zealand). Consequently, these could not be included in the dietary intake assessment.

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 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. 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.

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. Maori and Pacific Islanders were over-sampled in the 1997 NNS so that statistically valid assessments could be made for these population groups. As a result, there may be bias towards these population groups in the dietary exposure assessment because population weights were not used.

DIAMOND does not allow the identification of the state/territory in Australia that an NNS respondent lives. As a consequence, a dietary intake assessment could not be conducted using food consumption data for Tasmanians only for the ‘Tasmanian’ model.

To overcome this limitation, it was assumed that the food consumption data set for the 1995 NNS for all Australian respondents was representative of the food consumption patterns of Tasmanians.

Results

Estimated dietary intakes of iodine

The estimated dietary intakes of iodine for Australian and New Zealand population groups are shown in Table 5 and Figures 1 and 2. The results presented in Table 5 are for all population groups investigated for the purpose of comparison with the PTDI and EARs.

In general, young children (2-3 years and 2-6 years) had the highest dietary intakes of iodine (on a µg/kg bw/day basis) for all of the population groups examined. The dietary iodine intakes of all Australians aged 2 years and above were higher than the dietary intakes of New Zealanders aged 15 years and above. The higher dietary iodine intake by Australians may be due to the higher iodine content of Australian milk (133 µg/kg) in comparison to New Zealand milk (86 µg/kg) especially given that milk is a major contributor to dietary iodine intake.

For all Australians aged 2 years and above, the mean dietary intake of iodine increased above baseline by approximately:

- 30 µg/person/day for Scenario 1; and
- 40 µg/person/day for Scenario 2.

For Australian children aged 2-6 years, the mean dietary intake of iodine increased above baseline by approximately:

- 20 µg/person/day for Scenario 1; and
- 25 µg/person/day for Scenario 2.

For all New Zealanders aged 15 years and above, the mean dietary intake of iodine increased above baseline by approximately:

- 30 µg/person/day for Scenario 1; and
- 50 µg/person/day for Scenario 2.

For all Australians aged 2 years and above, the 95th percentile dietary intake of iodine increased above baseline by approximately:

- 50 µg/person/day for Scenario 1; and
- 65 µg/person/day for Scenario 2.

For Australian children aged 2-6 years, the 95th percentile dietary intakes of iodine increased above baseline by approximately:

- 25 µg/person/day for Scenario 1; and
- 35 µg/person/day for Scenario 2.

For all New Zealanders aged 15 years and above, the 95th percentile dietary intakes of iodine increased above baseline by approximately:

- 45 µg/person/day for Scenario 1; and
- 75 µg/person/day for Scenario 2.

Table 5: Estimated dietary intakes of iodine for Australian and New Zealand population groups for 'National' and 'Tasmanian' modelling

Country	**Population group**	**Model Type**	**Average body weight (kg)**	**No. of consumers of iodine**[◊]	**Consumers as a % of total respondents**[#]	**Mean all consumers µg/kg bw/day (µg/person/day)**			**95th percentile consumers µg/kg bw/day (µg/person/day)**		
						Baseline	Scenario 1	Scenario 2	Baseline	Scenario 1	Scenario 2
Australia	Whole population (2 years+)	National	67	13857	100	2.1 (118)	2.6 (148)	2.8 (159)	6.1 (275)	7.0 (323)	7.3 (339)
		Tasmanian	67	13857	100	2.6 (148)	3.1 (178)	3.3 (189)	7.2 (315)	8.0 (362)	8.4 (378)
	2-6 years	National	19	989	100	5.8 (105)	6.8 (123)	7.2 (130)	11.7 (206)	13.3 (228)	13.8 (240)
		Tasmanian	19	989	100	7.0 (128)	8.0 (146)	8.4 (153)	13.5 (236)	14.7 (266)	15.3 (273)
	2-3 years	National	16	383	100	6.9 (106)	8.0 (124)	8.5 (131)	13.3 (207)	14.7 (234)	15.4 (245)
		Tasmanian	16	383	100	8.2 (127)	9.3 (144)	9.8 (151)	15.0 (237)	16.6 (273)	17.3 (276)
	4-8 years	National	24	977	100	4.8 (109)	5.6 (128)	6.0 (137)	9.6 (217)	10.8 (241)	11.5 (254)
		Tasmanian	24	977	100	5.9 (135)	6.7 (154)	7.1 (162)	11.2 (251)	12.1 (279)	12.5 (290)
	9-13 years	National	43	913	100	3.2 (130)	3.8 (153)	4.1 (165)	7.2 (276)	8.1 (315)	8.5 (328)
		Tasmanian	43	913	100	4.0 (160)	4.5 (184)	4.8 (196)	8.3 (314)	9.1 (341)	9.5 (357)

Table 5: Estimated dietary intakes of iodine for Australian and New Zealand population groups for 'National' and 'Tasmanian' modelling

Country	**Population group**	**Model Type**	**Average body weight (kg)**	**No. of consumers of iodine**[◊]	**Consumers as a % of total respondents**[#]	**Mean all consumers µg/kg bw/day (µg/person/day)**			**95th percentile consumers µg/kg bw/day (µg/person/day)**		
						Baseline	Scenario 1	Scenario 2	Baseline	Scenario 1	Scenario 2
Australia	14-18 years	National	64	734	100	2.3 (142)	2.7 (170)	3.0 (184)	5.9 (339)	6.3 (396)	6.5 (404)
		Tasmanian	64	734	100	2.8 (175)	3.3 (202)	3.5 (216)	6.5 (387)	7.0 (438)	7.2 (448)
	19 years and above	National	74	10,850	100	1.6 (116)	2.1 (149)	2.2 (160)	3.9 (276)	4.6 (328)	4.9 (344)
		Tasmanian	74	10,850	100	2.0 (147)	2.5 (179)	2.6 (191)	4.5 (320)	5.2 (369)	5.4 (385)
New Zealand	Whole population (15 years+)	National	71	4636	100	1.3 (92)	1.7 (122)	2.0 (141)	3.1 (213)	3.6 (258)	4.1 (288)
	15-18 years	National	65	246	100	1.5 (93)	1.9 (119)	2.2 (139)	3.7 (219)	4.3 (257)	4.5 (296)
	19 years+	National	71	4390	100	1.3 (92)	1.7 (122)	1.9 (141)	3.0 (214)	3.6 (258)	4.1 (287)

[◊] Consumers only – This only includes the people who have consumed a food that contains iodine, in this case, all respondents are consumers.

Respondents – This includes all members of the survey population.

Figure 1: Estimated mean dietary iodine intakes before and after use of proposed iodine wash for fruits, vegetables (including herbs), nuts and eggs for Australian and New Zealand population groups for 'National' and 'Tasmanian' modelling.

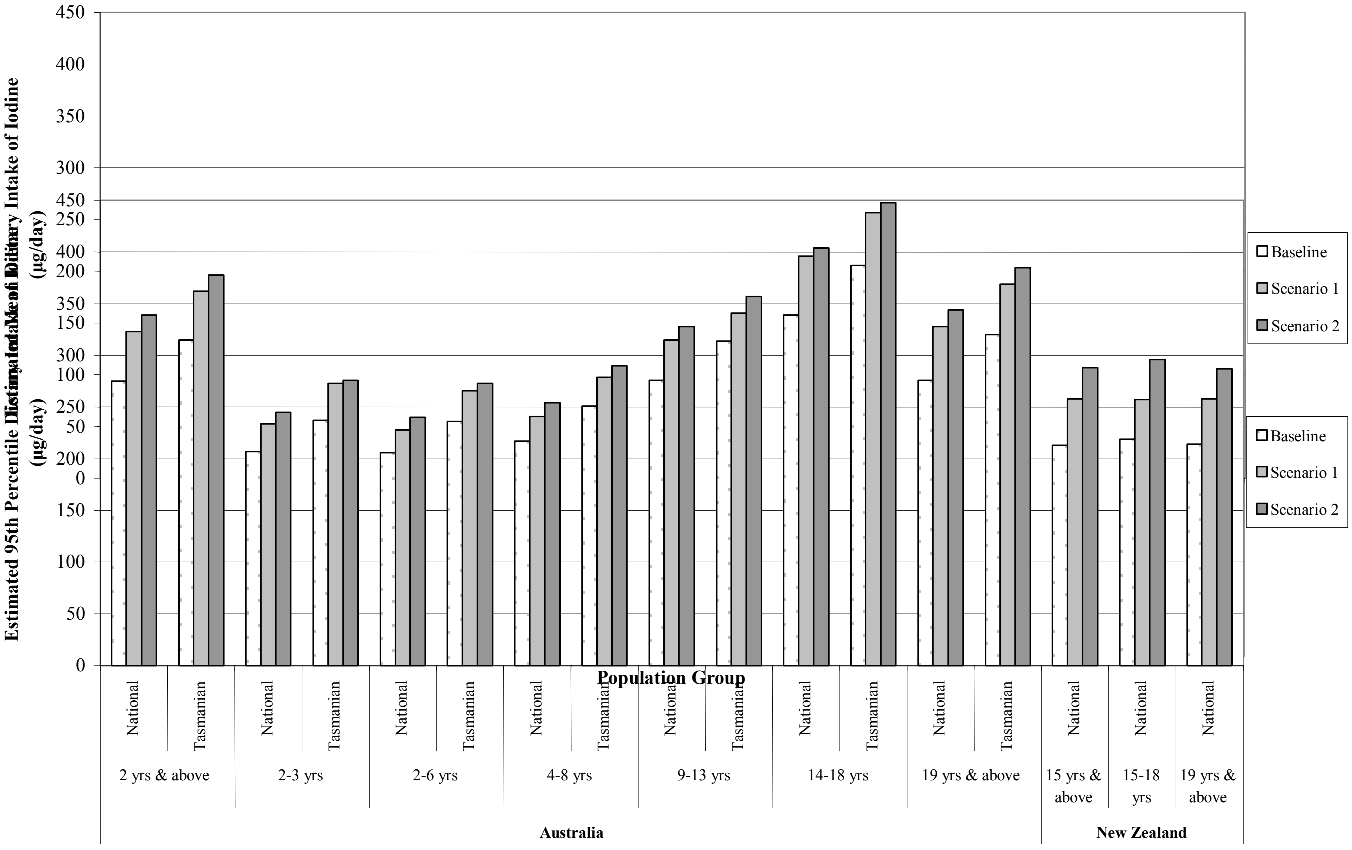


Figure 2: Estimated 95th percentile dietary iodine intakes before and after use of proposed iodine wash for fruits, vegetables (including herbs), nuts and eggs for Australian and New Zealand population groups for 'National' and 'Tasmanian' modelling.

‘Tasmanian’ Foods contributing to total estimated dietary intakes of iodine

The foods that contributed to the total estimated intakes of iodine are shown in Table 6 and Figures 3-7. These are displayed for the total population models as well as for the younger age group of 2-6 year old Australians. For all population groups, all model types and all scenarios, dairy products were the major contributor to dietary iodine intake. At baseline, dairy products contributed between 54 and 76% of estimated dietary iodine intake, depending on the model type and population group. For Scenario 1, dairy products contributed between 45 and 65% of estimated dietary iodine intake, depending on the model type and population group. For Scenario 2, dairy products contributed between 42 and 61% of estimated dietary iodine intake, depending on the model type and population group.

Baseline

For all model types, the major contributors (>5%), other than dairy products, to dietary iodine intake for all Australians aged 2 years and above at baseline were fruits and cereal foods. The other major contributors for Australian children aged 2-6 years were fruits for all model types, with cereal foods also being major contributors in the ‘Tasmanian’ model. For New Zealanders aged 15 years and above, the other major contributors were eggs, seafood and cereal foods.

Scenario 1

For all model types, the Scenario 1 major contributors, other than dairy products, to dietary iodine intake for all Australians aged 2 years and above and Australian children aged 2-6 years were vegetables and fruits, with cereal foods also being major contributors for the ‘Tasmanian’ model. For New Zealanders aged 15 years and above, the other major contributors were vegetables, eggs, seafood and fruits.

Scenario 2

For all model types, the Scenario 2 major contributors to dietary iodine intake for all Australians aged 2 years and above and Australian children aged 2-6 years, other than dairy products, were vegetables and fruits, with cereal foods also being major contributors for the ‘Tasmanian’ model. For New Zealanders aged 15 years and above, the major contributors, other than dairy products, were vegetables, eggs, seafood and fruits.

In general, the use of iodine wash on fruits and vegetables is likely to result in the decreased contribution of dairy products to total iodine intakes, and an increase in the contribution of fruits and vegetables to iodine intakes. Contributions of other food groups to iodine intakes are likely not to change a great deal with the introduction of the iodine wash system.

Table 6: Contributors to total iodine dietary intakes for Australia and New Zealand, for different population groups for ‘National’ and ‘Tasmanian’ models

Country	**Age group**	**Major contributing foods**	**Percentage of total iodine intakes (%)**					
			Baseline		**Scenario 1**		**Scenario 2**	
			‘National’	**‘Tasmanian’**	**‘National’**	**‘Tasmanian’**	**‘National’**	**‘Tasmanian’**
Australia	Whole population (2 years and above)	Dairy Products	**67.8**	**54.0**	**53.8**	**44.8**	**50.0**	**42.1**
		Meat & Poultry	0.9	0.7	0.7	0.6	0.7	0.6
		Eggs	4.5	3.6	4.3	3.6	4.0	3.4
		Seafood (including seaweed)	**5.3**	4.2	4.2	3.5	3.9	3.3
		Fruits (including melons)	**10.6**	**8.4**	**11.4**	**9.5**	**11.6**	**9.8**
		Vegetables (including herbs)	2.3	1.8	**18.7**	**15.6**	**23.4**	**19.7**
		Cereal Foods	**5.6**	**24.7**	4.4	**20.5**	4.1	**19.2**
		Water	1.5	1.2	1.2	1.0	1.1	0.9
		Other Foods	1.6	1.3	1.3	1.0	1.2	1.0

Table 6: Contributors to total iodine dietary intakes for Australia and New Zealand, for different population groups for 'National' and 'Tasmanian' models

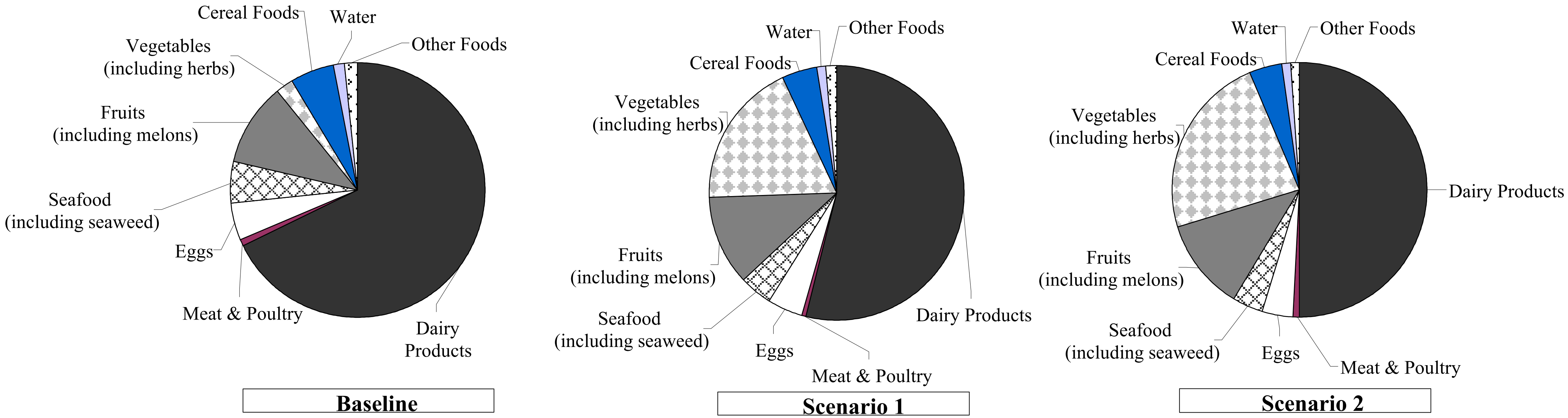
Country	Age group	Major contributing foods	Percentage of total iodine intakes (%)					
			Baseline		Scenario 1		Scenario 2	
			'National'	'Tasmanian'	'National'	'Tasmanian'	'National'	'Tasmanian'
Australia	2-6 years	Dairy Products	**75.8**	**62.1**	**64.7**	**54.5**	**61.1**	**51.9**
		Meat & Poultry	0.5	0.4	0.4	0.3	0.4	0.3
		Eggs	3.0	2.5	3.1	2.6	2.9	2.5
		Seafood (including seaweed)	1.4	1.1	1.2	1.0	1.1	0.9
		Fruits (including melons)	**12.6**	**10.3**	**16.6**	**14.0**	**16.9**	**14.4**
		Vegetables (including herbs)	1.1	0.9	**9.1**	**7.7**	**13.0**	**11.0**
		Cereal Foods	3.5	**20.9**	3.0	18.3	2.8	**17.5**
		Water	1.0	0.8	0.9	0.7	0.8	0.7
		Other Foods	1.2	1.0	1.0	0.8	0.9	0.8

Table 6: Contributors to total iodine dietary intakes for Australia and New Zealand, for different population groups for 'National' and 'Tasmanian' models

Country	Age group	Major contributing foods	Percentage of total iodine intakes (%)					
			Baseline		Scenario 1		Scenario 2	
			'National'	'Tasmanian'	'National'	'Tasmanian'	'National'	'Tasmanian'
New Zealand	Whole population (15 years & above)	Dairy Products	**64.6**		**48.8**		**42.2**	
		Meat & Poultry	2.0		1.5		1.3	
		Eggs	**12.8**		**11.0**		**9.5**	
		Seafood (including seaweed)	**8.7**		**6.5**		**5.7**	
		Fruits (including melons)	1.6		**5.1**		**5.8**	
		Vegetables (including herbs)	2.1		**20.8**		**30.1**	
		Cereal Foods	**5.2**		3.9		3.4	
		Water	1.9		1.4		1.2	
		Other Foods	1.1		0.9		0.7	

Note: the major contributors (>5%) to dietary iodine intake are listed in **bold** type.

Figure 3: Contributors to total iodine intakes for the Australian population aged 2 years and above for the 'National' model[15]



Baseline

Scenario 1

Scenario 2

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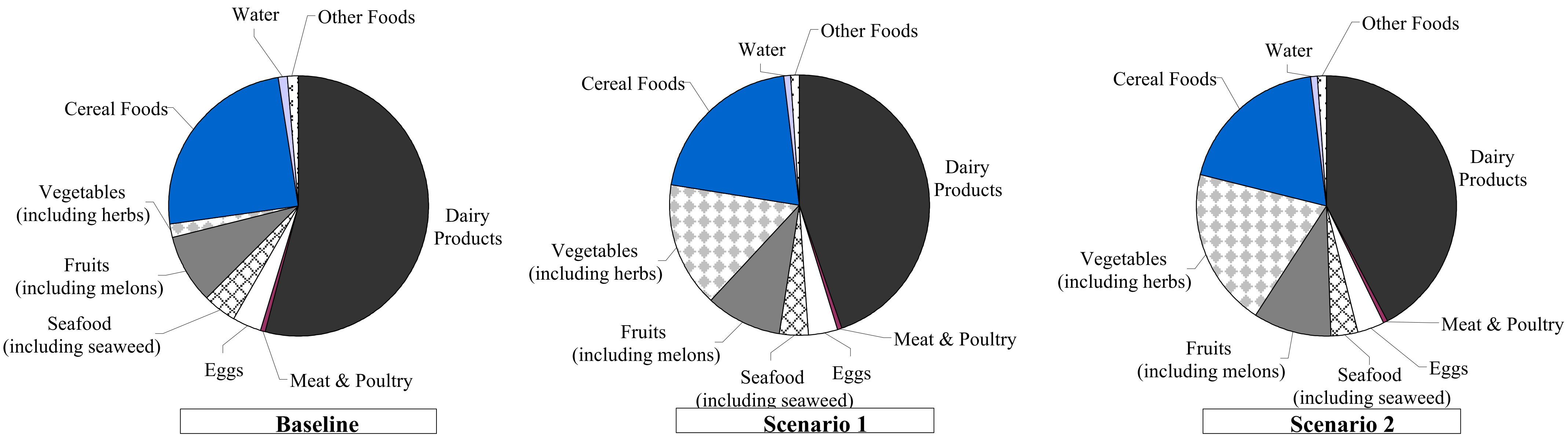
[15] Note: The per cent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario.

Figure 4: Contributors to total iodine intakes for the Australian population aged 2 years and above for the ‘Tasmanian’ model[16]



Baseline

Scenario 1

Scenario 2

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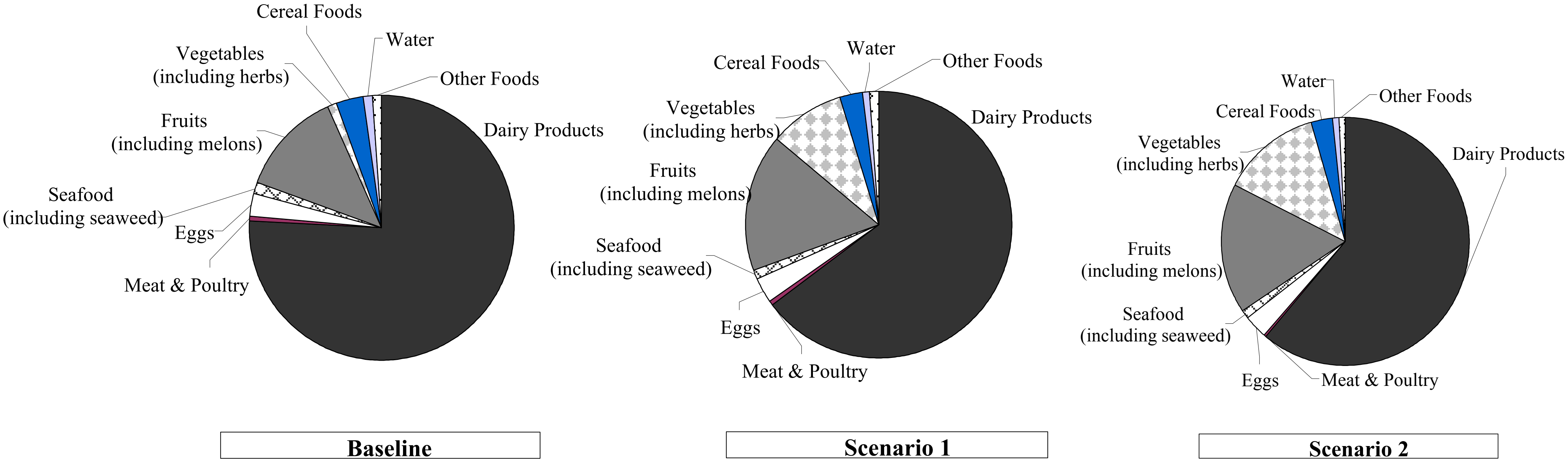
[16] Note: The per cent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario.

Figure 5: Contributors to total iodine intakes for the Australian population aged 2-6 years for the 'National' model[17]



Baseline

Scenario 1

Scenario 2

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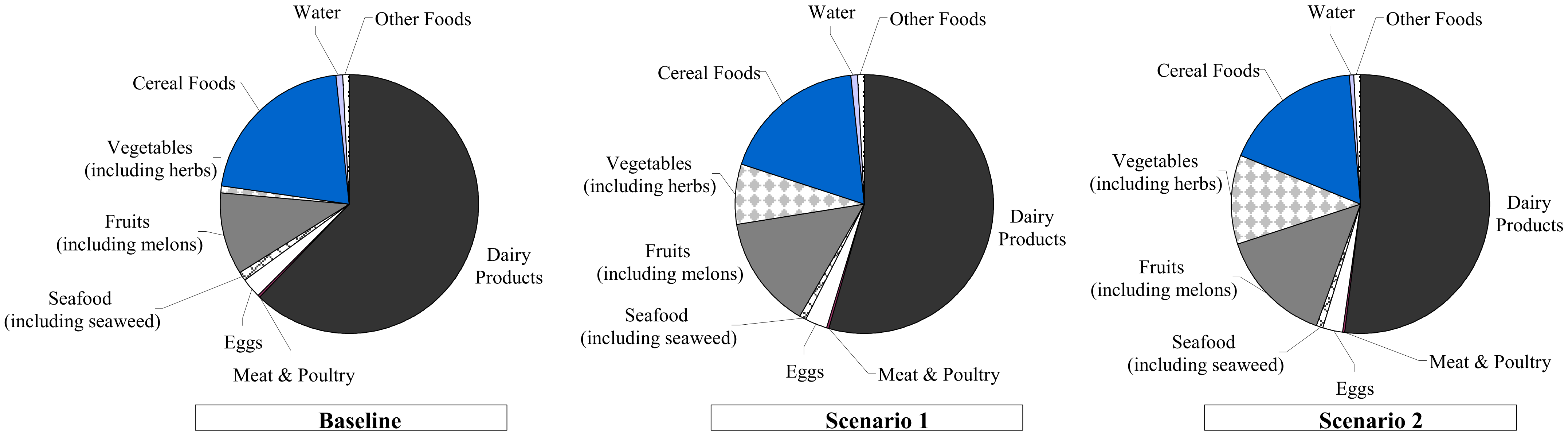
[17] Note: The per cent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario.

Figure 6: Contributors to total iodine intakes for the Australian population aged 2-6 years for the 'Tasmanian' model[18]



Baseline

Scenario 1

Scenario 2

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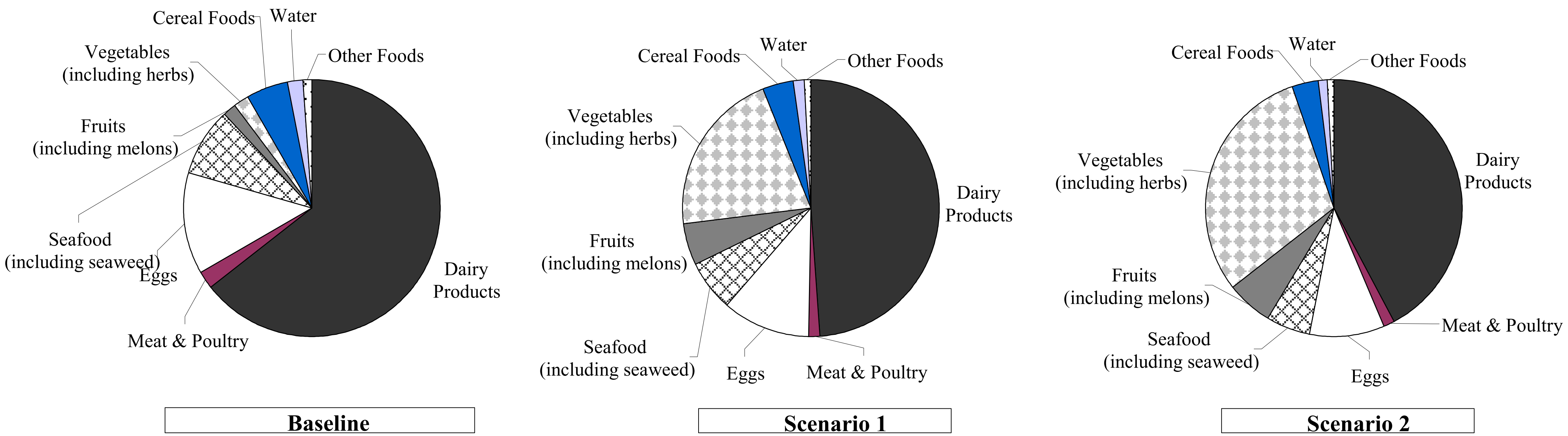
[18] Note: The per cent contribution of each food group is based on total iodine intakes for all consumers in the population groups assessed. Therefore the total iodine intakes differ for each population group and each scenario.

Figure 7: Contributors to total iodine intakes for the New Zealand population aged 15 years and above[19]



Baseline

Scenario 1

Scenario 2

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[19] Note: The per cent 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.

Risk Characterisation

Comparison of the estimated dietary intakes with the PTDI

In order to determine if the level of dietary intake of iodine will be a public health and safety concern if an iodine wash is applied to fruits, vegetables (including herbs), eggs and nuts, the estimated dietary intakes were compared to a Provisional Tolerable Daily Intake (PTDI) of 17 µg/kg body weight/day that was set by the FAO/WHO Joint Expert Committee on Food Additives (JECFA) (WHO 1989).

The results of the comparison between estimated dietary intake (in µg/kg bw/day) and the PTDI are given in Table 7 and Figures 8 and 9. Estimated mean dietary intakes of iodine were below the PTDI of 17 µg/kg body weight/day (WHO 1989) for all population groups, all scenarios and all model types examined. For all of the 'National' models, estimated 95th percentile dietary intakes of iodine were below the PTDI for all population groups and all scenarios. For the 'Tasmanian' model, the estimated 95th percentile dietary intakes of iodine were below the PTDI except for children aged 2-3 years for Scenario 2 (102% of the PTDI). However, the estimated dietary iodine intakes for Scenario 1 are more likely to represent actual dietary iodine intakes since it reflects the proportions of fruits and vegetables that are consumed with the peel, and therefore the additional iodine from the iodine wash, removed.

Due to the conservative assumptions made in this calculation and that the use of 24 hour dietary survey data tends to over-estimate habitual food consumption amounts for high consumers, it is likely that the 95th percentile dietary intake is an over-estimate. Additionally, the PTDI is set for a lifetime of exposure and the 'all population' models are a good indicator of the likely dietary exposures for the population over a lifetime.

Table 7: Estimated dietary intakes of iodine compared to the PTDI for 'National' and 'Tasmanian' modelling

Country	Population group	Model Type	Average body weight (kg)	No. of consumers of iodine[◊]	Consumers as a % of total respondents[#]	Mean all consumers (%PTDI)			95th percentile consumers (%PTDI)		
						Baseline	Scenario 1	Scenario 2	Baseline	Scenario 1	Scenario 2
Australia	Whole population (2 years+)	National	67	13857	100	12	15	17	36	41	43
		Tasmanian	67	13857	100	16	18	20	42	47	49
	2-6 years	National	19	989	100	34	40	42	69	78	81
		Tasmanian	19	989	100	41	47	50	79	87	90
	2-3 years	National	16	383	100	41	47	50	78	87	91
		Tasmanian	16	383	100	48	55	58	88	98	**102**
	4-8 years	National	24	977	100	28	33	35	57	64	67
		Tasmanian	24	977	100	35	40	42	66	71	73

Table 7: Estimated dietary intakes of iodine compared to the PTDI for ‘National’ and ‘Tasmanian’ modelling

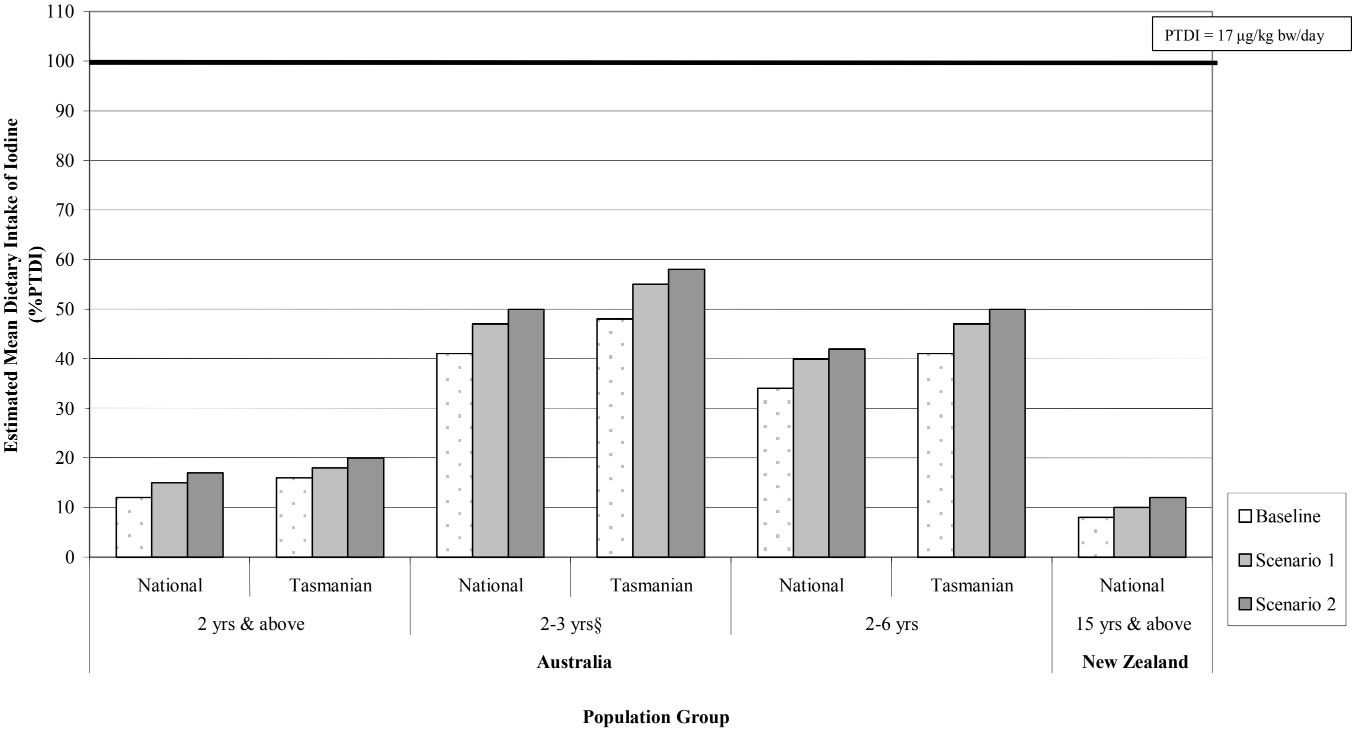
Country	**Population group**	**Model Type**	**Average body weight (kg)**	**No. of consumers of iodine**[◊]	**Consumers as a % of total respondents**[#]	**Mean all consumers (%PTDI)**			**95th percentile consumers (%PTDI)**		
						Baseline	Scenario 1	Scenario 2	Baseline	Scenario 1	Scenario 2
Australia	9-13 years	National	43	913	100	19	22	24	43	48	50
		Tasmanian	43	913	100	23	27	28	49	53	56
	14-18 years	National	64	734	100	14	16	17	34	37	38
		Tasmanian	64	734	100	17	19	20	38	41	42
	19 years and above	National	74	10,850	100	9	12	13	23	27	29
		Tasmanian	74	10,850	100	12	15	15	26	31	32
New Zealand	Whole population (15 years+)	National	71	4636	100	8	10	12	18	21	24
	15-18 years	National	65	246	100	9	11	13	22	26	26
	19 years+	National	71	4390	100	7	10	11	18	21	24

[◊] Consumers only – This only includes the people who have consumed a food that contains iodine, in this case, all respondents are consumers.

[#] Respondents – This includes all members of the survey population.

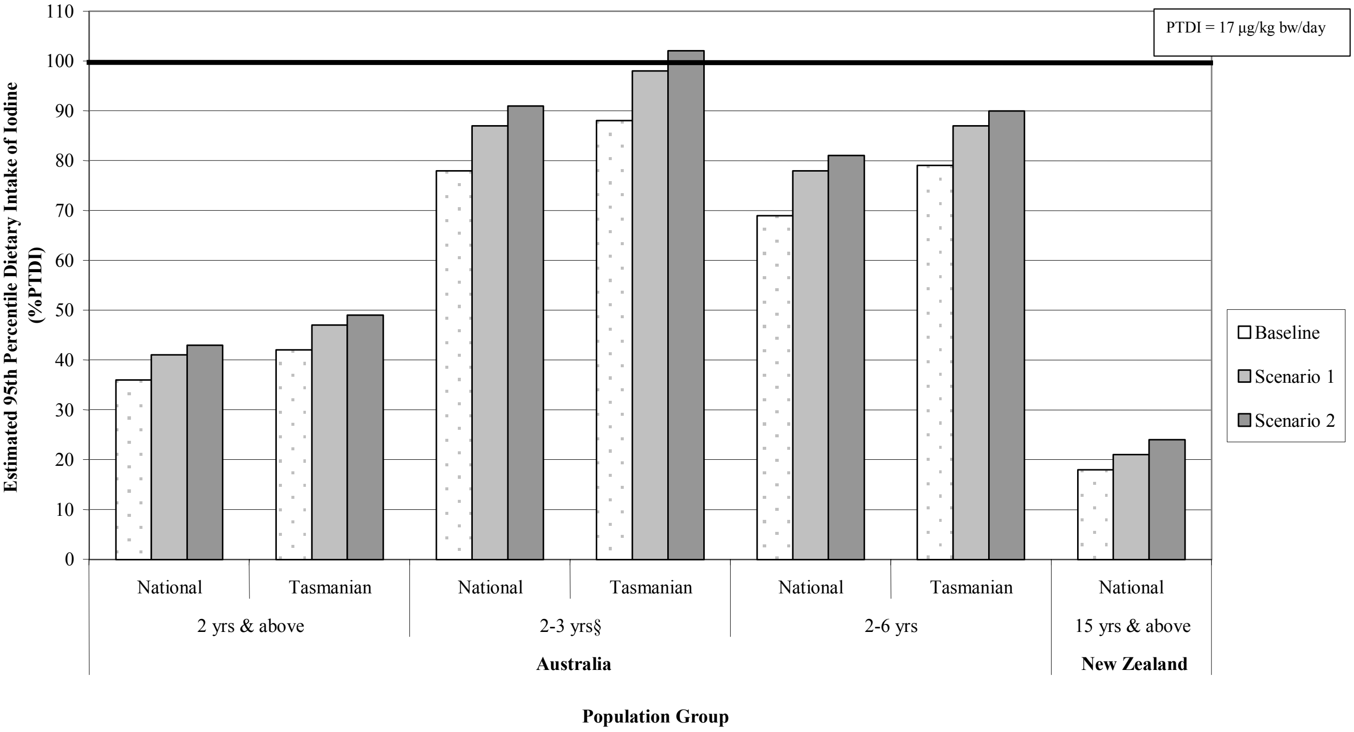
Note: where estimated dietary intakes of iodine exceeded the PTDI, these have been indicated in **bold** type.

Figure 8: Estimated mean dietary iodine intakes, as a percentage of the PTDI, before and after approval of iodine as a washing agent for fruits, vegetables (including herbs), nuts and eggs for Australian and New Zealand population groups.



[§] A dietary intake assessment was conducted for the 2-3 years age group to allow a comparison to the EAR. In conducting this assessment, the dietary intake was noted to exceed the PTDI and, for this reason, the data for the 2-3 years age group are presented.

Figure 9: Estimated 95th percentile dietary iodine intakes, as a percentage of the PTDI, before and after approval of iodine as a washing agent for fruits, vegetables (including herbs), nuts and eggs for Australian and New Zealand population groups.



[§] A dietary intake assessment was conducted for the 2-3 years age group to allow a comparison to the EAR. In conducting this assessment, the dietary intake was noted to exceed the PTDI and, for this reason, the data for the 2-3 years age group are presented.

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ATTACHMENT 5

NUTRITION RISK ASSESSMENT

The aim of this Nutrition Risk Assessment Report is to consider the current iodine status of the Australian and New Zealand populations, and to compare this with the results of dietary modelling (Attachment 4) in order to subsequently determine the nutritional risks, if any, to Australian and New Zealand populations from the proposed amendments to the Food Standards Code.

New policy guidelines on fortification have been established which recognise particular circumstances in which mandatory fortification to meet public health need is appropriate. FSANZ has raised a separate proposal (Proposal P230 Iodine Fortification) to investigate the need for increased iodine content in the Australia New Zealand food supply.

1. Current iodine status of the population

The International Council for the Control of Iodine Deficiency Disorders (ICCIDD) and the World Health Organization (WHO) have determined criteria for assessing population iodine status based on median urinary iodine concentrations. Many researchers have chosen to use these criteria in assessing their research population. Table 1 below describes the criteria for assessing iodine nutrition the population, and Table 2 illustrates the results of several studies conducted to examine the iodine status of study populations in Australia and New Zealand. Urinary iodine measures are more indicative of population iodine status than measures of dietary iodine intake.

Table 1: Epidemiological criteria for assessing iodine nutrition, based on median urinary iodine concentrations in school-aged children (ICCIDD)

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

The ICCIDD suggest that, in adults, a urinary iodine concentration of 100 µg/L corresponds roughly to a daily iodine intake of about 150 µg under steady state conditions (ICCIDD 2001). A median of 100 µg/L or greater is recommended by WHO as being indicative of iodine sufficiency in a population.

Table 2: Results from studies[1] investigating iodine status of Australian and New Zealand populations.

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

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[1] Further details of these studies can be found at Appendix 1.

[2] The WHO recommends that the median urinary iodine concentration for populations as a whole should be more than 100 µg/L, and that less than 20% of the populations should have a urinary iodine concentration below 50 µg/L as a measure of nutritional adequacy.

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

Studies shown in Table 2, indicate that iodine deficiency exists to various extents in both Australian and New Zealand population groups. In Australia, no national surveys have been undertaken to assess the iodine status of Australians, although national data collection in a National Iodine Nutrition study is currently in progress. New Zealand has regularly monitored national iodine status because of the low iodine content of its soils. Monitoring of iodine status also occurs in Tasmania where iodised salt is now used in the majority of Tasmanian bread manufacture, however the data are currently unpublished.

Both the WHO and the ICCIDD (ICCIDD 2001) suggest that no more than 20 per cent of a population should have a urinary iodine level less than 50 µg/L, and that a median urinary iodine of 100µg/L or greater is indicative of iodine sufficiency. The general conclusion from the studies of urinary iodine levels in Table 2 is that a sizable proportion of Australians and New Zealanders suffer from iodine deficiency to varying extents.

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

The EAR is defined as the level below which 50 per cent of the population may be at risk of having inadequate dietary intake and is used to estimate the prevalence of inadequate intakes in a population. Dietary modelling has been conducted to determine the percentage of Australian and New Zealand populations not meeting the EAR for iodine intake (baseline intake data). The food consumption data used in the dietary iodine intake assessment were as measured in the 1995 National Nutrition Surveys (NNS) and reflects the food consumption patterns prevailing at that time. Table 3 illustrates these results.

Table 3: Estimated percentage of respondents for Australian and New Zealand population groups consuming less than or equal to the Estimated Average Requirements (EAR) for Iodine at baseline

Country	**Population group**	**Average body weight (kg)**	**Percentage of Respondents with Dietary Intakes of Iodine ≤ EAR[1] (%)**	
			National	Tasmanian
Australia	2-3 years	16	28	16
	4-8 years	24	26	12
	9-13 years	43	28	14
	14-18 years	64	40	26
	19 years and above	74	52	35
New Zealand	15-18 years	65	65	na
	19 years and above	71	66	na

[1] The Estimated Average Requirement (EAR) for iodine intake of Australians and New Zealanders as proposed by Thomson 2002.

The data in Table 3 are only suggestive of iodine intake due to the difficulties in measuring iodine in the food supply. Also, discretionary salt use was not measured in the National Nutrition Surveys. Depending on the level of discretionary iodised salt use, the extent of dietary inadequacy shown by the data in Table 3 might be overestimated. The levels of iodine in foods that were used to establish the level of estimated dietary intake of iodine were derived from a number of sources including Australian, New Zealand, British, and German food composition data, the 1997-8 and 2003-4 New Zealand Total Diet Surveys, the Australian Dairy Corporation and the Applicant. Iodine composition varies from country to country depending on soil levels and use of iodophors. The iodine content of plants and animals reflects the environment in which they grow.

Although both types of data are not directly comparable, the general inference can be drawn that a considerable proportion of Australians and New Zealanders are mildly iodine deficient.

3. Nutrient interactions

Some nutrients are known to compete with others for absorption and bioavailability, for example, dietary calcium and iron compete for absorption in the body when consumed at the same meal. There is no literature to suggest that iodine competes with, or inhibits the bioavailability of any other nutrient. This suggests that increasing the levels of dietary iodine intake will not have an adverse consequential effect on the nutritional status of consumers.

4. Conclusion

Research in both Australia and New Zealand indicates that the prevalence of iodine deficiency disorders is likely to be increasing in some populations in Australia and New Zealand. Data on the median urinary iodine levels in Australian and New Zealand populations suggests the baseline levels of iodine intake used in the dietary modelling may be slightly higher than in reality. As with the use of iodophors, the use of iodine as a processing aid may result in adventitious contamination of the food supply. It is very unlikely that the observed increase in iodine intake as a result of this Application will cause imbalances with other nutrients; to the contrary, it may have the beneficial outcome of helping to replete populations with poor iodine status. There are no identified adverse nutritional risks created by the proposed amendment to the *Food Standards Code.* FSANZ is currently considering Proposal P230 Iodine Fortification. The use of iodine as a processing aid, and its contribution to iodine intake, will be taken into account should any iodine fortification program be implemented in the future.

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Appendix 1

STUDIES OF IODINE STATUS IN AUSTRALIA AND NEW ZEALAND DISCUSSED IN MAIN BODY OF REPORT.

(i) Gunton J, Hams G, Fiegert M, McElduff A. (1999). Iodine Deficiency in ambulatory patients at as Sydney Teaching Hospital; Is Australia Truly Iodine Replete? *Med J Aust*. 171: 467-470.

Study participants:

Study conducted at a tertiary referral hospital Sydney, Australia.

- 81 pregnant women attending obstetric clinic with 26 of the same women being retested at three months postpartum.
- 135 diabetes patients attending diabetes clinic for annual screening.
- 19 volunteers.

Methodology:

Spot urine samples were collected and urinary iodine measured by mass spectrometry. Iodine status based on urinary iodine concentration.

Results:

Table 1: Results of iodine deficiency in Sydney participants. Gunton et al

	Pregnant women	Postpartum women	Patients with diabetes	Volunteers
Number of participants	81	26	135	19
Mean age	32.9 ± 9.8	35.3 ± 11.3	50.1 ± 35.3	49.5 ± 17.4
% participants with severe to mod deficiency	19.8	19.2	34.1	26.3
% participants with mild deficiency	29.6	34.6	37.8	47.4
% participants with normal iodine status	50.6	46.1	28.1	26.3

A weakness of this study is that subjects were recruited from hospital rather than the community. The small number of community volunteers did show a similar pattern of iodine status as seen in those subjects with diabetes. All patients were out patients and generally well.

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

Study Participants:

- 324 children 5-13 years from a public school on the central coast of New South Wales.

Methods:

Thyroid ultra-sonography was used to determine thyroid volume. First morning g urine samples were collected.

Results:

Table 2: Urinary iodine concentration in children. Guttikonda et al.

	% Urinary iodine concentration < 50 μg/L	% Urinary iodine concentration 50-100 μg/L
n = 301	14	55

The median urinary iodide concentration was 81 μg/L for boys and 79 μg/L for girls with the over all median being 82 μg/L - indicative of mild iodine deficiency according to ICCIDD guidelines.

3% of the 144 girls had thyroid volumes above the WHO/ICCIDD median by age and 1% had thyroid volumes above the WHO/ICCIDD by body surface area. None of the boys had thyroid volumes above the WHO/ICCIDD medians. The results are indicative of long-term iodine deficiency in a small number of the population.

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

Study participants:

Study was undertaken in Sydney late 1998 and early 1999.

- 94 Healthy children aged 6-13 years randomly selected from a Western Suburb – upper middle income homes.
- 101 full term pregnant women attending antenatal classes at Westmead Hospital.
- 86 healthy Institute of Clinical Pathology and Medical Research Staff aged 21-60 years – subjects had not knowingly taken iodine medications or supplements in the previous 6 months.
- 85 people with diabetes.

Methods:

Urine samples were analysed for urinary iodine concentration.

Results:

Table 3: Urinary iodine concentration in Sydney populations 1998/99. Li et al

	% urinary iodine concentration < 50 µg/L	Median Urinary Iodine excretion
94 children 6- 13 years - Sydney	13.8	84 µg/L
101 Pregnant women from antenatal class, Sydney	20.6	88 µg/L
86 Adult volunteers, medical staff, Sydney	18	88 µg/L
85 Diabetes patients	23	69 µg/L

Approximately 60% of pregnant women in study displayed urinary iodine concentrations consistent with mild to moderate iodine deficiency.

(iv) McDonnell C, Harris M, Zacharin M. (2003). Iodine Deficiency and Goitre in School Children in Melbourne, 2001. *Med J Aust.* 178: 159-162.

<u>Study participants:</u>

- 607 children aged 11 –18 years from private schools, suggesting that they were not socio economically disadvantaged.

<u>Methods:</u>

577 children provided urine samples two hours after getting out of bed. Urinary iodine was measured by Sandell-Koltoff reaction:

<u>Results:</u>

Table 4: Urinary iodine excretion Melbourne school children. McDonnell et al.

	< 50 µg/L	50 – 99 µg/L	> 100 µg/L
Male (n=167)	17%	51%	32%
Female (n=410)	31%	48%	21%
Total (n=577)	27%	49%	24%

Median urinary iodine excretion for the total population was 70µg/L, indicative of mild iodine deficiency.

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

<u>Study participants:</u>

Subjects were recruited between November 1993 and June 1994

- 189 subjects (102 males, 87 females) from Dunedin Blood Transfusion Centre
- 144 (67 males, 77 females) from the Waikato Blood Transfusion Centre

Methods:

Blood was collected and assayed for serum free T_3, free T_4 and TSH to determine circulating levels.

The following urine samples were also collected - fasting over night, and complete 24-hour specimen – urine collections were started two days after the blood donation to allow for dehydration of body fluids.

93 per cent of subjects reported using iodised salt and 1.7 per cent reported using non-iodised salt. 48 per cent reported never adding salt to food at the table; 23 per cent always and 29 per cent sometimes; 30 per cent never used salt in cooking; 50 per cent always and 19 per cent sometimes. There was no difference in salt usage between the two geographical regions. Subjects also provided information regarding iodine supplement use.

Results:

Table 5: Urinary iodide concentrations in Dunedin and Waikato subjects (median values with ranges in parentheses). Thompson et al

	Male		Female	
	All Subjects	Non-supplementers*	All Subjects	Non-supplementers*
n	169	156	164	155
24 hour iodide (µg/day)	73 (13-323)	70 (13-193)	62 (15-421)	59 (15-165)
Iodide concentration (µg/L) 24 hour urine	49 (12-281)	45 (12-152)	44 (6-350)	42 (6-123)
Iodide concentration (µg/L) Fasting morning urine	51 (9-240)	49 (9-200)	42 (8-384)	40 (8-130)

* Subjects who did not report taking regular supplements or medicines

Table 6: Proportion of subjects at risk from iodine deficiency disorders (IDD) according to Urinary iodine concentration and 24h iodide excretion. Thompson et al

	Urinary Iodide concentration		24h Iodide excretion	
Risk of IDD	Criteria	% of study population	Criteria	% of study population
Severe	< 20 µg/L	7%	< 25 µg/day	5%
Moderate	20 – 49 µg/L	50%	25-49 µg/day	26%
Mild	50 – 100 µg/L	35%	50-100 µg/day	50%
None	> 100 µg/L	8%	>100 µg/day	19%

The authors concluded that although 24-hour urine samples are difficult to collect on a population level, they suggest that for research purposes that they are the most suitable and accurate measure of iodine status.

(vi) Ministry of Health 2003. *NZ food NZ children: key results of the 2002 National Children's Nutrition Survey*. Wellington: Ministry of Health.

Subjects:

- 24-hour dietary recall from 3275 participants from urban and rural children around New Zealand. Urine and blood samples were collected from those participants who live in urban areas (number unknown). Children were aged between 5 and 14 years.

Results:

Median urinary iodine concentration of 66 μg/L (males 68 μg/L and females 62 μg/L). Twenty eight per cent of children had a urinary iodine concentration of less than 50μg/L, indicative of IDD.

Urinary iodine concentration did not differ across the three age groups (5-6 years, 7-10 years, 11-14 years). Females had a lower mean urinary iodine concentration than males.

Maori children had a lower mean urinary iodine concentration than New Zealand European and Pacific children.

Children from the lowest socio economic quartile had lower mean urinary iodine levels than those in the highest socio economic quartile.

(vii) Skeaff S, Thomson C, Gibson R. (2002). Mild Iodine Deficiency in a Sample of New Zealand School Children. *Eur J Clin Nutr.* 56: 1169-1175.

Study participants:

- 282 children aged 8-10 years randomly selected from 30 schools in Dunedin and Wellington, New Zealand.

Methods:
Casual urine sample taken and frozen within 24 hrs before being analysed by single technician. Thyroid volume determined by ultra-sonography as an average of both thyroid lobes.

Results:

Table 7: Urinary iodine levels and percentage of children below cut offs (WHO and ICCIDD) for severe, moderate and milk iodine deficiency. Skeaff et al

Age (y)	n	median (inter quartile range) μg/L	% <20 μg/L	percentage <50 μg/L	percentage < 100μg/L
Girls 8 years	34	67 (41-93)	3.1	42.8	76.5
Girls 9 years	57	67 (46-84)	1.9	26.2	85.2
Girls 10 years	48	61 (41-82)	6.4	35.8	87.2
Boys 8 years	54	56 (47-93)	5.4	34.0	77.4
Boys 9 years	57	71 (46-96)	3.7	27.6	78.8
Boys 10 years	32	75 (60-102)	0.0	24.0	68.1
TOTAL	282	66 (45-91)	3.6	31.4	79.7

The mean urinary iodine level for this population was 66 μg/L and clearly indicative of mild IDD. Thirty per cent of the children in the study had iodine levels below 50 μg/L.

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

Study participants:

- 350 Otago residents aged 18-49 years, initially selected randomly from electoral roll then later non-randomly from blood donors. 233 participants completed the research.

Methods:

350 participants collected complete 24 hour urine samples on two occasions.
233 then gave blood for assessment of thyroid hormone status and had their thyroid volumes measured by ultrasonography.

Results:

Table 8: Urinary iodine status and thyroid status of all subjects (n = 233) in Otago study 1997/1998. Thomson et al

	Mean ± s.d.	Median	CI (95th)
Age (y)	32±7	33	31-33
Weight (kg)	77±16	75	75-79
24h creatinine (g/day)	1.60±0.46	1.55	1.54-1.66
Iodide excretion 24 hour urinary iodide(µg/day)	86±49	75	80-93
Iodide/creatinine ratio (µg/g Cr)	57±35	47	53-62
Urinary iodide concentration (µg/L)	59±33	54	55-64
Thyroid status TSH (µIU/mL)	1.63±0.78	1.55	1.53-1.74
T4 (µg/dL)	7.3±1.8	7.2	7.0-7.6
Thyroglobin (ng/mL)	6.9±6.1	5.1	6.1-7.7
Thyroid volume (mL)	14.8±6.0	14.2	13.9-15.6

The authors comment that the median measures of urinary iodide excretion were lower than mean values due to very high excretions, 60 participants had median excretions higher than 100 µg/day. All of these participants reported consuming kelp, iodine containing supplements or iodine containing medicines. When subjects with excretion >140 µg/day were excluded, the mean and median values for urinary iodine excretion were 75±25 and 76 µg/day for males and 71±28 and 67 µg/day for females.

Significant inverse correlations were found for relationships between two measures of urinary iodide excretion (total 24h excretion and iodide/creatinine ratio) and thyroid volume and thyroglobin. Inverse correlations for urinary iodide concentration were significant for thyroglobin but not for thyroid volume.

Comments:

The overall aim of the study was to ascertain the correlation between the urinary iodide excretion and measures of thyroid status. For this reason there was no breakdown of numbers of participants into groups that may be disposed to various levels of IDD according to international cut offs.

ATTACHMENT 6

SUMMARY OF PUBLIC COMMENTS

SUMMARY OF SECOND ROUND PUBLIC SUBMISSIONS

1. *Dietitians' Association of Australia*

- Supports Option 2 to approve the use of iodine as a sanitizing agent as the dietary modelling indicates that dietary intakes of 1000 µg/day will not be exceeded.

2. *Australian Food and Grocery Council (AFGC)*

- In view of the safety finding the AFGC supports the Application. Supports the finding that the use of iodine as a processing aid is technologically justified. Supports the risk assessment finding and conclusion.

- Suggest that under the *Impact Analysis* FSANZ include that Option 1 may disadvantage consumers by denying them potentially safer food, and consistent with this, that under Option 2 there may be an advantage to consumers in the potential for increased safety in certain foods. Supports the amendment to the Food Standards Code.

3. *New Zealand Food Safety Authority (NZFSA)*

- Noted that the areas it expected to see addressed at the draft assessment stage have been adequately covered. NZFSA had no further comments to make on the Draft Assessment.

4. *Manu Maggu*

- States that the Code should be amended to include the use of iodine as an agent for the surface sanitisation of foods, especially fruits, vegetables, nuts and eggs.

5. *Emily Choi*

- Iodine is an alternative sanitizer or washing agent, which can be more effective and also can provide iodine as an essential micronutrient.

- According to the estimated iodine intake from iodine treated fruit and vegetables, excess iodine intake is not a big concern. However, experts should examine this.

- If iodine fortification is going to be approved then the iodine level from the fruit and vegetables need to be taken into account.

6. *New South Wales Food Authority*

- NSW Food Authority supports option 2 to approve iodine as a processing aid.

- The Authority notes the concerns raised by Tasmania Health in Application A528 and the potential impact of this Application. The Authority would therefore urge FSANZ to monitor iodine levels in the relevant foods over the next few years to determine the impact of these applications and to consider if necessary the need to re-evaluate.

7. *Queensland Health (with input from Queensland Department of Primary Industries and Fisheries)*

- The Food Technology report (**Attachment 2**) is not properly referenced (using websites, sometimes not accessible), specifically the following claims:

  - iodine is said to not be as readily inactivated by organic matter
  - chlorine reacts with organic matter to produce unpleasant by-products that are carcinogenic and may cause flavour taints

- In response to above issues Queensland Health questions whether chlorine compounds needs further investigation. Also are there iodinated compounds formed that may also be harmful?

- In the public submissions (p18) the following claims needs to be referenced:

  - iodine remaining on these foods will largely be in the form of iodide, which has virtually no biocidal activity

- The Food Technology Report states that it is best to keep the water pH below 8.5 to limit iodate production. This raised two questions by Queensland Health: Does iodate end up as a residue in food and is it of concern. Another question is whether the Applicant have appropriate methodology for monitoring of pH.

- Queensland Health is also interested to see whether the Applicant has analytical methods available.

- In the Dietary Intake Assessment, the iodine levels appear to be total iodine and to be calculated values. No actual data on measured levels of iodine and iodate in foods have been included. Furthermore, in the description of Scenario 1 on page 46 indicates that the Applicant stated that all of the iodine stays on the surface of the produce, essentially remaining on the surface or within a few millimetres of the surface of the produce. Queensland Health asks whether this statement is supported by data.

- There are limitations to the FSANZ dietary intake assessment, although these have been acknowledged.

- After considering the Report, Queensland Health supports option 1 – maintain the status quo and not approve the use of iodine as a processing aid – until the above questions are adequately addressed.

8. *Food Technology Association of Victoria (FTA)*

- The FTA agreed with option 2 – to amend the Code and approve the use of iodine as a processing aid.

9. *Department of Health and Human Service, Tasmania*

- Tasmania is very concerned about Australia's capacity to assess the potential health impact of applications of this nature in the absence of current:

  - food consumption and food composition data for dietary modelling
  - comprehensive data on nutritional status of the population
  - Australian nutrient reference values (previously known as RDIs)

- It is acknowledged that responsibility for most of these issues lies outside the control of FSANZ, these information gaps limit the scientific credibility of this assessment report.

- Milk iodine levels are higher in Tasmania than the New Zealand levels used in the modelling, additional data are provided by Tasmania and Tasmania would appreciate an additional scenario be included incorporating levels of iodine found in milk in Tasmania.

- In October 2001, Tasmania introduced an Iodine supplementation program, which asked bread manufacturers to switch to iodised salt in place of regular salt. Some levels of iodine in bread were submitted, and again Tasmania would like to see the modelling repeated taking into consideration bread baked with iodised salt.

- Timing overlap with potential introduction of iodine fortification.

- Tasmania is concerned that the effects of iodine fortification combined with the higher milk levels of iodine seen in Tasmania added to iodine residues in vegetables, fruit, nuts and eggs may be potential for iodine intakes to exceed the provisional maximum tolerable daily intake.

- This Application if approved would create a situation where it would be very difficult to predict the level of iodine intake. This would make the management of public health measures to maintain adequate population iodine status very tricky.

- Monitoring use of iodine as a processing aid.

- Clearly relying on residues on fruit and vegetables is an inappropriate way to address iodine deficiency, as pointed out in the Draft Assessment.

- If this Application were approved, Tasmania strongly recommends there be some system of monitoring the use of iodine as processing aid (who is using it, on what products; the level of iodine in the final product, and how widely the products are distributed and consumed)

10. Croydon Conservation Society

- Croydon Conservation Society believe in the precautionary principle and is opposed to the sanitising of our foods with another potentially hazardous chemical, in a way that is not easily identifiable or avoidable.

11. Elisabeth Jameson

- Supports option 1 – not to approve iodine as a processing aid, because it will cause health problems in the future.

SUMMARY OF FIRST ROUND PUBLIC SUBMISSIONS

1. Queensland Health

- Tentatively supports Option 2 – to amend the Code and approve the use of iodine as a food processing aid.

- Acknowledges the previous use of iodine for cleaning and sanitising in the dairy industry.

- The safety and efficacy of iodine as a washing agent for foods will need to be more fully considered.

- Questions why the permission should involve all foods.

2. Mr Keith Richardson, Food Science Australia

- Supports the progression of the Application.

- There is ample evidence that the washing agents already approved have limited effectiveness in the decontamination of fresh cut fruit and vegetables.

- If the material in the Application is substantiated, iodine would appear to be a useful addition to those washing agents already approved.

3. Western Australia Department of Health

- Has considered various issues including the comparison of iodine with chlorine agents, food tainting, the use of iodine in various industries and the cessation of iodine sanitiser use in the dairy industry and the concerns of allergic reaction by sensitive individuals to iodine products.

- Notes that iodine intake in Australia is relatively low but not significant enough to warrant intervention, and that incidental intake of iodine through foods subject to water treatment agents may not present a public health and safety concern.

- Recognises that iodine is comparatively a more stable surface sanitiser than chlorine and has greater potential effects against a wide range of microorganisms.

- Notes that iodine residues are more likely to remain on food surfaces and reach the final consumer, which raises the issue of the appropriateness of classifying iodine as a Processing Aid.

- Seeks further clarification on the use and methods of Application and the proposed control measure for iodine.

- Prefers Option 1 – maintain the status quo and not approve the use of iodine as a food processing aid.

- Will reconsider the Application as additional information becomes available.

4. *Professor Joe Montecalvo, California Polytechnic State University*

- Supports the Application.

- Has been conducting a detailed review of direct contact sanitisers for use within the fruit and vegetable segment of the industry, especially the whole fruit and fresh cut convenience products and has also studied the Applicant's Iodoclean™ System.

- Has found the Iodoclean™ System to not only be effective in the reduction of the risk of microbial food infections and food borne disease but also to be the most significant advancement in sanitation technology in the past twenty years. His assessment is based on rapid microbial kill rates with longer shelf life possibilities. The system also offers very significant advantages especially in environmental, equipment maintenances and occupational health and safety.

5. *Dr Stephen Morris, Sydney Postharvest Laboratory*

- There is a shortage of effective sanitisers that can be used directly on foodstuffs and which do not have major problems with undesirable breakdown products, waste disposal and maintaining accurate sanitiser levels. The Iodoclean™ System is a useful addition to the available sanitisers.

- In a range of tests undertaken at the laboratory, iodine was found to be more effective than chlorine against a considerable number of bacteria and fungi. It was also more effective than chlorine when the dip became contaminated with dirt or small particles of organic material.

- The treatment of food does result in an increase of iodide in the food. For fruits and vegetables, the increase can be as little as 10%, however over a range of fruits and vegetables and a range of concentrations the increase was found to be about 100%. Fruits and vegetables only account for about 5% of dietary iodine, and the typical Australian diet has been reported as significantly deficient in iodine.

6. *Dr Kerry McDonalds, Department of Crop Sciences, University of Sydney*

- It has long been demanded that an alternative to chlorine washes be found.

- Chlorine is used widely as a washing agent for fresh produce but is not very safe for consumers and is also corrosive for the processing plants.

- Approval for the use of iodine as a washing agent would provide an additional option for the food processing industry.

- The levels of iodine used would not be harmful for human consumption and will add dietary iodine to the food supply.

7. Australian Quarantine and Inspection Service (AQIS)

- AQIS will assess the regulatory impact on AQIS operations of any proposed amendment to the Code after the draft assessment stage has been completed.

8. New Zealand Food Safety Authority

- Cannot comment on the safety aspects or the nutritional implications as the Application is still at Initial Assessment.

- Trusts that when preparing the Draft Assessment, FSANZ will consider the following:

  - the bioavailability of iodine from this source;
  - the function of iodine when used as a sanitising agent to determine if it is solely acting as a processing aid, or is there also a food additive function;
  - whether iodine is approved for this use in any other jurisdiction.

9. Ms Jenny Jobling

- Saw the Iodoclean™ System on television and was impressed with the invention and considers it to be an excellent new technology.

- Believes iodine would be a useful addition to the food sanitisers available to the Australian food industry.

10. Australian Food and Grocery Council

- Supports the Application, subject to an appropriate safety assessment by FSANZ.

- The use of iodine in the washing of fruits and vegetables could be useful in reducing the bacterial load, and studies submitted by the Applicant in support of this.

- Some years ago, iodine was used as a sanitising agent in the dairy industry and, when high residual levels were found in dairy products, a maximum level of 500 µg/L was imposed for milk and liquid milk products. This restriction, however, has not been carried over into the new Code, as iodophors are no longer used in the dairy industry.

- Concerns have been expressed that iodine consumption in Australia may be below optimum levels and even some suggestion that mandatory fortification of certain foods with iodine should be considered. This would seem to be a point in favour of approving this Application.

- The Applicant has stated increased iodine intake would be relatively low as fruit and vegetables contribute only about 5% of the iodine in an average diet. This clearly ignores other potential sources of increased iodine intake if the Application were to be approved for foods generally. The Application therefore requires a thorough assessment.

- Should FSANZ decide that approving the use of iodine as a processing aid for foods generally with a residual subject only to GMP, poses a potential risk to public health, FSANZ has three options other than rejecting the Application outright. These are: approve for foods generally but with a prescribed maximum residue, approve for fruits and vegetables with a residue subject to GMP; and approve for fruits and vegetables with a prescribed maximum level.

11. *Food Technology Association of Victoria Inc*

- Agrees with Option 2 – to amend the Code and approve the use of iodine as a food processing aid in the Applications nominated by the Applicant.

12. *Dietitians Association of Australia*

- Although there is some evidence that dietary intakes of iodine may be below the recommended levels for prevention of iodine deficiency disorders in selected populations in Sydney, Melbourne and Tasmania, there is no evidence to support an increased incidence of IDD in conjunction with the lower urinary iodine excretion values.

- A national survey to more fully document iodine nutritional status in Australia as well as the prevalence of IDD would provide data to develop an appropriate public health policy if necessary.

- The DAA understands that such a survey is currently underway but the results will not be available until mid 2004.

- The DAA believes that the reintroduction of iodine as a sanitising agent may be a suitable replacement for chlorine-based sanitising agents, but should not be seen as a way of correcting nutritional inadequacies.

- The DAA recommends strongly that modelling be done to estimate the maximum exposure to iodine, if it were used in a wide range of foods, to ensure that maximum dietary intakes would not exceed 1000 μg/day.