

**CONSIDERATION OF MANDATORY
FORTIFICATION WITH IODINE
FOR AUSTRALIA AND NEW ZEALAND**

**SUMMARY OF SUBMISSIONS TO
PROPOSAL P230 DRAFT ASSESSMENT REPORT**

December 2007

Summary of Submissions

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

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

Option 1 – Maintaining the *status quo*; and

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

Key Issues Identified from Submissions

1. Regulatory options

1.1 *Maintaining the Status Quo*

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

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

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

1.2 *Proposed Mandatory Fortification Scenario*

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

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

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

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

2. Alternative Suggestions for Addressing Iodine Deficiency

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

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

2.2 Universal Salt Iodisation

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

3. Food Vehicles

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

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

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

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

4. Safety and Efficacy

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

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

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

5. Level of Fortification

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

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

6. Consumer Choice

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

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

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

7. Impact of Fortification on Industry

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

Industry concerns raised in submissions included:

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

8. Trade

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

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

9. Labelling and Claims

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

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

10. Current Salt Permissions

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

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

11. Use of Salt in Non-Mandated Foods

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

12. Implementation and Transition Period

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

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

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

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

13. Cost/Benefit Analysis

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

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

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

14. Monitoring and Compliance

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

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

15. Communication and Education

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

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

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

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

16. Dietary Intake Assessment

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

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

17. Consistency with Policy Guidelines

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

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

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

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

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

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

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

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

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

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Other issues</i></p> <ul style="list-style-type: none"> • Before any mandatory fortification is undertaken, a deficiency sufficient to warrant fortification of all basic cereal based food stuffs should be established. • Random sampling and testing of school children is considered an adequate marker of iodine status of any given population. If deficiency is detected then ultrasonography and blood tests should follow. • If a significant deficiency is established, voluntary fortification of some cereal foods might be a more sensible and less costly approach.
<p>Liz Sanzaro Private Australia</p>	<p>Appears to support Option 2 – Mandatory iodine fortification</p> <ul style="list-style-type: none"> • States ‘I am not one for the notion of fiddling with our food’ but also states ‘I am far more likely to be persuaded that the fortification of our regular food items with iodine is necessary.’ • Does not support mandatory fortification of cereals with folic acid or calcium in fruit juice or other manipulation of food in general. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Family predisposition for the reduced TSH synthesis (submitter and both parents on thyroid replacement therapy) • States that iodine deficiency is a reality for many Australians. • Notes that recorded incidence has increased recently. • Notes that a significant number of females in mid to later years are affected by hypothyroidism, possibly caused by low dietary iodine intake. • Is aware of a disproportionate number of people in her community with swollen thyroid glands, or thyroid gland nodules (needing surgical removal) or pregnancy induced goitre.
<p>Lai Ho Seet Private Australia</p>	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <ul style="list-style-type: none"> • Supports enhanced education on food choices to increase iodine intake. • Submits from personal experience of Grave’s disease. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Considers it ‘fruitless’ to add iodine when data does not indicate a local deficiency e.g. Perth / Western Australia. • Concerned as Grave’s disease worsens with excessive iodine. Considers the risk of hidden iodine in food for those with hyperthyroidism is too great compared with the prevention of potential cretinism, which is not seen in developed countries with good education and low poverty. • Concerned that excessive iodine supplementation may lead to hypothyroidism and thyroiditis. • Concerned those with hyperthyroidism will worsen with excess iodine. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Freedom of choice important. Considers it unfair to be forced to have different food to the family. Notes salt-free bread, biscuits and cereals from specialty stores are more expensive. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Education of the target group would be more useful than the addition of iodine to bread, cereals and biscuits e.g. potential mothers and parents of toddlers.

SUBMITTER	SUBMISSION COMMENTS
	<p><i>Other issues</i></p> <ul style="list-style-type: none"> • There is more iodine in many diets than ever before with cultural diversity and more people consuming a southeast Asian diet. • Notes the role of soy products as a possible modern cause of hypothyroidism rather than lack of iodine. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Considers WHO data outdated and limited. Believes Australia cannot be compared to third world countries with high rates of poverty.
<p>Leah Voysey Private Australia</p>	<p>Support option not stated - but concerned about mandatory iodine fortification</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned at ‘medicating’ the whole community when this could be harmful to those with autoimmune hyperthyroidism, especially as it is well documented that women in pregnancy or following childbirth can develop hyperthyroidism. • Refers to adverse reactions to supplements containing iodine and foods containing high levels of iodine in those with Grave’s disease. • Queries whether education has been considered fully as a viable part of an alternative strategy.
<p>Francine Worboys Private Australia</p>	<p>Preferred option not specified.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned about the effect of adding extra iodine to the diet for those with hyperthyroidism. Asks if this has been considered when proposing mandatory fortification.
<p>Australian Food and Grocery Council (AFGC) Australia David Roberts</p>	<p>Supports a modified Option 1 - with a Memorandum of Understanding (MoU) with industry for the voluntary use of iodised salt in food manufacture.</p> <p>This would be combined with:</p> <ul style="list-style-type: none"> • an industry awareness campaign promoting the need for iodised salt in food manufacture; • a consumer education campaign aimed at the target population; and • Trans-Tasman monitoring programme for urinary iodine status in the target population. <p><i>Features of the alternative approach (above):</i></p> <ul style="list-style-type: none"> • Shown to be effective in Tasmania and internationally; • Promotes consumer choice; • Has no WTO implications; • Allows those with coeliac disease to be reached; • Is consistent with the policies of COAG, ANZFRMC and FSANZ. • Recommends the approach could be applied regionally, and adjusted from time to time on a regional basis. <p><i>Disadvantages of the preferred mandatory approach:</i></p> <ul style="list-style-type: none"> • Is not the most effective strategy; • Does not meet policy requirements for mandatory fortification; • Removes consumer choice;

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Is not an effective solution for those with coeliac disease who do not consume wheat-based products; • Creates unjustified trade restrictions for imported foods causing potential WTO action; and • Mandatory fortification is not supported by the best available evidence, which supports voluntary use of iodised salt. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • AFGC notes that milk and milk products are major contributors to iodine intakes for both the target groups and all Australians aged two years and above, and for New Zealanders aged 15 years and above. However, these have not been included in the modelling scenarios as possible food vehicles. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Proposal fails to consider consumer views in Australia, and relies on the outcome of the voluntary program for iodine fortification in Tasmania. Assumes there has been no consumer concern at the mandated addition of thiamine 17 years ago. • Rejects the ‘choice’ of unleavened bread and salt free cereals for consumers as these are entirely different products and cannot be compared to the regular products. • Notes the consumer research in New Zealand by NZFSA indicating strong opposition to the mandating of folic acid addition to the food supply because it removed consumer choice. • Refers to a recent survey of consumers undertaken by a business likely to be affected by the proposed mandatory fortification with folic acid and iodine in September 2006. This survey showed 84% of respondents thought voluntary fortification was preferable to mandatory fortification, and 62% respondents were concerned that mandatory fortification shows a trend to making staple foods such as bread act like medicine. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • A 12 month implementation period will cause unnecessary costs to industry and is not achievable due to the volume of labels and relatively small size of the label change and printing industries. • An acceptable time frame to allow for labelling changes is two years for short shelf life products and four years for long life shelf life. • The current Standard 1.3.2 limits food companies from using labels as an effective way of helping to support the communication and education strategy that FSANZ indicates is critical to the success of the proposal. • Recommends a pre-approved iodine health claim for foods fortified with iodised salt in order to enhance communication and education about the importance of iodine in the diet. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Mandatory fortification could be seen as a technical barrier to trade, and therefore will require careful handling by FSANZ to avoid WTO intervention. For example, Australian businesses manufacturing in China for export to Australia will not conform to Australian requirements as China has a different iodisation level for salt from that proposed in P230. Exports to the Japanese market are not permitted to utilise iodised salt in manufacture, and manufacturers may not be able to remain competitive due to additional costs of maintaining two salt supplies and associated costs – this has been noted as a problem for a cereal manufacturer.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • The MoU will allow the necessary flexibility to meet the needs of the Australian market and export markets. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • AFGC recommends FSANZ exempt imported food from the requirement to use iodised salt and focus on agreements via MoU with Australian based manufacturers. This will require further modelling to determine the impact of the proposed exemption. • The four week consultation period has prevented AFGC from obtaining sufficient details on imported foods for this submission. AFGC will however continue to provide FSANZ with such information after the close of submissions to assist the FSANZ modelling and decision making. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> • Supports the retention of current permission for iodised salt for discretionary use. • Recommends promoting the substitution of iodised salt for un-iodised salt. • Australian data indicates that salt use has remained stable over the past 5 years, while iodised salt intake has risen, indicating consumers are choosing to use iodised salt over un-iodised. <p><i>Use of salt in non-mandated foods</i></p> <ul style="list-style-type: none"> • At production sites where foods other than the proposed mandated products are produced, it is likely that all foods would use iodised salt because of the difficulty of sourcing two supplies, maintaining separate storage areas, and additional quality control measures. • At production sites where products are physically separated (different plant) from mandatory products then continued use of un-iodised salt would occur. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Does not believe the proposal meets policy guidelines. • The proposed MoU does meet policy guidelines. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Recommends a Trans-Tasman monitoring program be developed and maintained for urinary iodine status in the target population. <p><i>Communication and education strategies</i></p> <ul style="list-style-type: none"> • Recommends industry awareness campaign to raise and maintain awareness of the need to use iodised salt in food manufacture. • Recommends ongoing consumer education campaign aimed at target population at risk promoting the importance of iodine in the diet. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Notes uncertainties around the economic value of the benefits from mandatory fortification, but no corresponding uncertainty regarding costs to industry and to government. • Compliments Access Economics on their full use of industry supplied data in their report. • Suggests that the AFGC solution of a MoU will deliver the desired outcome without incurring excessive costs to all parties, and will maintain consumer choice.

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	<p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> Notes the lack of up to date data on current intake of iodine for Australia which hampers risk assessment. Believes that FSANZ should seek further information from stakeholders at each stage of consultation, and in the event that it is necessary to use patterns from 1995 consumption, FSANZ should model a wider range of consumptions to ensure they capture upper and lower intake levels. FSANZ should check outlier results with relevant industry stakeholders for validation. It is incorrect to presume that all sodium reported on a label is derived from sodium chloride. This is incorrect for many foods e.g. biscuits contain sodium bicarbonate as a raising agent. This has the effect of overestimating the iodine contribution modelled in scenario one. The effect is lesser in scenario two. Aztec data (scanned sales data for the total retail salt market) indicates the true figure for discretionary salt is closer to 18% (17.7%) for Australia and 75% for New Zealand. FSANZ should utilise the updated figures for iodised salt in future baseline modelling. Notes that no comprehensive survey of Australian consumer attitudes to fortification has been undertaken. <p><i>Attachments:</i></p> <p>Draft Memorandum of Understanding and membership of AFGC attached to submission.</p>
<p>Bayer HealthCare Australia Ayumi Uyeda</p>	<p>Supports Option 2 – Preferred approach for mandatory iodine fortification and commends the salt industry for their encouraging approach.</p> <p>A pharmaceutical company.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Questions the evidence for selecting the proposed fortification level of 25 – 40 mg/kg iodine in salt and the timeline for expecting an improvement in the mean urinary iodine concentrations. Notes that the level of iodisation of salt in the USA is 100 mg/kg and questions whether this level has shown adverse effects or would be of benefit in Australia. Also questions the need for a higher level of iodine to be added to salt to address the trend to reduce overall salt intake by society in general, and especially by some sections of the population, e.g. patients with high blood pressure and pregnant women. Acknowledges that the implications of iodine are well documented and well understood. <p><i>Implementation</i></p> <ul style="list-style-type: none"> Questions whether the fortification period could be implemented earlier than one year to address those in the Eastern States at greatest risk of iodine deficiency. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Supports increasing awareness within specific groups at risk of iodine deficiency.
<p>Campbell Arnott’s Australia Michael Depalo</p>	<p>Supports a Modified Option 1 – Maintaining the <i>status quo</i></p> <ul style="list-style-type: none"> Supports expanded voluntary iodine fortification of foods targeted to the at risk population groups, with consumer education. Fortification could be through iodised salt or other sources of iodine.

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	<ul style="list-style-type: none"> • Recommends the development of a MOU with industry enabling a targeted application of voluntary fortification with iodised salt to targeted foods. • Campbell Arnott's would be willing to participate in a MoU. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Notes potential risk to those with hyperthyroidism. Mandatory iodine fortification in Denmark created side effects from increasing iodine intakes too quickly in a marginally deficient population. In Tasmania Connolly notes unacceptable high rates of thyrotoxicosis following implementation of universal iodine supplementation in the late 1960s. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Refers to a NZFSA report indicating 84% of consumers were not in favour of mandatory fortification of foods. More than 75% of participants stressed the desire for choice. • Considers salt free varieties of bread, breakfast cereals and biscuits are not acceptable alternatives and there are technical hurdles to producing salt free bread. • Application of a MOU to a large company would allow smaller independent bakeries to produce iodine free bread and biscuits ensuring choice. <p><i>Trade/impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Concerned the application of iodised salt in the production of products in other countries at the same level as in Australia will be complex to manage and impact on imports e.g. Arnott's imports several biscuit products from Indonesia. Monitoring of will be costly and time consuming. Requiring imported foods to meet the requirements could be a barrier to trade. • Recommends FSANZ consider exempting imported foods and focus on a MOU with Australian based manufacturing across a range of products. This will require further modelling – the shortened consultation period had not allowed Arnott's to obtain sufficient detail of imported goods by close of submissions, but can provide this to assist FSANZ analysis. • Considers export is also impacted by the proposal e.g. Japan maintains an absolute ban on fortification with iodine in all foods. This would require alternative formulations of major brands solely for export. Voluntary fortification would offer flexibility. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Technical issues: notes iodine is a known oxidant and there is some evidence that iodising salt significantly increases the risk of oxidative rancidity. This could pose a risk for the shelf-life of products such as biscuits and cereals. Considers issues affecting the provision of safe and high quality products to consumers must be addressed before progressing with the proposal. • Transition period: recommends concessions be made to allow product labels to be updated in line with the normal cycle of reviews by industry to keep costs to a minimum. Recommends a 3 year transition period with the provision of an additional year for stock in trade. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Considers the proposal does not meet the Ministerial Council Policy Guideline which requires fortification to be monitored and reviewed. Concerned agreement on the exact nature of the monitoring system has yet to be reached with other agencies and that there is no indication of commitment to the required levels of monitoring. • Recommends the need to consider both urinary iodine content and frequency of

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	<p>hyperthyroidism.</p> <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports an education campaign that is consistent with the national nutrition guidelines of both Australia and NZ. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Concerned iodine intakes are based on NNS data that is more than 10 years old. Supports the commissioning of a new NNS to provide contemporary and robust data as there have been significant changes to the food supply. • Believes the model used by FSANZ assumes all sodium on the NIP is from sodium chloride. Notes many foods especially biscuits use sodium bicarbonate as a raising agent which contributes up to 75% of the sodium content. As biscuits are a target food this could overestimate the iodine contribution. • Notes also that in mixed foods such as biscuits and cereals salt may be added as a component of composite ingredients such as seasoning and salted butter – understands this does not need to be iodised but could result in overestimation of the iodine contribution from these foods. Recommends appropriate modelling be carried out with industry supplied data to confirm potential iodine load.
<p>Cerebos Foods Australia & New Zealand Patricia Verhoeven (Member of AFGC)</p>	<p>Supports Option 1 – Maintaining the <i>status quo</i> with MoUs with industry. Supports the AFGC submission as an alternative effective and economical source of iodine.</p> <p>Does NOT support Option 2 - preferred approach for mandatory iodine fortification as the most effective solution as:</p> <ul style="list-style-type: none"> • it denies consumer choice; • introduces trade restrictions for imported foods. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Recognises that iodisation of salt is an effective way of increasing the iodine intake of populations at risk of IDD. • Supports voluntary use of iodised salt as has been demonstrated as an effective solution in Germany, Switzerland, Netherlands and USA. • Also supported by Tasmanian experience which showed a decrease in iodine deficiency from 21% to 10.9% in 4 years. • Supports voluntary MoU with industry which would allow industry to select those products most suited to the target population to contain iodised salt e.g. avoid using indulgent biscuits as a vehicle for promoting a public health solution. • Recognises the medical evidence linking reduced iodine intake with adverse health outcomes such as Iodine Deficiency Disorders (IDD). • Expressed concern that population groups with Graves’ disease would have their dietary choices severely restricted by mandatory fortification. • Believes that mandatory fortification is not an effective mechanism to reach those with Coeliac disease who are required to restrict gluten containing cereals, notably wheat which is the primary ingredient of bread and biscuits. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Iodised salt is recognised locally and internationally as an effective source of iodine. <p><i>Dietary modelling</i></p>

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	<ul style="list-style-type: none"> • Included data which showed that consumers are choosing to select iodised salt over non-iodised salt with no growth in total discretionary salt volumes. • Noted that estimated percentages for discretionary salt used in the Draft Assessment Report are incorrect and should be updated and the data remodelled to assess the impact on dietary exposure and upper limits (17.7% instead of 15% in Australia and 74.5% instead of 50% in New Zealand). <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Notes that there would be no alternatives to leavened bread for consumers who do not wish to consume iodine fortified bread under mandatory fortification. • Voluntary MoU retains consumer choice across food categories – especially through small retail businesses such as independent bakeries. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Encourages FSANZ to review current prohibitions on making iodine content claims on food labels. Under current prohibitions in Standard 1.3.2 - Vitamins and minerals and Standard 1.1A.2 - Transitional Standard for Health Claims, iodine claims are either prohibited or severely restricted on products (Iodine content claims are currently permitted under Standard 1.3.2 when certain criteria are met, but are limited to cereal, dairy, fruit and vegetable juice and analogue products) • Supports provisions to allow content claims on a wider range of products containing at least 10% of the RDI for iodine. • Believes allowing manufacturers who voluntarily add iodised salt to products to promote the awareness of the importance of iodine on their products may result in greater industry adoption of voluntary addition of iodine to manufactured foods. • Believes that iodised salt should be permitted to carry iodine content claims to enable consumers to monitor their iodine intake via their use of discretionary salt and to obtain information from the label. (Salt manufacturers are prohibited from making any claims regarding iodine content in packaging thereby preventing assistance with communication, education and awareness messages on salt products) which are a common • Requests FSANZ pre-approve an iodine health claim based on cause and effect evidence used as the basis for recommending mandatory fortification. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Expressed concern about restrictions and complexity for businesses that supply local biscuits to both domestic and export countries where the use of iodised salt is not permitted. • Voluntary solution would remove any potential trade restrictions for both import and export markets. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Believes mandatory fortification can create trade restrictions for imported foods therefore triggering WTO notification. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Strongly supports retaining the current voluntary permission for iodised salt as an alternative, effective and economical source of iodine. • Believes removal of voluntary permission would further restrict consumer choice and iodine intake and create consumer confusion by removing a well established source of iodine in the food supply.

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	<ul style="list-style-type: none"> • Currently, 74.5% of New Zealand discretionary salt is iodised. Removal of this source of iodine is contrary to health outcome seeking to increase iodine status. • Noted that the NZ dietary guideline would need to be changed if voluntary permission is removed. • Noted that iodised salt is a source of iodine for those with celiac disease. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Believes 12 month implementation period is insufficient due to the volume of labelling changes that would be required and the ability of the label change and printing industries to accommodate these demands within the timeframe. • Recommends a minimum implementation period of 24 months. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports importance of communication and education strategy to raise awareness and understanding of the need to increase iodine status of the population. • Believes that allowing industry to communicate the benefits associated with iodine on food labels would enable labels to be used effectively as part of the education and communication strategy.
<p>Cheetham Salt Australia Wally Rickard</p>	<p>Support Option 2 – Mandatory fortification</p> <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Encourage FSANZ to discuss the use of descriptors such as ‘natural food’ and ‘organic foods’ with The Australian Competition and Consumer Commission and the New Zealand Commerce Commission to clarify the status of foods using iodised salt with regards to fair trading labelling requirements. • Believes it is an overreaction to remove such descriptors because: <ul style="list-style-type: none"> - fortification with iodine is a mandatory requirement; - fortification benefits public health; and - products will contain only a minute amount of iodine. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Suggests voluntary permission not be removed. It would be a backward step in reducing iodine deficiency in the community. • It would prevent manufacturers from using iodised salt in any other food product. • Might be an impediment to manufacturers who co-process multiple food items with a single supply of salt. • Voluntary permission will allow manufacturers to add iodised salt to other processed foods, which could increase iodine in commercial foods.
<p>Complementary Healthcare Council of Australia Australia Allan Crosthwaite</p>	<p>Appears to support Option 2 – Preferred approach for mandatory iodine fortification. (Provides in principle support to the Draft Assessment Report). Peak industry body representing therapeutic product sponsors, raw material suppliers, manufacturers, food manufacturers, wholesalers, distributors, Importers and retailers of complementary healthcare and healthfood products. Also represents consultants, practitioner associations, practitioners and consumers.</p> <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports monitoring as an essential component of mandatory fortification. • Monitoring program should include tracking of changes in iodine supplement usage

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	<p>and consumer attitudes to supplementation as well as fortified foods.</p> <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Considers supplement usage to be an integral message when raising awareness of fortification. • Supports communication and education, particularly to those target groups who will not increase their iodine levels through the consumption of bread etc. This is particularly important in light of other contradictory messages to reduce salt and refined carbohydrates in the diet. • The Complementary Healthcare industry would welcome a collaborative relationship with FSANZ to ensure that public awareness is raised regarding the need for supplement use by at risk individuals and groups to achieve an optimum lifestyle in conjunction with a healthy diet.
<p>Dairy Australia Australia Jacinta Orr</p>	<p>Supports neither Option</p> <p>Supports extending the voluntary fortification of foods with iodine, supported by region-specific public education programs as most effective strategy to address regional suboptimal iodine status in Australia.</p> <p>Mandatory fortification may result in unnecessary consumption of iodine across large areas of Australia. Baseline data is not sufficiently robust to support mandatory fortification. With more thorough investigation of the issue it may be that quite different strategies are more appropriate to provide a safe level of dietary intake of iodine for the Australian population.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Acknowledges that increased iodine intakes will improve the iodine status of deficient populations. • However the current prevalence of iodine deficiency in Australia indicates a non-uniform distribution of iodine insufficiency across Australia. • Before mandatory iodine fortification is considered there should be a broader study of all population groups in all regions of Australia. • It appears that iodine fortification is not necessary in Western Australia or Queensland and the need in the Northern Territory is undetermined. • Mandatory fortification would apply to the entire population, rather than targeting problem areas. The iodine studies FSANZ cites have been done on ‘at risk’ sections of the population, such as schoolchildren and pregnant women. • Re-emergence of iodine insufficiency in some areas of Australia coincides with changes in practices in cleaning of milking equipment. A large number of iodophors were used as teat disinfectants in the dairy industry but tighter controls were introduced in the 1970s. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Welcomes the suggestion that all dietary sources of iodine should be monitored. • Believes adequate monitoring is fundamental and important for risk management and to inform future policy and strongly supports monitoring as part of food fortification. • The Draft Assessment provides a good theoretical outline of the important components of a monitoring program including the need for baseline data. • There is insufficient information regarding which agencies would be responsible for what and about review periods. • It is important to monitor iodine intake because there may be industry changes that

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	<p>effect iodine intake similar to those of the dairy industry in the 1970s.</p> <ul style="list-style-type: none"> • A lack of regular monitoring has hampered the appropriate assessment of the impact of iodine fortification in other countries. <p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • The dairy industry is interested in voluntary fortification of dairy foods with iodine however fortifying may pose technical difficulties for some dairy foods. • Extending voluntary fortification would encourage the industry to invest in research and overcome some of the technical difficulties. • The dairy uses salt in cheese production but would not choose to use iodised salt in cheese as it might be a barrier to trade. • The Australian Dietary Guidelines encourage Australians to reduce their intake of salt. While increased attention on the status of iodine is important, need to ensure that this does not obstruct the need for a lower salt intake. • Removing salt iodisation permissions would provide greater certainty in estimating salt intake. • Dairy Australia does not believe that this is an adequate reason to decrease the variety of food in which iodine is available. Reducing the variety of food sources of a nutrient is ill advised. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Public education, particularly in iodine deficient areas, would allow consumers to choose iodised products according to their needs. • Supports continuous national education strategies that use a variety of mediums appropriate to the target audience. • Dairy Australia distributes educational material as part of their Nutrition Program. Resources could emphasise that iodine is a natural constituent of dairy foods and support any government nutrition education initiatives.
<p>Dominion Salt Limited New Zealand Brett Hobson</p>	<p>Does not directly state support for mandatory fortification, but is willing to work with FSANZ to implement the proposal.</p> <p>Commends FSANZ’s work on the proposal which it hopes will address this concerning health issue for New Zealanders.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Is willing to work with FSANZ to implement the proposal. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Recommends clarification of definitions for cereal product salt and whether coatings and sprinkles will require iodisation as well as salt used in the primary dough mix. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Notes reduction of consumer choice with mandatory iodine fortification. • Raises concern regarding organic status of ‘organic’ bread which contain iodised salt. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Considers 12-month transition period to be workable.

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	<ul style="list-style-type: none"> • Supports a single level of iodine input for discretionary (Table salt) and cereal salt to avoid complexity and confusion in manufacturing and complicating monitoring and enforcement. • Support iodine fortification level of 20-45 mg/kg salt. • Identifies technical difficulties with iodisation of coarse grain salts used for toppings and coatings e.g. on focaccia bread. • Also notes a reduced choice for cereal producers as it will not be practical to supply full range of salt grades in an iodised version – there may be 2-3 iodised grades vs. the +10 currently available. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Support monitoring across several fronts e.g. is willing to supply data on iodised salt usage updates for New Zealand produced salt (proposed on an annual basis.)
<p>Flour Millers Council of Australia Australia Graeme Lukey</p>	<p>Appears to Support Option 1 – Maintaining the <i>status quo</i> Represents companies engaged in flour milling in Australia Does NOT support Option 2. <i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Acknowledges that substitution of non-iodised salt with iodised salt can raise the dietary intake of iodine and therefore address iodine deficiency in affected populations. • States that they ‘do not accept that mandatory fortification is the most effective public health strategy to address a health problem not demonstrated to be shared by the population at large’. • Believes the Tasmanian trial using bread with iodised salt demonstrates that specific strategies developed with the food industry can meet objectives for target populations. • Expressed concern about mandatory fortification of the food supply, impacting on the whole population, when only certain segments of the population are identified to be at risk e.g. Tasmania and New Zealand are of particular concern and warrant special attention. • Raised awareness about the discontinuation of a previous program of iodine supplementation in Tasmania due to high rates of thyrotoxicosis (Connolly RJ et al. (1977) Increase in thyrotoxicosis in endemic goitre area after iodation of bread. <i>Lancet</i>). <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Acknowledges reasons for iodine deficiency are not fully understood. • Supports government research to make best decision to determine effective public health policy e.g. whether by modifying agricultural practice or using processed food. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Supports availability of iodised salt and products manufactured with iodised salt so consumers can consume or avoid as they choose. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Raised concern that discontinuation of previous iodine supplementation in Tasmania demonstrates that Australian government has not met its responsibility to public health in the past. • Upholds the ‘Ministerial Council Policy Guideline for Fortification of food with vitamins and minerals’ that requires that ‘any agreement to require fortification

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	<p>should require that it be monitored and formally reviewed to assess the effectiveness of and continued need for mandating of fortification?.</p> <ul style="list-style-type: none"> • Suggests that any legislation for mandatory fortification should include a sunset clause to provide for review of effectiveness of the intended initiative based on formal monitoring of dietary intakes and health effects. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Ongoing monitoring programs of dietary intake patterns aligned to health trends is a key element for creditable public health policy. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Considers ongoing public communication and education initiatives through schools, medical practitioners and consumers to enable informed decision making is a key element for creditable public health policy.
<p>The Food Technology Association of Australia (Formerly the Food Technology Association Victoria) David Gill</p>	<p>Accepts Option 2 – Mandatory fortification Made no further comment</p>
<p>Food and Beverage Importers Australia Australia Tony Beaver</p>	<p>Supports Option 1 – <i>status quo</i> Believes the case for mandatory fortification has not been clearly established. Considers alternatives to mandatory fortification should be investigated first.</p> <p><i>Trade</i></p> <ul style="list-style-type: none"> • Biscuits are imported in significant quantities into Australia (excluding imports from New Zealand \$130 million in 2003/4 and \$140 million in 2004/5). • The major sources were the United Kingdom (12%), China (12%), and the United States (10%). • It would be unlikely that any imported biscuits would currently comply with the Standard. • In terms of world trade, Australia is not a major importer of cereal products (importing less than 1%). It is unlikely that products would be reformulated for the Australian market. Although there may be some imports, where the brand is owned by the importer which could be reformulated if an iodine source could be found. • The impact of the proposal would be to significantly curtail trade in biscuits and would lead to the majority of imported biscuits being withdrawn from the Australian market. • It would be simpler to adopt a voluntary program that would encourage customers to use iodised salt and manufacturers to replace salt in their products with iodised salt. • An education program to raise awareness of the importance of iodine and problems associated with iodine deficiency could be initiated. <ul style="list-style-type: none"> • Australia already has a mandatory fortification for thiamine and before

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	<p>implementing another mandatory fortification measure there should be an evaluation of thiamine fortification to ascertain its effectiveness, benefits and costs.</p> <ul style="list-style-type: none"> • A 12 month transition period is far too short a period for industry to prepare for the change.
<p>George Weston Foods Limited (GWF) Australia and New Zealand Fiona Fleming</p>	<p>Fully supports Modified Option 1 – Maintaining the <i>status quo</i> plus (as per the AFGC's recommendation)</p> <ul style="list-style-type: none"> • Recommends an agreed MoU with industry to voluntarily use iodised salt in food manufacture; and education campaign that encourages consumers to seek out products fortified with iodine. <p>Does NOT support Option 2 as it:</p> <ul style="list-style-type: none"> • fails to meet the policy requirements for mandatory fortification; • removes consumer choice from those products; • fails to be an effective solution for those with coeliac disease and/or those who are wheat intolerant, or who do not consume wheat based products; • creates unjustified trade restrictions for imported foods causing potential WTO action; and • is not mandatory in most countries where the salt has been adopted as the delivery vehicle for iodine. <p>Supports AFGC's recommendation for a modified option for voluntary fortification involving MoUs with industry as it:</p> <ul style="list-style-type: none"> • has evidence of effectiveness in the Australian market; • retains consumer choice; • has no WTO implications; • through use in non-wheat based products, it allows those with coeliac disease to be reached; • has been shown to be effective internationally; <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Expresses concern that mandatory fortification will fail to reach all parts of the population – e.g. those people who avoid wheat based products due to wheat intolerance or coeliac disease. • Majority of international iodine fortification programs use voluntary fortification rather than mandatory fortification. • Notes the success of the Tasmanian experience of developing MoUs with industry, in increasing the iodine status and its broad acceptance by the general population. With 80% of bread currently fortified, consumers were offered choice in relation to bread and other products. • Believes that a similar approach could be adopted Australia wide and in New Zealand. This would be consistent with Ministerial Policy guidelines which require assessment of alternative strategies prior to choosing mandatory fortification. • Suggested strategies to improve the iodine status of Tasmania include widening the range of foods under MoU to include cereals and biscuits and/or increasing the range of iodised salt included in the products. <ul style="list-style-type: none"> • Questions why industry was not consulted prior to selection of two FSANZ

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	<p>scenarios (cereal based foods and processed foods).</p> <ul style="list-style-type: none"> • Questions the effectiveness of the proposal to improve the iodine status of women of child bearing age in South Eastern Australia because they will still require supplementation. • Acknowledges that the use of iodised salt in place of non-iodised salt can be an effective strategy to address iodine deficiency in affected populations. • Noted health concerns related to iodine intake e.g. individuals who may have a pre-existing thyroid condition or who are sensitive to iodine even within recommended range and potential product liability issues for manufacturers. • Questions the need to subject the whole Australian and New Zealand populations to mandatory fortification of staple food products (Queensland and WA had adequate iodine status). • Concerned that some elderly patients could experience iodine induced hyperthyroidism for up to 10 years when there are no health benefits for this age group. • Concerned that FSANZ is not able to accurately assess the outcomes of the mandatory fortification program in WA and Qld and thus are at an increased risk of iodine excess. • Questions inconsistent conflicting statements in the Draft Assessment Report in relation to the association between iodine intake and thyroid cancer. • Notes that some groups will exceed the UL. • Concerned about the availability of food vehicles for Indigenous Australians. • Recommends access to non-iodised products for those at risk of adverse health risks e.g. those with hyperthyroidism and young children. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Questions why milk and milk products have not been used as a possible food vehicle given they are major contributors to iodine intake. • Questions the use of 10 year old data for selecting the food vehicle. • Concerned that using cereal-based foods fails to reach those suffering from celiac disease (prevalence of one in 100 in Australia and 1 in 84 in New Zealand) <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Questions the reliability of the NNS as a data source for dietary modelling. • Believes FSANZ's dietary modelling has ignored the contribution of milk to dietary intakes and has potentially overestimated the contribution of salt from bread (compared with GWF data - average proportion of salt in GWF products is 0.7 - 1.25% compared with 1.36% used by FSANZ). • FSANZ should obtain up to date information on these products from manufacturers prior to undertaking dietary modelling. • Questions whether FSANZ used 2006 bread consumption data in the dietary modelling. • As one of the main target groups for mandatory fortification, it is not adequate to use theoretical diets to assess the dietary intakes of Australian and New Zealand children. • Questions assumptions used in dietary modelling about consumer behaviour. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Believes that there is a lack of consumer choice within the product categories

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	<p>proposed for fortification.</p> <ul style="list-style-type: none"> • Those with pre-existing thyroid conditions advised to limit their iodine intake may need to avoid staple products if there are no non-iodised options available. • GWF undertook consumer research (n = 1310) to determine community attitudes towards food fortification in Australia. Results indicated that the Australian population is opposed to compulsory fortification of food and want to be given choice. Key findings include: <ul style="list-style-type: none"> - 84% of respondents preferred voluntary fortification to compulsory fortification; and - 62% of respondents were concerned that compulsory fortification shows a trend towards making staple foods, such as bread, act like medicine. • Believes the proposal does not meet FSANZ's primary objective to ensure 'provision of adequate information to enable consumers to make informed choices' as consumers are not made aware of the possibility of iodine-induced hyperthyroidism and the lack of availability of non-iodised versions of the selected food vehicles. • Does not consider salt-free bread or breakfast cereals to be a viable alternative for those wishing to avoid fortified versions. • Believes MoU with industry will provide more consumer choice. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Labelling requirements will not provide consumers with amounts of added iodine. • Questions FSANZ calculations used to determine whether bread would qualify for a 'source' claim. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Expressed concern that the proposal may create artificial barriers to imported products being able to compete fairly in the Australian market. • Recommend consulting the Dept. of Foreign Affairs and Trade to ensure that the mandatory fortification proposal is not in breach of Australia's obligations under the WTO. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> • Supported retaining the current permission for iodised salt for discretionary use, promoting substitution of iodised salt for non-iodised salt for such use. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Considers removal of voluntary permission of salt iodisation is for FSANZ to determine through dietary modelling, not for industry. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Supports a transition period of two years due to demand for advertising agencies and printers. • Two year implementation would also allow time to implement baseline monitoring and would minimise cost to industry for packaging changes. • Align labelling changes with other changes such as health claims, folic acid fortification and nutrient reference values. <ul style="list-style-type: none"> • Recommends FSANZ consult with industry prior to developing an implementation guide which should be finalised well before any changes to the

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	<p>Code come into effect.</p> <p><i>Use of salt in non-mandated foods</i></p> <ul style="list-style-type: none"> • GWF will provide this information as part of the MoU proposal. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> • Believes the current mandatory proposal is NOT consistent with the Policy Guideline. The proposal is based on 11 years old nutrition data and there is no acceptable monitoring program in place. • Alternative public health strategies such as voluntary fortification and education strategies have not been properly assessed. • Believes voluntary fortification will meet policy guidelines more effectively than mandatory fortification. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Notes monitoring and evaluation is a fundamental component of any mandatory fortification system, especially for risk of IHH as well as effectiveness of iodine deficiency. • Notes that the monitoring system is still to be negotiated with other health and regulatory agencies in Australia and New Zealand, so there is no commitment in place and not a good track record with thiamine or voluntary folic acid fortification. • Cites reference for frequency and complications of iodine induced hyperthyroidism as a result of poor monitoring of salt iodine concentration which permits uneven rations of iodine, and inadequate medical attention which delays diagnosis and treatment. (Dunn et al 1998a) • Refers to WHO reference (WHO 2001) which raises questions to be addressed by a monitoring program including salt iodisation, whether the target population is being reached, impact on iodine status and IDD as a public health problem. • Notes negative outcomes observed in overseas countries with limited monitoring. (Delange et al 2001) • Considers monitoring is often neglected in favour of implementation. • Supports developing and maintaining a trans Tasman monitoring program for urinary iodine status in the target population to estimate prevalence of IDD. • Recommends also monitor use of discretionary salt. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports developing and maintaining an industry awareness campaign of the need to use iodised salt in food manufacture. • Supports developing and maintaining a consumer education campaign aimed at the target population about the importance of iodine in the diet. • Education needs to be targeted on individual needs, and depending on whether an area is iodine deficient or iodine replete. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • FSANZ's proposal cannot be justified as cost benefit analysis could not conclude there is a net benefit associated with mandatory fortification. • Notes the Cost Benefit Analysis prepared by Access Economics suggests exploring an alternative proposal which embraces all of the potential benefits or finding another vehicle which better targets those in need, including those in

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	<p>geographic areas of Australia where iodine was identified.</p> <ul style="list-style-type: none"> • Concerned about a rise in bread prices as a result of iodine and folic acid fortification and GWF is willing to provide confidential information to support these statements. • Concerned that GWF research shows that consumers may choose to avoid fortified cereal based products due to opposition to fortification. • Suggests perhaps industry should be directly compensated for costs incurred. • Notes the short time given (one week) to provide estimates on cost to industry to Access Economics. • Notes no cost is quantified for reduced consumer choice of products or cost to coeliacs who will have limited access to cereal based products. • Should include costs to governments of anti-discrimination action taken by those adversely affected by the decision to mandate the addition of iodine to bread. • The cost of potential health risks to identified vulnerable groups have not been included which brings into question the integrity of the report. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • Concerned regarding the short consultation period (1 month). • Notes that two major proposals affecting the bread industry were undertaken close together with shortened consultation times. • The objective to reduce the prevalence of iodine deficiency lacks specificity in stating the size and time period for the reduction. • Expresses concern that the issues raised in the Summary of Submissions for the Initial Assessment Report have not been adequately addressed in the Draft Assessment, namely: <ul style="list-style-type: none"> - success of current fortification strategies to increase iodine intake; and - lack of consumer choice associated with mandatory fortification.
<p>Go Grains and Nutrition Ltd Australia Trish Griffiths</p>	<p>Supports Modified Option 1</p> <ul style="list-style-type: none"> • Supports extending voluntary permissions for iodine fortification for a wider range of foods together with target strategies for populations in areas of deficiency. • Accepts the use of iodised salt in place of non-iodised salt can be an effective strategy to address iodine deficiency but does not believe mandatory fortification of all bread, breakfast cereals and biscuits is consistent with the Policy Guideline. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • The food vehicle assumes bread is a staple food widely consumed by the target population. Questions whether the 1995 NNS data reflects the type of food eaten in 2006. • Limited data available suggests bread may not be the best vehicle to reach women. Notes a Newspoll survey in 2006 found women of childbearing age ate only 11 slices of bread a week with 21% eating no bread at all. Refers to several Go Grains surveys indicating negative attitudes to bread especially amongst women. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Long term safety: considers it essential attention is given to long-term risk of unintentional adverse effects on other population groups, especially those with hypothyroidism who may be sensitive to sudden increases in iodine intake.

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	<p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Believes mandatory fortification compromises consumer choice and that salt free products are not acceptable choices. <p><i>Implementation</i></p> <ul style="list-style-type: none"> Technical issues: notes there is some evidence iodising salt increases the oxidising potential, increasing the risk of rancidity. This risk needs to be clarified to the satisfaction of industry. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> Considers data is lacking to demonstrate mandatory fortification will deliver a sufficient amount of iodine to the target population. There is not a system in place to monitor effectiveness. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> An appropriate monitoring and surveillance system needs to be implemented prior to any change in fortification practice in Australia. There is no indication of a commitment to monitoring and enforcement and the track record is not encouraging e.g. thiamin and voluntary folate fortification. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> Concerned the CBA does not include costs of establishing an ongoing monitoring system. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> Considers the proposal is based on out dated consumption data and this is not an acceptable basis to make a decision about mandatory fortification for a whole population. Notes iodine status of pregnant and breastfeeding women is lacking – baseline data is needed for a minimum of 12 months prior to implementation to assess the effectiveness. Considers the monitoring strategy as proposed is unlikely to be achievable in terms of budget and timeframe, with reliance on the new NNS. <p><i>Other issues</i></p> <ul style="list-style-type: none"> Requests clarification of the definition of biscuits and bread – e.g. it is not clear whether specialty bread such as organic and gluten free are included in the proposal. If all bread are included the issues and costs will need to be addressed by other industries e.g. the rice industry is substantially different to the wheat industry.
<p>Heinz Australia and Heinz Wattie's Australia and New Zealand Lisa Warren</p>	<p>Supports Modified Option 1</p> <ul style="list-style-type: none"> Continues to favour extension of permissions for voluntary iodine fortification as well as promotion of voluntary options to increase industry uptake. Requests that mandatory fortification of iodine does not include Standard 2.9.2 - Foods for Infants, where an infant is determined as a person up to the age of 12 months. <p><i>Safety and efficacy/food vehicle</i></p> <ul style="list-style-type: none"> Notes commercially prepared infant foods are low in sodium. Questions the usefulness of mandatory iodine fortification of foods within Standard 2.9.2 due to the extremely low quantities of salt permitted. The exception is teething rusks

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	<p>where salt is added to obtain a hard texture.</p> <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> Notes that although the Draft Assessment refers to the need to increase iodine intakes of infants, the data only refers to young children over the age of one year.
<p>Kraft Foods Limited Australia Allan Poynton</p>	<p>Supports Option 1 – status quo</p> <ul style="list-style-type: none"> Acknowledge iodine deficiency disorders and accepts increasing iodine intake can alleviate these. Does not agree that the information provided constitutes sufficient grounds for mandatory fortification. Is prepared to discuss a MoU whereby the majority of biscuits sold in Australia could be manufactured with iodised salt. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Suggests identification of subsets of the population would help to identify appropriate vehicles for fortification other than discretionary salt and salt for bread making. Believes bread would appear to be the most suitable vehicle. Salt intake via bread would be higher than biscuits. Bread is more uniform product and can be tailored for regional / local markets. Notes processed foods are more likely to be imported and exported with trade issues. Does not consider biscuits to be a useful carrier for iodine for several reasons: <ul style="list-style-type: none"> salt levels are variable, delivery would not be evenly distributed; the salt level in biscuits is quite low; the consumption of biscuits is far less uniform than bread across the population; and peaks and troughs in iodine intake from biscuits would put people on iodine controlled diets most at risk. If FSANZ continues with fortification of biscuits, then a MoU rather than mandatory fortification would be a practical mechanism, combined with education. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerned about those in the population on iodine controlled diets - providing a varied diet will become even more challenging if staple foods are iodised. <p><i>Trade</i></p> <ul style="list-style-type: none"> Notes all biscuits Kraft Foods Ltd. sells in Australia are imported from Kraft locations overseas which raises practical issues with compliance to mandatory fortification, with the majority from China. China sources salt from the Chinese government only and this is iodised at a rate of 20-35 mg/kg. Salt iodised at any other level is not able to be obtained. The Australian market is quite small and other countries do not require iodised salt in biscuits. This would add complexity and costs to manage. <ul style="list-style-type: none"> As Australia is a small percentage of the total, there is likely to be non compliance with small volumes. Importers of these biscuits would consider mandating the use of iodised salt for Australian biscuits to be a barrier to trade.

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	<ul style="list-style-type: none"> • Japan will not allow iodised salt – Japan is a profitable market and important for Australia’s balance of trade. • Estimates approximately 25% of all biscuits sold in Australia are imported from different countries with differing requirements. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • In line with providing choice, voluntary permissions should be allowed to stay unless there is shown to be an issue. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Considers it is the responsibility of Governments, not industry to inform people they need to increase their iodine intake. Considers the public respond more positively to information that an issue can be addressed through food consumption, rather than through authorities medicating through food. • Believes food companies cannot and should not lead an awareness campaign. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Notes the data indicates deficiencies in parts of Australia and NZ. However, little evidence has been provided of subsets of the population at most risk. • Considers the data does not seem to support universal mandatory fortification so does not appear to comply with the FSANZ requirement for risk based analysis.
<p>NZ Association of Bakers Inc New Zealand Marcia Dunnett</p>	<p>Does not support Option 2 – provides an alternative proposal</p> <ul style="list-style-type: none"> • Remains fundamentally opposed to mandatory fortification of all bread with any additives. • Considers mandatory fortification of all bread is an excessive response. <p>Recommends an alternative proposal:</p> <ul style="list-style-type: none"> • fortify a significant proportion of a range of bread (e.g. all but the heavy health segment) so that an element of consumer choice remains; and • Actively promote through a government funded and industry supported education campaign (point of sale material and labelling) on the benefits of bread containing iodised salt. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Refers to consumer research which showed NZ consumers are strongly opposed to mandatory fortification with any additive, and considered mandatory fortification of bread would alter their view of bread as a wholesome health product. • There are sufficient differences between NZ and Australia to warrant the implementation of the alternative approach submitted which maintains consumer choice while the vast majority of bread consumed, particularly by children, would be fortified. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Export risk: consider it is not clear in the proposal that iodised salt will not be required to be used in export products unless it was a requirement of the final destination. Requests this be clearly outlined in the final report. <p><i>Implementation/ cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Believes it will be extremely difficult to implement the changes for both folate and iodine in a 12 month period. • Considers costs outlined in the proposal are grossly underestimated and that the 12

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	<p>month timeframe would require significant write-off of packaging.</p> <ul style="list-style-type: none"> Believes clarification of these costs and timeframe are essential before the final recommendation is put forward. Notes the proposed alternative would require bakeries that produce heavy health bread to carry two salt lines but that this is not regarded as a major issue. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Stresses the need for independent validation from the health Authorities to ensure consumer buy-in. Questions the nature of the educational campaign – asks will it identify that changes have been instigated by FSANZ rather than the baking industry?
<p>New Zealand Food and Grocery Council New Zealand Brenda Cutress</p>	<p>Appears to support Option 1 – Maintaining the <i>status quo</i> plus MoUs with industry as per Tasmania, providing it is accompanied by effective education.</p> <p>Does NOT support Option 2 – Preferred approach for mandatory iodine fortification.</p> <ul style="list-style-type: none"> The Draft Assessment should give similar consideration other alternatives to mandatory fortification. These other alternative strategies would be more effective in achieving the outcome. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Does not support mandatory approach which should only be used as a last resort if other approaches fail and even then there may be reasons why a mandatory approach may not be acceptable. Believes that the proposal is not based on best evidence (from the information included in the Draft Assessment on experience from overseas countries which have used mandatory and voluntary fortification). Argues that a voluntary approach is the most effective strategy and preferable, and cites Tasmania as a successful program. In Denmark, mandatory fortification resulted in a tendency to increase hyperthyroidism, albeit of an acceptable magnitude. Supports voluntary fortification with selection of a range of products which meet the objective of raising the iodine status to the desired level to overcome deficiencies while ensuring the risks of overexposure do not occur. Recognises that iodised salt (beyond current permissions) will assist in alleviating the current concerns of a re-emergence of mild to moderate iodine deficiency resulting from inadequate iodine intake in New Zealand and parts of Australia <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> Concerned that percentage of salt in final product is not accurate. New Zealand Bakers Association notes that the percentage of salt in the majority of bread is 1.75 – 2% salt on cereal weight therefore the percentage of salt in the final product is closer to 1% rather than 1.36% as included in the Draft Report. Notes that not all sodium on the label is from salt (some may be sodium bicarbonate) – resulting in an overestimation of the contribution of iodised salt in the dietary modelling. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Mandatory fortification will result in a lack of consumer choice. Believes FSANZ downplays results of NZ studies which have shown that

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	<p>consumers do not approve of mandatory fortification even where there are health benefits.</p> <ul style="list-style-type: none"> • There is an extremely limited range of salt-free breakfast cereals and unleavened bread available in NZ meaning there is no real choice for consumers who wish to avoid food containing iodised salt. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Considers FSANZ has not given sufficient regard to the impact of mandatory fortification of cereal based foods on trade, especially in New Zealand which is a larger importer of biscuits and exporter of cereal-based products. • Supports exemption for imports from mandatory fortification to avoid different ranges of iodine levels permitted in salt in overseas countries. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Notes that 12 month implementation is insufficient for some companies which build up stocks of labels for two – three years. • Believes cost of label changes has been underestimated (can cost between \$50,000 for a smaller company with approximately 50SKUs to over \$1.5million for a large company with many hundreds of SKUs). • Recommend coordinating label changes with other changes to the Food Standards Code to contain costs. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Considers monitoring the key sources of dietary iodine on iodine status in the target and non-target populations to be an essential and fundamental component of fortification whether mandatory or voluntary fortification is adopted. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports a campaign to encourage use of iodised discretionary salt (where used) and selection of processed products that contain iodised rather than non-iodised salt. The majority of New Zealand consumers would be unaware of NZ Health and Nutrition guidelines that emphasise the desirability of using iodised salt (when used). • Also supports the importance of raising awareness with the industry of using iodised salt. <p><i>Other issues –short time period</i></p> <ul style="list-style-type: none"> • Short time for public consultation has precluded more detailed import/export statistics or the iodine permissions in countries of import and export (FGC will submit this information at a later date). <p><i>Other issues – natural foods</i></p> <ul style="list-style-type: none"> • Considers natural foods are disadvantaged under the current mandatory fortification proposal as they would not be able to claim ‘natural’ in New Zealand under the Fair Trading Act. Seeks an exemption if this concern is confirmed by the NZ Commerce Commission.
<p>Salt Institute USA Richard Hanneman</p>	<p>Supports Option 2 – Mandatory iodine fortification</p> <ul style="list-style-type: none"> • Highly supportive of FSANZ approach using iodised salt as the vehicle and extending its use in measured steps - consistent with overseas experiences. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports addition of iodised salt to bread, breakfast cereals and biscuits and

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	<p>extending use in measured steps if inadequate improvement in iodine status.</p> <ul style="list-style-type: none"> • Consumers preparing less food at home, using more processed foods and restaurant or takeaway foods. • Notes the recent decline in packaged salt sales and consumers not choosing <i>iodised</i> table salt. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Dismisses the implications for trading with Japan of introducing mandatory fortification as domestic producers will continue to supply unfortified salt to most of the food processing industry. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports monitoring to determine need to extend use of iodised salt to other foods or to increase iodine added to salt if current intervention is inadequate. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Believes the proposal would be strengthened by including a statement that the government is committed to protecting mental development of next generation through iodisation of salt and this is first step to carry that proposal into effect. • Supports public education campaign, especially in schools. • Supports education program targeting pregnant women advising the importance of their iodine intake for the mental development of their developing child. <p><i>Technical issues</i></p> <ul style="list-style-type: none"> • No technical issues for salt producers to adjust fortification level. <p><i>Other issues</i></p> <ul style="list-style-type: none"> • The declining iodine nutrition status of Australians and New Zealanders parallels that of Americans and Canadians.
<p>Soil & Health Association of New Zealand New Zealand Steffan Browning</p>	<p>Appears to support Modified Option 1 – Maintaining the <i>status quo</i></p> <p>Does not support Option 2 – Preferred approach is mandatory iodine fortification and recommends an exemption for organic foods if mandatory iodine fortification is adopted.</p> <p>Represents companies producing organic food and organic farming in NZ.</p> <p>States their motto is <i>‘Healthy soil, healthy food, healthy people’</i></p> <p>‘An exemption would allow the organic producers to continue exploring genetic material and growing methods that deliver ‘genuine’ organic whole foods and will also give consumers a choice.’</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Recommends an exemption for certified organic producers and processors in the event that mandatory fortification with iodine is adopted. • Does not support mass medication. <ul style="list-style-type: none"> • Expressed concern that components such as soy products and fluoride in the contemporary diet may be factors in the rise in iodine deficiency. • Acknowledges the Draft Assessment finding that pregnant and breastfeeding women in Australia and New Zealand may require daily iodine supplements. <p><i>Consumer choice</i></p>

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	<ul style="list-style-type: none"> • Supports informed and fair consumer choice. • States that organic consumers prefer a solution to the cause rather than a focus on the treatment of symptoms. • States that in the event of a need for supplementation, natural products as ingredients are preferred e.g. seaweeds and certified organic kelp are used by organic consumers as a natural source of iodine. • Acknowledges the high level of nutritional and health awareness of organic consumers. • Expresses concern that fortification with any synthetic additive is contrary to the ideals of the organic consumers and believes mandatory fortification will reduce choice for those wanting to avoid additives. • Considers that broader consumer choice than unleavened bread and a few cereals are appropriate as choices in the Draft Assessment are not really choices. • Notes that current voluntary fortification requirements allow consumer choice and fair trade as long as clear labelling is present. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Advises that organic production and processing is based on minimum alteration or addition to food composition. Organic processing standards restrict additives in bread. • Expressed concern that the standard for organic bread would have to be changed to something less than consumer expectations if mandatory fortification is introduced. • Noted the requirement for food labelling and promotional claims to be in accordance with the fair trading legislation of Australia and New Zealand and that FSANZ is clarifying the use of descriptors such as ‘natural food’ and ‘organic foods’ with the ACCC and the NZCC in relation to foods using iodised salt. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Expresses concern that mandatory fortification requirements disadvantages small commercial operations e.g. small domestic market focussed bakeries may have difficulty complying with mandatory fortification requirements. They consider that these bakeries and access to markets requiring no added iodine need to be permitted in the interest of fair trade. An exemption for organic foods would reduce the level of commercial disadvantage. • Believes an appropriate descriptor or definition of ‘organic’ produce or goods is likely to be ‘that which has been produced according to either a ‘National’ organic standard, or is organically certified and that the proposed 12 month transition period is sufficient time for that mechanism to be established. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • If an exemption from fortification is granted for organic foods, monitoring will show any need for increased education or recommendations required for organic consumer groups. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports an education program through the health system, including information on iodine sources and inhibitors, with optional supplementation a possibility.

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<p>Uncle Toby's Australia Kirsten Grinter</p>	<p>Supports Modified Option 1 – Maintaining the status quo plus MoUs with industry</p> <p>Supports development of a comprehensive voluntary program - including development of a MoU, an industry awareness program and consumer education program.</p> <p>Considers that extending the permissions for iodine fortification to a wider range of foods in conjunction with industry awareness and consumer education program will provide consumers with a greater product choice to achieve an appropriate amount of iodine in their diet to meet the health objective without compromising consumer choice.</p> <p>Does not support option 2 as it :</p> <ul style="list-style-type: none"> • fails to meet the objective of being effective; • fails to meet the policy requirements for mandatory fortification; • removes consumer choice; • fails to be an effective solution for those with coeliac disease who do not consume wheat based products; • creates unjustified trade restrictions for imported food causing potential WTO issues; and • has not been shown to be effective internationally. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Prevalence of iodine deficiency in Tasmanian children fell from 21% to 10.9% following introduction of voluntary iodine fortification in Tasmania. However, the level of iodine in salt was too low to eliminate the issue altogether and the food vehicles too limited to reach the target group or perhaps the consumer education program was not sufficiently sustained. • Acknowledges the medical evidence that indicates the adverse health effects collectively referred to as iodine deficiency disorders (IDD) and accepts that increasing population iodine intake can prevent adverse health effects. • Identifies need for assessment of the long term risk of high iodine intakes across the general population, particularly in the absence of adequate data on iodine status of the Australian population. • Expresses concern that the addition of iodised salt to non-mandated foods could increase exposure of consumers to iodine. • Expresses concern regarding the risk of unintentional adverse health effects, especially in individuals who have a long history of iodine deficiency and who may respond adversely to increased intake well below the provisional maximum tolerable daily intake of 17 ug per kg body weight. • Acknowledges that NZ data indicate that 28% of children in NZ could be classified as iodine deficient while Australian National Iodine Nutrition Survey results indicated a mild deficiency in children in NSW, Vic and SA but not in WA or Queensland. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Expresses concerns that evaluation of potential food groups for iodine fortification has been based on 12 year old nutrition survey data, and significant changes to the food supply have occurred since then. The data no longer accurately reflects the types of food eaten nor provides relevant information about consumption of foods by population segments.

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	<ul style="list-style-type: none"> • There is a lack of data on current intakes of iodine in Australia and New Zealand. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • Under voluntary fortification, increased permissions can achieve the objective of preventing IDD without removing consumer choice. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Supports maintaining current permissions for iodised salt for discretionary use and promoting substitution of iodised salt for non-iodised salt. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Notes the need for a considerable lead time for manufacturers if significant proportions of manufacturers moved to iodised salt. <p><i>Use of salt in non-mandated foods</i></p> <ul style="list-style-type: none"> • Notes that small to medium-sized businesses could encounter difficulties in handling more than one supply of salt and may prefer to use one salt supply which could result in the addition of iodised salt to a wider than anticipated range of foods. • Notes that the company has the capacity to manage alternative salt supplies within the manufacturing plant, but that this would add to the burden of complexity. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports developing and maintaining a trans-Tasman monitoring program for urinary iodine status in the target population to estimate prevalence of IDD. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports development and maintenance of a comprehensive consumer education program about the importance of iodine in the diet, aimed at the target population, predominantly in NSW, Vic, SA and NZ. • Supports developing and maintaining an industry awareness campaign of the need for iodised salt in food manufacture. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Notes increased cost of moving to iodised salt is \$20 per tonne. • Notes increased cost of small impact labelling changes is approximately \$1500 per change. The cost significantly escalates depending on the number of SKUs. • Notes ongoing costs for analytical testing of iodine content of the mix, pre-mix or final product to verify the addition of iodine and the level added. <p><i>Other</i></p> <ul style="list-style-type: none"> • Expresses concern that the Scope of the Proposal does not seem to reflect the international evidence supporting mandatory fortification in Reference Material on ‘International Experience with Iodine Fortification Programs’ associated with this Proposal. • Suggests FSANZ investigate international voluntary programs to be able to implement a comprehensive successful program that will meet the public health objectives.
<p>School of Public Health University of Sydney</p>	<p>Prefers Option 2 – Mandatory fortification</p> <ul style="list-style-type: none"> • But believe the fortification of salt with iodine in bread, biscuits and breakfast cereals <i>only</i> is inadequate and will not meet daily iodine requirements. Realises that FSANZ’s decision will have a long lasting effect on the iodine status for the people and urge them to take a stand to ensure the mental and physical health of future generations are not compromised by giving into industry’s pressure for a half

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<p>Australia Mu Li</p>	<p>hearted mandatory iodine fortification.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> The Proposal is based on data which is 10 years old. Demography and eating patterns have likely changed. The traditional cereal based diet may not be as pervasive through the population as it once was. Believe that cereal based products are not the best vehicle because vulnerable groups, like women of child bearing age and young children, may not consume enough of the fortified cereal foods. Salt has been chosen globally as the main vehicle for iodine fortification because it is widely consumed by the population. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> Disappointed that the Proposal suggests lowering the iodine level in table salt. Evidence points to a deficient intake of iodine. China only lowered iodine fortification level when the population median UIE reached 300 µg/L.
<p>Australian Medical Association (AMA) Australia Josie Hill</p>	<p>Supports Option 2 – Mandatory fortification</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> While the AMA supports mandatory fortification, it does not support FSANZ’s preferred approach. <i>Universal salt iodisation</i> is the most appropriate and simplest public health approach. However, believes any progress in mandatory fortification has a potential for public benefit. The AMA supports the WHO, ICCIDD and UNICEF who advocate universal salt iodisation. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> Believes the likely costs of iodine fortification are moderate and a good investment to avoid the effects of iodine deficiency. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> On the available evidence, believes that mandatory fortification does not pose a health risk to the general public and only a low risk to those who are sensitive to iodine. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Monitoring issues should be resolved before the proposed iodine fortification. However, does not believe they should contribute to delay in advancing progress on iodine fortification. Ongoing monitoring is important to gauge effectiveness of fortification. Monitoring must include a National Nutrition Survey. Current data is 10 years old. Although applauding the intention of the commonwealth government to measure the nutritional habits of children, also need to collect data on other sections of the community, e.g. women of childbearing age, particularly important for iodine fortification. AMA calls for a National Nutrition Centre to monitor urine samples and to work collaboratively with FSANZ on issues relating to iodine fortification. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Believes that doctors and medical professionals are well placed to assist with the transition into a fortified food environment.

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<p>Australian Division of World Action Group on Salt and Health Australia Caryl Nowson</p>	<p>Does not support current mandatory fortification proposal</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Believes salt iodisation conflicts with current Australian nutrition policies and dietary guidelines and world accepted nutrition policies (WHO and SACN, UK). • There is strong evidence that a reduction in dietary salt can reduce cardiovascular disease. Current nutrition guidelines aim to reduce the dietary intake of salt at a population level. • Over 75% of dietary sodium is derived from manufactured foods. • A gradual reduction, over a five year period, in the sodium content of manufactured foods, could reduce the average intake of salt from 9g/day to 6 g/day, in line with current government policy, and the stated upper limit. • This would necessitate the co-operation of the food industry. • Iodisation of salt will provide conflicting messages to the public. • To achieve adequate iodine an adult would have to consume 5 g of salt per day if all manufactured foods were fortified at 20 mg/kg, which is above the UL for sodium, and is 1 g higher than the Suggested Dietary Target. <p><i>Bread, breakfast cereals, biscuits</i></p> <ul style="list-style-type: none"> • Those choosing lower sodium/salt reduced bread and cereals are unlikely to achieve the recommended intake of iodine. • The salt content of these foods is extremely variable: <ul style="list-style-type: none"> - breakfast cereals vary from 3 to 820 mg/100 g (a 270-fold difference, making iodine fortification erratic - biscuits vary from 20 to 1390 mg/100g a 70 fold difference - breads vary from 400 – 725 mg/100g. • The high fat, sugar, and/or salt content of many breakfast cereals and biscuits is contrary to Australian Dietary Guidelines, and it is not appropriate to give people a health reason for buying them. • The health giving reputation of supplementary iodine would risk a boost in sales of many foods of questionable nutritional value. • Bread has some advantages as a vehicle for iodine: <ul style="list-style-type: none"> - bread is a staple food and is included in the Australian Guide to Healthy Eating; and - all bread would qualify for inclusion when recommending Australians to eat more bread. • Alternative approaches to achieving iodine sufficiency: <ul style="list-style-type: none"> - A specific amount of iodine should be mandated in specific core foods, rather than in three restricted food groups. - Exclude biscuits and crackers as a vehicle for iodisation. - Manufacturers could choose their own method of iodisation. As iodisation of salt is not the only method available. - There needs to be continued investigation of alternative methods of iodine delivery (see Trevor Beard’s submission). <p><i>Monitoring and compliance</i></p>

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	<ul style="list-style-type: none"> • FSANZ must take responsibility for ensuring adequate monitoring of dietary intake of iodine through regular surveys utilising urine collections. • There needs to be an ongoing government funded program of monitoring under the direction of FSANZ. • Responsibility for implementation of iodisation and monitoring must be administered by the same government body. • Dietary modelling must be assessed to ensure that all sections of the population can achieve an adequate intake of iodine, whilst achieving the Suggested Dietary Target for sodium.
<p>Crop and Food Research New Zealand food composition database NZFCD Jason McLaughlin</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Notes mandatory iodine fortification will improve the database’s ability to provide complete data on the levels of iodine in foods. They are currently entering additional iodine values on 2700 foods into database. Of these values only 11% are New Zealand analytical values and the remainder are imputed or derived. Coverage of baked products is slightly better at 17%. NZFCD also uses the Manufactured Foods Database (MFD) but this is also incomplete as manufacturers do not always provide the required information.</p> <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Note that Nutrient Information Panels will now need to declare if iodised salt was used in the product. This information will assist NZFCD to determine which foods will need to have an updated iodine value in the database. • The MFD would be a better source of information on iodine fortified products after adoption of mandatory fortification. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Envisage the need to collaborate with FSANZ Food Composition program and /or the food industry to develop protocols for calculating appropriate iodine values for the NZFCD. • The resources required to update the national food composition database for New Zealand will require a formalised working partnership with external stakeholders such as FSANZ, NZ Ministry of Health and NZ Food Safety Authority. <p><i>Level of fortification</i></p> <ul style="list-style-type: none"> • Calculation of iodine content of fortified foods will be difficult given the wide range of fortification permitted (e.g. 20 – 45 mg iodine / kg salt)
<p>Dietitians Association of Australia (DAA) Kate Poyner</p>	<p>Supports Option 2 - Mandatory fortification</p> <p>DAA Represents 3000 dietitians, dietetic students and associate members. They believe mandatory fortification will reduce the mild to moderate iodine deficiency in Australia and New Zealand. Considers the Tasmanian experience has provided compelling evidence of improved iodine status of the population through fortifying bread with iodine.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Recognises that mandatory fortification of food with iodine will improve the iodine status for the population of Australia and New Zealand. <p><i>Vulnerable groups</i></p> <ul style="list-style-type: none"> • Many pregnant and breastfeeding women may still find it difficult to achieve NRVs for iodine intake.

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	<ul style="list-style-type: none"> • Additional iodine supplementation may be necessary for many women of childbearing age, particularly those living in iodine depleted areas like SE Australia and New Zealand. • There may be a need for a low cost vitamin and mineral supplement for women to meet the increased nutritional needs of pregnancy and lactation. • People with existing thyroid conditions may need a change of management with increased iodine in food supply. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> • DAA supports current salt permissions. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • There is consensus among DAA members that a comprehensive monitoring and review program is essential to assess the effectiveness of, continuing need for, and any adverse effects from iodine fortification. • DAA asks for a firm commitment from Commonwealth, State and Territory governments in Australia and from the New Zealand Government that appropriate monitoring be undertaken. • DAA acknowledges that monitoring all age groups is desirable but costly and believes that a monitoring program would ideally consider: <ul style="list-style-type: none"> - - health status, including but not limited to iodine deficiency disorders; - - urinary iodine excretion (UIE), in school age children, women of childbearing age and children under three; - - nutrient intake and food consumption patterns as assessed by food frequency questionnaires; - - food composition data on iodine from major dietary sources; - - compliance modelling for industry; and - - monitoring should be across all States and territories of Australia and New Zealand due to variation of naturally occurring iodine. • Australia and New Zealand have relatively good baseline data on population iodine status. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • There is a need for public health programs to highlight the importance of nutrition both before conception and during pregnancy and lactation. Iodine, folic acid and many other nutrients are essential before and during pregnancy. • A broad based education program for women of childbearing age is essential because: <ul style="list-style-type: none"> - - the level of mandatory supplementation will not enable many women to achieve NRVs for iodine during pregnancy and lactation; - - women may incorrectly believe that they do not need any supplementation if foods are fortified with iodine; and - - some women will consume little or none of the iodine fortified foods. This would include those women who are allergic or intolerant to wheat, those who consume little bread and /or those who limit processed food intake in order to limit sodium intake. • DAA believes that supplement programs and education programs are a government responsibility and will require ongoing support. • DAA considers that human development programs at secondary school are an ideal

SUBMITTER	SUBMISSION COMMENTS
	<p>time to educate girls about iodine.</p> <ul style="list-style-type: none"> • Education programs may need to be tailored for particular states to suit iodine availability in local food supplies.
<p>Manufactured Foods Database New Zealand Lyn Gillanders, Allannah Steeper</p>	<p>Supports Option 2 – Mandatory iodine fortification</p> <p>MFD compiles a database on food ingredients, and presence/absence of common allergens, from information supplied by New Zealand and Australian food manufacturers. This includes a list of foods that are voluntarily fortified. They currently have self reported sodium values for all 6.000 foods on the database.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports fortification of biscuits, bread and breakfast cereals but notes that reducing discretionary salt intake is a current health goal for New Zealanders. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Notes that salt begins to be listed as an ingredient when sodium is greater than 20 mg/100 gm. • Estimates that 25% of breakfast cereals do not have added salt. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Supports monitoring and review as a fundamental component of the proposal to assess the effectiveness of and continuing need for the mandating of fortification. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Iodine public health education has been ‘lost on a generation of younger people’. • Adequate funding will be needed for effective public education. • Lifestyle and cooking magazines advocate use of sea salt and this dilutes any health messages to use iodised salt. These publications could be used to increase public awareness of need to use iodised salt.
<p>Massey University New Zealand Janet Weber</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Emphatic support for Option 2. Prefers universal salt iodisation (scenario 2 in the Draft Assessment) but accepts it may not be warranted considering the extra cost to industry and the relatively small number of people not covered under scenario 1 (bread, breakfast cereals and biscuits). If scenario 1 is adopted recommend mandatory fortification of all table salt or, at a minimum support the continuing need for the voluntary permission to iodise table salt.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Need to consider alternative vehicles for those who don’t eat very much or any, wheat, gluten or other cereal products. <p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • If iodised salt widely taken up by industry, (likely if health claims allowed), there is a possibility of excess intake for parts of population. • Voluntary permissions should be allowed only for other cereal foods e.g. pikelets, cakes etc • Voluntary fortification is dangerous because there is little control over how much iodine is consumed.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Prefers mandatory iodisation of table salt because this would result in a smaller number of people with intake under the EAR (from Draft assessment - Table 5). • Concerned that the proposed reduction in iodine level in table salt will affect some at risk groups (see below) <p><i>Level of fortification</i></p> <ul style="list-style-type: none"> • Notes that iodisation level of 20-45 mg iodine per kg salt is higher than in other countries and reflects the current high salt intake of Australians and New Zealanders especially through processed foods. • Suggests a government funded incentive to reduce sodium levels in food in association with the mandatory fortification process. • Current level of fortification will have to be reassessed and adjusted as necessary. • This would proactively address the contradictory messages of the need to ingest more salt for its iodine content and less salt for its sodium content. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considers nutrition related health claims should not be allowed for iodine except for naturally occurring iodine. As iodine is linked with salt, a high level of iodine will also signal a high sodium content. • Iodine content should be permitted on the NIP, to assist consumers to make a food choice. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Believes monitoring of the food supply and population is crucial to ensure that iodine intake does not become excessive. In South Africa following mandatory fortification of table salt manufacturers were unaware that they were using iodised salt. • Adequate funds must be assured for the comprehensive monitoring outlined in the proposal. • Without financial commitment to monitoring the voluntary permission to allow iodised salt in other processed foods should be revoked • Notes WHO provides useful guidelines for monitoring programs. • Recent monitoring program developed in Denmark may provide an exemplary monitoring model. • Important to collect baseline data. • Casual urine sampling in conjunction with the NNS, would be adequate to assess urinary iodine excretion. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Vulnerable groups like gluten intolerant people and ethnic groups who do not eat foods fortified with iodine, will need to be sampled separately. Asians are not currently included in NNS at a level for statistical inference to be made. • Need to monitor for increased incidence of autoimmune thyroid disease and thyroid papillary cancers which may increase as iodine levels go up, particularly in areas with people with the highest iodine deficiency levels. • Need to monitor the use of iodine containing colouring agents in foods, pharmaceuticals and cosmetics. These have been linked to thyroid toxicity (IOM 2001) (Currently the monitoring of thyroid function of those taking the drug amiodarone is inadequate with respect to recommended guidelines, and is probably due to lack of knowledge of the guidelines). <p><i>Communication and education</i></p>

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Considers it important to educate physicians prescribing drugs which contain iodine so they can monitor their patients and recommend iodine free salt, bread, breakfast cereals if necessary. • Nutrition education should target all at risk populations, including pregnant and lactating women, women of childbearing age, parents of young children, gluten sensitive people, ethnic groups who do not eat fortified foods and people suffering from thyroid conditions. • Physicians and health care professionals will need continuing education on iodine fortification and be included in the monitoring process/information. • Clear guidelines on how much iodine fortified foods to consume in order to get recommended levels of iodine • Education on lowering sodium levels in diet addressed alongside iodine education. • Supplements need to be readily available, and may be the best option for those who do not consume adequate quantity of fortified foods regularly.
<p>Menzies Research Institute Australia Trevor Beard</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>‘The problem with iodising bread with salt is to reconcile the conflict between providing iodine and progressively reducing salt.’</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Considers salt is an easy and quick vehicle for iodising food. However, using salt as the iodising vehicle would ‘block’ the voluntary reduction of salt in bread. The Heart Foundation has started reducing the salt allowed in bread for the ‘Tick’ and has announced further reductions. Further reductions in the salt content of bread would also reduce the iodine content. • Although salt strengthens gluten, slows the rise and adds flavour to bread, many successful No Salt and Low Salt bread are being produced. • AWASH, (Australian Division of World Action on Salt and Health) is campaigning for less salt, but if salt is iodised, reducing the salt content will also reduce the iodine content. • The Heart Foundation and individual bakeries must be free to promote healthier low salt bread and cater for people who want it. • Blocking the voluntary reduction of salt in bread will obstruct progress in controlling hypertension and its complications (heart disease, stroke and kidney failure). • Hypertension is as serious and prevalent as iodine deficiency disorders. Of those who reach middle age, 90% will develop hypertension. <ul style="list-style-type: none"> • Hypertension/prehypertension can be treated very effectively with a healthier diet and exercise. A healthy target for salt/sodium intake is 65 mmol/day and Australia’s NRVs set a target intake for salt/sodium at 75 mmol/day. The diet group that reversed prehypertension in the DASH diet used low salt bread (sodium ≤ 120 mg/100 g). • Proposes three possible solutions: <ul style="list-style-type: none"> - Iodine fortification should be permitted by any other means at the discretion of the baker. This would be an outcome based standard which would be

SUBMITTER	SUBMISSION COMMENTS
	<p>randomly monitored.</p> <ul style="list-style-type: none"> - Make fortification levels high enough for low salt bread. Bread salt to be iodised at a rate, high enough to deliver the full dose of iodine when added at 0.4% of the flour weight. This low salt bread would comply with Australian Dietary Guidelines. In higher salt breads the extra salt would be uniodised. - A mandatory program of progressive reduction in salt content (e.g. 10% per annum) could continue until all Australian bread was low salt. <p>This might be acceptable to the bakery industry who would all be on an level playing ground, i.e. no one company would lose market share to another making bread with a higher salt content.</p> <p>Suggests a cap on salt content in bread of 1.8% of the dry ingredients.</p> <p>While salt content of bread was gradually reduced Option 1 could also be incorporated.</p> <p><i>Other possible vehicles for iodine</i></p> <ul style="list-style-type: none"> • Considers salt is a good vehicle because if an error occurred in production the strong taste of salt would alert consumers to a possible overdose of iodine. However, the two best vehicles for iodine are dough improvers and dough making flour. • Fortification of flour would take time to develop. • It would be cheap and easy to reintroduce the bread improver iodised with potassium iodate that was used in Tasmania in the 1960s. • Potassium iodate is an excellent dough improver, and can be added in varying proportions to a variety of bread improvers, to provide the correct dose of iodine. • Iodine content of bread using iodised bread improver is more reliable than in bread using iodised salt due to difficulties with quality control of salt iodisation techniques. • Homemade, no added salt bread can be fortified with iodine at the rate of 15 µgm per slice by using a reliable 0.4% potassium iodide solution delivered from a dropper.
<p>National Heart Foundation (NHF) Australia Barbara Eden</p>	<p>Does not Support Option 1 or 2</p> <ul style="list-style-type: none"> • The NHF does not support the fortification of any foods with iodine using iodised salt because this method of delivery: <ul style="list-style-type: none"> - conflicts with Australian and International public health recommendations; - conflicts with evidence-based nutrition; - conflicts with the Heart Foundation’s Tick program; and - may risk encouraging the food industry to add more salt to their foods. • The NHF believes that FSANZ has made a strong case for fortification of core foods with iodine and encourages FSANZ to consider alternative approaches for achieving iodine sufficiency in the Australian and New Zealand population. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Does not support Option 1 because they understand there is a re-emergence of iodine deficiency in Australia and New Zealand that needs to be addressed. <p><i>Food vehicle</i></p> <p><u>Salt</u></p>

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	<ul style="list-style-type: none"> • Does not support option 2 because they believe that salt is an inappropriate food vehicle for iodine fortification. <p>i) Health recommendations</p> <ul style="list-style-type: none"> • Concerned that using salt as the vehicle for iodine fortification sends a conflicting message about salt intake to consumers because it conflicts with Australian and International health messages e.g. <ul style="list-style-type: none"> - NRVs for Australia and new Zealand recommends an upper limit (UL) of sodium for adults of 100 mmol/day and a suggested dietary target (SDT) of 70 mmol/day to reduce risk of chronic disease; - To achieve iodine sufficiency, and meet EAR of 100 µg/day an adult would need to consume at least 100 mmol of sodium/day. This is higher than the SDT of 70 mmol/day; - Dietary Guidelines for Australian Adults recommends that consumers choose foods low in salt and warns against consuming processed cereals with high salt levels; - To achieve NRVs the Dietary Guidelines recommend that adults should consume fresh food, foods normally processed without salt and low salt or no-added-salt groceries, and they should avoid adding salt to food; - WHO recommends that all adults consume less than 5 g salt /day and UK Food Standards Agency has set a target for average salt intake to be reduced to 6 g salt/day. <p>ii) Evidence</p> <ul style="list-style-type: none"> • Using salt as a vehicle for iodine fortification conflicts with the Heart Foundation’s evidence-based nutrition reviews. The Heart Foundation will continue to support further decrease in sodium intake through further gradual reductions in our food supply. Evidence on the effects of sodium on blood pressure, stroke and cardiovascular disease includes: <ul style="list-style-type: none"> - Reducing dietary sodium from 140 to 100 mmol/day is associated with a fall in systolic blood pressure of 2 mmHg in hypertensive and normotensive individuals - Reducing dietary sodium from 140 to 65 mmol/day is associated with a fall in systolic blood pressure of 7 mmHg in hypertensive and normotensive individuals - High dietary sodium intake is associated with increased stroke incidence, and mortality from coronary heart disease and cardiovascular disease - A general reduction in sodium intake could be better achieved by a general reduction in the sodium content of manufactured food products than by dietary advice alone <p>iii) Heart Foundation, NHMRC and the food industry</p> <ul style="list-style-type: none"> • Much of the salt consumed by Australians is from manufactured foods. • Australian studies have shown that major food manufacturers have been lowering the salt content of foods in response to consumer demands and nutrition benchmarks, (including the Tick program). • The food industry needs incentives to decrease sodium levels in products which have added salt or other sodium compounds. • Sodium content can be lowered without loss of product acceptability. • NHF has been advocating for less salt for 40 years. The Tick program has been challenging manufacturers for 17 years and has driven reformulation and new

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	<p>formulations of food products, for example:</p> <ul style="list-style-type: none"> - 235 tonnes of sodium were removed annually from the food supply by Kellogg reformulating 12 cereals; - A range of Tick approved luncheon meats developed with 50% less sodium than similar products; - Tick meat pies contain 50% less sodium than average pies; - The Tick program is incrementally reducing the sodium content of bread from 450 mg to 400 mg/100 g over 2 years in consultation with the bread industry; and - A recent review of the Tick criteria shows further sodium reduction in 10 categories. <ul style="list-style-type: none"> • In 1982 NHMRC recommended that food manufacturers be asked to lower the salt content of food. Manufacturers responded with a range of reduced and low salt alternatives now available. A survey found an overall decrease in sodium content of 10% compared to 15 years ago. <p>iv) Iodine related health claims</p> <ul style="list-style-type: none"> • Concerned that Proposal P230 states that ‘mandatory fortification presents the opportunity for food manufacturers to make nutrition and health claims’ and that fortification with iodine will encourage industry to use higher salt levels in manufactured foods so that they can make health claims related to iodine • Proposal P230 has the potential to set back the progress made by the food industry over the past 20 years which has seen a reduction in salt levels and new products with low salt levels. <p><u>Biscuits</u></p> <ul style="list-style-type: none"> • The Heart Foundation recommends that biscuits be consumed only once a week as they are not core foods and can increase saturated and trans fat intake. • The Australian Guide to healthy eating lists biscuits as extra foods together with meat pies and hot chips. <p><i>Alternative approaches</i></p> <ul style="list-style-type: none"> • Supports the alternative approaches suggested by AWASH (see Trevor Beard’s submission).
<p>The New Zealand Nutrition Foundation New Zealand Sue Pollard</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Agrees in principle with increasing the iodine status of the population through fortification but concerned with the use of salt as the vehicle. This may give inconsistent messages to the population with regard to reducing salt intake, making it difficult for the population to achieve adequate levels of iodine if salt intake is reduced.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Agrees that a long term fortification strategy is needed to target the population as a whole with an appropriate level of iodine. • Concerned with the effects of iodine deficiency, during pregnancy, on the unborn foetus and on mental development in early childhood. • Supports additional mechanisms to ensure that women receive sufficient iodine. • Concerned that children should not receive more than the upper limit for iodine (200 µg per day in 1-3 year olds and 300 µg per day in 4-8 year olds). • Concerned for people who avoid bread and cereals for various reasons, e.g. those with wheat allergy and coeliac disease. Believes it is important to establish how/if

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	<p>the iodine needs for these groups can be met.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Fortification of bread and breakfast cereals is appropriate because these foods form the basis of a healthy diet. • Fortification of salt with iodine will give a contradictory message not consistent with Australian and New Zealand nutritional guidelines. • Supports the replacement of non-iodised salt with iodised salt only where it is absolutely necessary to use salt in foods. • Has concerns about using iodised salt as the only (or major means of fortification). High salt intakes are linked to hypertension which increases the risk of heart disease. Heart disease was the leading cause of death in 2000. • Concerned that iodising salt will lead to an increase in salt intake in the NZ population. • 85% of salt intake is from manufactured foods. While some salt is necessary for functionality and taste, manufacturers should reduce the salt content of foods as far as practically possible. • Food manufacturers should be discouraged from adding salt to an extended range of their processed foods in order to promote iodine intakes. • Those food manufacturers who already have salt reduction policies in place should be commended. • Would not recommend maintaining current salt use in order to supply sufficient levels of iodine. • Suggests that part of the decreasing iodine intake may be due to decreased intake of salt in response to health messages. • Believes that other strategies for increasing iodine intake will be needed to ensure adequate iodine intakes ‘in the absence of excess sodium intakes.’ • Believes there is a need for a coordinated program of research to identify alternative ways of fortifying foods with iodine, e.g. direct addition of potassium iodide or iodate to food. This would involve ascertaining the levels of iodine that could be added to foods before bioavailability was affected and the possibility of altering/reducing the shelf life of the food vehicle(s). <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> • As all staple/ cereal foods/major food group will be fortified with iodine, those consumers wishing to avoid iodine in their diet have limited food options. • Some consumers wish to avoid salted products while still consuming adequate iodine. This is not possible if salt is the vehicle for fortification. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Appropriate labelling of iodine in foods will allow consumers to avoid iodised products. • Labelling should guide and inform customers with the amount of iodine and percentage of RDI provided by a specified serving size. • Because food composition tables do not include iodine, this will necessitate analysis of foods. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • The iodine status of the population should be monitored as an integral part of the

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	<p>iodine fortification approach to ensure ongoing safety and effectiveness.</p> <ul style="list-style-type: none"> • The iodine content of foods with both fortified and naturally occurring iodine should be monitored. • Monitoring is important to ensure that the safe upper limit for iodine is not exceeded, especially if iodine is added to a wide variety of foods. • Excess levels of iodine can lead to hyperthyroidism. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • A marketing and education strategy should go ‘hand in hand’ with fortification. • It is important to raise awareness of the issue amongst New Zealand consumers, in particular pregnant and breastfeeding women and parents or guardians of young children. • It is also important to raise awareness of iodine among health professionals so that pregnant and breastfeeding women are advised to regularly consume iodine containing foods and to take an oral iodine supplement if one becomes available as a registered medicine.
<p>NSW Centre for Public Health Nutrition Australia Vicki Flood</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Notes issues concerning the choice of food vehicle but ‘this should not detract from’ support for mandatory fortification of foods with iodine.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Although acknowledging that WHO has recommended adding iodine to salt and previous experience adding iodine to salt, query whether salt is the most appropriate food vehicle. • The Australian Dietary Guidelines recommend the use of foods low in salt and the NRVs recommend a lower sodium intake so there is potential for an inconsistent health message to the public about use of salt. • If the sodium content of future food products is decreased some increase in the dose of iodine will need to be considered. • Concerned about the use of energy dense, nutrient poor, ‘extra’ foods like biscuits to provide iodine in the diet. • Believes that bread is an appropriate food for fortification as it is a staple. There may be some population subgroups who consume little bread and other cereal products e.g. coeliacs and some ethnic communities. • Suggests considering other core foods as vehicles for iodine fortification e.g. milk and milk products. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believes there is good evidence to suggest a mild to moderate iodine deficiency in the Australian population. • As children in Queensland and Western Australia have adequate iodine status, concerned that mandatory fortification may cause more children to exceed the upper limit for iodine. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Supports the addition of iodine to the Nutrition Information Panel to inform consumers on the amount of iodine present in fortified foods which could vary within food types dependent on the amount of salt in the food. <p><i>Monitoring and compliance</i></p>

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	<ul style="list-style-type: none"> • Mandatory fortification requires adequate monitoring of the iodine content of foods, iodine status of the population and at-risk groups and thyroid disease surveillance. • The monitoring system should be in place before any fortification measures are instigated. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports an extensive education campaign to inform the public about iodine fortification and the need for pregnant and breastfeeding women to be supplemented in addition to consuming iodine fortified foods. • Need for education of consumers and medical practitioners to raise awareness about iodine induced hypothyroidism and hyperthyroidism. • Groups who eat little bread and/or cereal foods may need education to encourage consumption of iodine from other sources.
<p>NZ Dietetics Association New Zealand Jan Milne</p>	<p>Supports Option 2 - Mandatory fortification (only for bread and breakfast cereals, not for biscuits)</p> <p><i>Food vehicle</i></p> <p><u>Salt</u></p> <ul style="list-style-type: none"> • Have grave concerns if the use of salt as the fortification vehicle resulted in any increase in salt consumption. (The NZ Food and Nutrition Guidelines recommend that salt and sodium be kept to a minimum. New Zealanders consume 7.1-10.1 g of salt per day). <p><u>Bread and breakfast cereals</u></p> <ul style="list-style-type: none"> • Bread and breakfast cereals contribute 25.7% and 5.8% respectively of New Zealanders total salt intake. • The New Zealand Food and Nutrition Guidelines encourage new Zealanders to eat at least 4, (preschoolers) and 6, (adults) serves of bread and cereals daily, which makes them appropriate choices for fortification. • Endorse replacement of existing salt with iodised salt in these foods but advise caution, (even sodium restrictions or salt reductions) so that the salt content of these foods are not increased. <p><u>Biscuits</u></p> <ul style="list-style-type: none"> • NZDA members do not support the fortification of biscuits with iodised salt as NZ has an obesity epidemic and they feel a responsibility to promote foods that will enhance population health. • Biscuits were the main food contributor of energy, total fat and saturated fat in the 2002 Children’s Nutrition Survey. The NZ Food and Nutrition Guidelines do not encourage their regular consumption. • Iodine fortification may be interpreted as a ploy to increase their marketability, where we are encouraging decreased consumption of these items. • It may be necessary to increase the fortification of bread and breakfast cereals in order to achieve the desired levels of iodine in the food supply. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Reinforce the importance of a sound monitoring system if mandatory fortification is introduced. • Monitoring should be the responsibility of the Ministry of Health in New Zealand

SUBMITTER	SUBMISSION COMMENTS
	<p>and should be incorporated into national health and nutrition surveys.</p> <ul style="list-style-type: none"> • Urinary iodine and sodium secretion should be monitored. • There needs to be a commitment to regularly checking and enforcing the requirements of mandatory fortification in both local and imported foods. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Moderate iodine deficiency reported in pregnant women and 6-12 month infants. • Iodine status of New Zealand children was low and indicative of mild iodine deficiency (Children’s Nutrition Survey 2002). • Decreasing levels of iodine intake in adults (1997-98 NZ Total Diet Survey), below the Australian Recommended Dietary Intakes (RDIs). • Some population groups, e.g. Asian communities or people with coeliac disease, may not benefit from the fortification of bread and breakfast cereals. May need to consider their needs separately, with targeted campaigns for alternative sources of iodine. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Fish and seafood are expensive food items. If there was an effective campaign for the population to increase seafood intake market forces could cause further price rises, making seafood intake beyond the financial reach of many New Zealanders.
<p>Gesundheitsamt Public Health Board Germany Eugen Kriener</p>	<p>Preferred option not stated</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Extrapolating the Upper Level of Iodine Intake for children from adult data on a metabolic bodyweight basis is inappropriate. Recommends the use the Upper Limit for iodine set out in Chapter 12 of the joint FAO/WHO expert consultation on human vitamin and mineral requirements i.e. 50 ug per kg of bodyweight per day for children aged 1-6 years. • Notes that despite public health campaigns to promote the use of iodine supplements for pregnant a lactating women, only a small proportion of pregnant and lactating women in Germany take iodine supplements. • Suggests that fortification should seek to raise intake of the 90% of the population to or above the RDI as opposed to the EAR. • Questions if iodine losses during processing, storage and cooking have been estimated correctly suggesting such losses are in the range of 6-20%. <ul style="list-style-type: none"> • Notes that even moderate deficiency does not have ‘moderate’ consequences citing delayed mental function, learning capacities and motor functions. • Advocates the same level of iodisation in discretionary salt in line with mandatory fortification concentrations. • Advocates provision of iodine supplements to pregnant and breastfeeding women at a level appropriate to those at the lower end of iodine intake. • Notes that in Germany despite long-standing guidelines advocating iodine supplements the only thing many doctors know about iodine is that ‘it could be too much’. • Suggests iodine fortification of animal feeds to augment iodisation of the human food supply. <p><i>Other issues</i></p>

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	<ul style="list-style-type: none"> Notes that a statement made by the ICCIDD (www.iccidd.org) writes about the German government declaring that iodised salt is not required for bakeries, meat, sausages, or industrial foods is incorrect. Instead, in 1993, the Ministry of Nutrition, Agriculture and Costumer Protection declared that for non-packaged food, in contrast to packaged food, the use of iodised salt need not be declared.
<p>Royal New Zealand Plunket Society (Inc)</p> <p>New Zealand</p> <p>Angela Baldwin</p>	<p>Supports Option 2 – Mandatory iodine fortification Fully supports the proposal.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Considers mandatory fortification to be clearly in line with well child health goals. Supports plans to reduce concentration of iodine in salt. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Believes it is important for the population to feel confident in managing the levels of iodine they and their children take in. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Supports monitoring consumer behaviour and the effect of mandatory iodine fortification on the population. Urges timely assessment of the effects, positive or negative on the health of infants and young children. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Supports need for supplemental iodine intake by pregnant and breastfeeding women and those of child bearing age.
<p>Taranaki District Health Board (TDHB)</p> <p>New Zealand</p> <p>Jill Nicholls (Representing dietitians and nutritionists)</p>	<p>Supports Option 2 – Mandatory fortification</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Believes that the mandatory use of iodised salt in all bread, biscuits and breakfast cereals is a good way to ensure adequate iodine intakes. <p><i>Removal of voluntary permission of salt iodisation/use of salt in non-mandated foods</i></p> <ul style="list-style-type: none"> Believes that once iodine fortification is implemented other voluntary use of iodised salt by industry should not be permitted because it may result in excessive iodine intake. Concerned at possibility of food manufacturers adding iodised salt to high salt, pre-packaged foods and marketing them as healthy due to their being a source of iodine. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Believes that a considerable number of New Zealanders are no longer getting an adequate intake of iodine because they have taken up the public health message to use less salt. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Concerned that the potential for public misinformation is great, especially with reference to food manufacturers making health claims for iodine content of their foods. Suggests that well funded wide reaching, and ongoing education campaigns targeted at entire population should be an important adjunct of this proposal.

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	<ul style="list-style-type: none"> Ongoing education programs for pregnant and breastfeeding women are important.
<p>Tasmanian Ministerial Thyroid Advisory Committee Tasmania Judy Seal</p>	<p>Supports Option 2 – Mandatory fortification</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Disappointed that mandatory universal salt iodisation has not been supported as the preferred option. Believes USI would: <ul style="list-style-type: none"> be more effective; simplify communication with manufacturers; simplify enforcement; simplify monitoring of food composition; result in a more sustainable solution; and be consistent with international recommendations. Believes that voluntary fortification is an inadequate response to protecting public health and safety and commend the fact that voluntary fortification has not been considered. While Tasmania has had some success with voluntary fortification concerned about the reach of the program to subpopulation groups, sustainability and ongoing costs of maintaining industry commitment. Understand that reluctance to increase the level of iodine fortification, relates to minimising the proportion of individuals who exceed the upper limit. Draft Assessment highlights the upper limits do not represent absolute thresholds for toxicity and there is a wide margin for safety and intakes in young children are unlikely to be a safety risk. There is a risk that cautious language about exceeding the UL implies toxicity and may lead to a misunderstanding with the general public.
<p>JC Stewart Private Australia</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Studied iodine nutrition and thyroid disorders for 40 years. Member of Thyroid Clinic at Launceston General Hospital and of the State Thyroid Advisory Committee from 1968-2003. Co-authored a number of papers concerning the occurrence of IHH.</p> <p>Would prefer universal salt iodisation, (USI) but is happy to support the current proposals subject to a higher level of fortification.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Believes that only a mandatory approach to iodine fortification would work. Is aware of no voluntary scheme of iodine supplementation that has been of lasting benefit. The proposed level of iodisation is insufficient to meet the needs of pregnant and lactating women. With a minimal increase in real risk the iodisation level could, and should be raised. Thanks to iodophors in milk, the Australian population was iodine replete for about 30 years starting in the mid sixties, and there is unlikely to be a pool of people at risk of IHH. Young children can tolerate a much higher daily intake than the proposed upper limit. Unjustified fear of adverse effects risks making the proposal more of a gesture than

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	<p>a serious attempt to eradicate iodine deficiency.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • No explanation given in Draft Assessment for not recommending USI as advocated by the ICCIDD. • Believes that USI would be simpler to effect and more dependably successful. • By confining iodine to a few foods some consumers will not receive iodine. • Manufacturers of these foods may feel they are being victimised and oppose the measure. • Here are so many bakeries in the country that policing compliance would be practically impossible. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Milk still contains appreciable quantities of iodine, from teat dips (about 150 µg). But this level may fall if another teat dip were used. The population would then have a significantly lower iodine intake. • Monitoring of urinary iodine levels is essential in perpetuity because of the possibility of unforeseeable changes in dietary iodine. • There should be provision for rapid adjustment to the level of fortification should such a change occur.
<p>Endocrine Society of Australia (ESA)</p> <p>Australia</p>	<p>Supports Option 2 – Mandatory fortification</p> <p>Strongly supports the proposed mandatory iodine fortification of salt but does not believe this proposal will address iodine deficiency in crucial groups e.g. pregnant and breastfeeding women.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believe a mandatory program is justified because voluntary programs have not been successful elsewhere. • Because of the importance of iodine for brain development in newborn babies, ESA recommends that all pregnant and breastfeeding women and all women planning pregnant should be iodine replete. • They recommend an intake of 250 µg/day, in line with the WHO guidelines. • Even with iodine fortification, to reach this intake, supplementation of these women, would be necessary. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Prefers universal salt iodisation (USI), (consistent with the WHO position on iodine fortification). <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • A system of monitoring of iodine status, especially of vulnerable groups, should be set up in conjunction with the introduction of iodine fortification. • Monitoring should be ongoing, to prevent re-emergence of iodine deficiency. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Recognise that there are issues of personal choice and commercial costs, but believe that the balance of public good markedly favours mandatory iodine fortification. • The small risk of iodine-induced hyperthyroidism is manageable and outweighed by the public good.

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<p>National Heart Foundation of New Zealand</p> <p>New Zealand</p> <p>David Munro</p>	<p>Supports Option 1 – Maintaining the <i>status quo</i></p> <p>Agrees there is an emerging problem with iodine deficiency in New Zealand but does not believe FSANZ has presented enough evidence to support Option 2.</p> <p>Is concerned that using salt as a vehicle for iodine is inconsistent with national dietary guidelines and could stifle efforts to reduce the sodium content of food.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • High blood pressure is an important risk factor for cardiovascular disease and stroke with a continuous association and no lower threshold. Many cardiovascular events occur at below predefined cut-offs for hypertension. High blood pressure has been estimated to cause 3699 deaths in 1997. • Dietary sodium is an important determinant of blood pressure. New Zealanders dietary intake of sodium is generally excessive, averaging 113-150 mmol/L. This is seven times the adequate intake and 113-150% of the upper limit. • Reducing New Zealanders’ exposure to salt is one of the key population health messages underpinning the New Zealand Ministry of Health’s Healthy Eating – Healthy Action implementation plan 2004-2010. • Analysis of New Zealanders dietary intake show that breads continue to contribute the majority of dietary sodium and are therefore an important vector for reducing the population’s exposure to sodium. Stepwise reduction of sodium in bread has the potential to reduce population intakes of dietary sodium thereby reducing hypertension. • This seems feasible as research has shown there is a wide range of sodium levels in New Zealand breads 350 – 600 mg/100g. • Lower priced bread and breakfast cereals typically contain higher sodium levels. There is a need for sodium reduction across the board but especially in low cost food categories. Lower socio-economic groups have a higher rate of cardiovascular disease. • A multifaceted approach including regulatory and industry led initiatives to reduce sodium content of commercially prepared foods is recommended. • A decrease in dietary sodium of 100 mmol/day could lower systolic pressure by 6 mmHg and could prevent 282 deaths a year in New Zealand from 2011. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Dietary modelling or further risk assessment is needed to ensure that the fortification of iodine into high salt foods such as bread and breakfast cereals will not adversely affect public health and stifle current and future attempts to remove sodium from the food supply.
<p>School of Public Health</p> <p>The University of Sydney</p> <p>Australia</p> <p>Soja John Thaikattil</p>	<p>Supports Option 2 – Mandatory fortification</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Believes that mandatory programs are more effective for population wide public issues. • Industry is driven and motivated by profit, and it is almost futile to ask them to act against their own self interest. But there is room to encourage them to be part of this public health initiative. <p><i>Food vehicle</i></p>

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	<ul style="list-style-type: none"> • The diverse dietary habits of different groups who might not benefit from the current choice of food vehicle should be identified. • Mandatory fortification could then be extended to include iodised salt to appropriate diets of such ethnic groups. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Believes there should be a National Nutrition Survey (NNS) within the next 12 months to collect baseline data, another 2 years after fortification comes into effect, for assessment of immediate benefit and risk, and thereafter in conjunction with the National Census. • The advantages of baseline data include: <ul style="list-style-type: none"> - a better basis for monitoring the efficacy of the fortification program; - the current data available to FSANZ for their policy decision is too old; - dietary habits change with time and new products are introduced constantly. FSANZ needs to understand the current trends in consumption to make well informed policy decisions; and - FSANZ would have the opportunity to detect negative trends and outcomes early and take steps to resolve them if possible. • The NNS questionnaire should be designed so it can detect dietary habits of all ethnic groups, some of whom may not benefit from the current proposed food vehicles. • It would be useful to determine which ethnic groups may not require the use of additional iodised salt because their diet already contains adequate iodine e.g. those who eat large quantities of seafood. • Unidentified food frequency questionnaire (FFQ) could be made available on the FSANZ website. • School teachers could give guidance about filling in FFQ. • Unidentified FFQ could be distributed to households with census papers. • A randomly selected sample of the population could be invited to give blood samples. • The cost of regular NNS could be passed on to the public in some way, after raising public awareness of the importance of folic acid and iodine. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • There should be general public awareness campaigns. • The role of iodine for mother and child could be included in school sex education programs along with the importance of folic acid in prevention of NTDs. Education in school paves the way for making information public knowledge with time. • Health professionals should continue to be involved in educating the would-be mother and recommend or prescribe supplements as required. • The public needs to be informed that the benefits of iodine fortification are subtle and can only be fully appreciated in the next generation.
University of Otago New Zealand	<p>Supports Option 2 – Mandatory fortification</p> <p>Commends ‘FSANZ on a thorough and balanced report on this topic’. Believes that ‘mandatory fortification is an excellent first step in addressing iodine deficiency in</p>

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Sheila Skeaff	<p>school aged children and adults but concerned that the proposal will not provide enough iodine to children under 3 (particularly those living in New Zealand) and to pregnant and lactating women.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Because the adverse effects of iodine deficiency are most pronounced during early life, pregnant and lactating women should be the ‘specific objective of the regulatory measures outlined in this Proposal’. • This proposal is unlikely to increase the iodine content of the diets of pregnant and lactating women to adequate much less optimal levels. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Believe that despite widespread education programmes and a recommendation for pregnant and lactating women to take iodine supplements many will continue to have inadequate iodine status. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • There is an obvious need for ongoing surveillance of the population particularly at risk groups such as very young children, and pregnant and lactating women. • The effect of the proposal on iodine status will need to be re-evaluated at regular intervals.
Private Australia Max Watson	<p>Strong argument for supporting Option 2 - Mandatory iodine fortification</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports fortification of cereal flour as suitable vehicle. However, suggests little thought given to mandating use of iodised salt across the food industry generally (with due consideration to fortification level) which would benefit consumers with poorer diets and at higher risk of iodine insufficiency. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Monitoring and enforcement of compliance is an essential component and high priority for successful implementation. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • As with fortification with folic acid, concern expressed that compliance with addition of iodine is rated as ‘low-medium’. • Notes importance of adequate monitoring and surveillance, particularly for unanticipated outcomes.
Private Australia Beverley Wood (Consultant dietitian)	<p>Supports Option 2 – Mandatory iodine fortification</p> <p>Commends FSANZ for a well written and researched report.</p> <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Use of iodised salt in manufacture of bread, breakfast cereals and biscuits is well supported by arguments in the report. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> • Believes that most bread, breakfast cereals and biscuits are manufactured in Australia and NZ. • Proposal may limit small manufacturers importing some ethnic /unusual products into Australia. <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> • Does not support removal of voluntary permission for iodisation of table salt.

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	<ul style="list-style-type: none"> Believes that only smaller manufacturers would choose to add iodised salt to other foods they manufacture because iodised salt is more expensive. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Advises continuous monitoring should be a feature of the implementation strategy.
<p>Department of Agriculture, Fisheries and Forestry (DAFF) Australia Richard Souness and Mark Schipp</p>	<p>Does not support the preferred approach</p> <ul style="list-style-type: none"> Supports strategies to address iodine deficiency, however believes that initiatives should impose minimal regulatory and financial burden on industry. DAFF have a number of concerns with the preferred approach and considers that further work is required to address these concerns to ensure the most effective approach for achieving adequate iodine intake. Concerned that following Ministerial advice the regulatory options of extended voluntary permissions and promotion of voluntary options to increase industry uptake were removed, both of which DAFF supported. Considers the expansion of voluntary fortification with iodine should not be eliminated as it would increase consumer access to a wider range of iodine sources, and its potential has been demonstrated by the improvement in iodine status following the introduction of a voluntary program in Tasmania. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerned that the proposed approach has the potential for some individuals to exceed the upper limit, especially young children and those with a thyroid condition. Considers that mandatory fortification may create the perception that mandatory fortification alone will meet the requirements of the target group. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Considers that mandatory fortification eliminates consumer choice, and some people may wish to consume non-fortified products. <p><i>Trade</i></p> <ul style="list-style-type: none"> Concern about the trade-related costs of mandatory fortification on manufacturers exporting to countries that prohibit the importation of foods fortified with iodine. Estimates the additional costs to these manufacturers of maintaining separate production lines and associated costs to be more than \$2.3 million in ongoing outlays per year. Considers a voluntary approach to iodine fortification allows manufacturers the flexibility to cater to the needs of export markets. <p><i>Impact of mandatory fortification on imported food vehicles</i></p> <ul style="list-style-type: none"> Notes that Australia imports biscuits – worth \$177 million in 2004/05. (Listed 19 countries that exported biscuits to Australia.) <p><i>Voluntary permissions</i></p> <ul style="list-style-type: none"> Considers existing permissions for voluntary iodine fortification should not be removed and the range of voluntarily fortified foods extended, rather than implementation of mandatory fortification. <p><i>Consistency with policy guidelines</i></p> <ul style="list-style-type: none"> Concerned that the first Specific Order Policy Principle for mandatory fortification has not been met, as they consider the results of the National Iodine Nutrition Study do not establish that the extent of iodine deficiency in Australia is of a

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	<p>severity or prevalence as to require the introduction of mandatory fortification.</p> <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Concerned that the prioritisation of enforcement activity will be difficult, as checking labels of specific imported food for the presence of iodised salt does not provide a direct link to public health and safety. Therefore, considers voluntary fortification options and surveillance activities by FSANZ such as through the Total Diet Survey would be more appropriate. • Considers the geographic diversity in iodine status has the potential to produce inconsistent implementation and compliance with, and enforcement of, mandatory fortification, resulting in an uneven playing field for industry, particularly for manufacturers in areas identified as iodine deficient. • Due to the potential health risks, advocates that any decision to implement mandatory fortification needs to be accompanied by a robust monitoring framework with a definite timeframe. • Considers there needs to be a coordinated commitment from states and territory governments to allocate funding for monitoring activities. • Advocates monitoring as considers it is unfair on industry to impose a long-term strategy which may not achieve the desired outcome. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Supports the implementation of appropriate health promotion and education strategies to promote awareness of iodine, particularly for those groups such as pregnant and lactating women whose needs will unlikely be met by fortification alone. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Considers the difficulty in quantifying any potential benefits in monetary terms, particularly in regard to improved productivity, highlights the inequitable burden that would be imposed on industry if this Proposal is approved. • Notes that according to the cost benefit analysis, industry would bear the majority of the upfront and ongoing costs.

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<p>Department of Human Services Victoria Australia Victor Di Paola</p>	<p>Does not support either option</p> <ul style="list-style-type: none"> Does not support either of the options as currently drafted, and instead provides an alternative option. Their major concerns are the inconsistency of the proposed food vehicles with national nutrition policies, fundamental flaws with the dietary modelling and lack of adherence to Ministerial Policy Guidelines. However, considers addressing the mildly iodine deficient status of the Victorian and NSW populations is a matter of urgency in order to prevent a further deterioration in iodine status. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> Notes that some products within these food vehicle categories have a high fat and/or sugar and/or salt content, and that this is inconsistent with the Ministerial Policy Guideline. Concerned that these products will be able to carry a nutrient content claim for iodine, and that inappropriate or misleading information could reach the consumer, including messages that these are appropriate food choices regardless of their fat/sugar/salt content. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concerned that any supplementation may increase the percentage of children with urinary iodine excretion levels above 300 µg/L. Cites a paper by Mu <i>et al</i> that showed more than 10% of children in Western Australia and 5% in Queensland have urinary iodine excretion levels of greater than 300 µg/L. Considers that if a national program is to proceed that it needs to ensure that in replete States a normal distribution of iodine intake occurs, and not a distribution skewed toward higher iodine intakes. Notes that iodine fortification will not reach minority groups such as those with coeliac disease, wheat sensitivity, and some ethnic groups and the Australian Indigenous population who have a lower consumption of processed foods or who prepare bread alternatives in the home. Recommends a targeted communication and education strategy to address these minority groups. <p><i>Consumer choice</i></p> <ul style="list-style-type: none"> Considers consumer choice is potentially less vital when fortifying a food supply to restore a nutrient to adequate levels and correct a deficiency in a population. However, concerned that the proposed approach is a nationwide measure despite only mild deficiency being demonstrated in certain populations and only in two states in Australia (considers Tasmania is now replete). Instead considers iodine deficiency to be a localised issue that should be addressed through campaigns targeting those affected. <p><i>Trade</i></p> <ul style="list-style-type: none"> Considers the Proposal has considerable implications for the import and export of organic products, as current organic standards generally don't permit iodised salt in certified products. Considers organic imports would be most greatly affected as the majority of products imported are processed foods including cereal products. Notes that the financial cost of this potential loss of trade to Victoria has not been estimated.

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	<p data-bbox="448 255 695 286"><i>Voluntary fortification</i></p> <ul data-bbox="448 304 1394 533" style="list-style-type: none"> <li data-bbox="448 304 1394 394">• Acknowledges that iodised discretionary salt will provide a source of iodine for those people who are low consumers of the selected food vehicles and is consistent with the New Zealand dietary guidelines. <li data-bbox="448 412 1394 533">• Comments that it is not possible to predict the degree that iodised salt that will be used in other food products, and therefore a potential risk to public health may arise due to over consumption of iodine, particularly in young children. Notes that FSANZ has not proposed a strategy to manage this risk. <p data-bbox="448 551 823 582"><i>Consistency with policy guidelines</i></p> <ul data-bbox="448 600 1394 1084" style="list-style-type: none"> <li data-bbox="448 600 1394 658">• Principle 1: Considers the health need has only been demonstrated in two States, not for the whole Australian population. <li data-bbox="448 676 1394 766">• Principle 2: Considers that FSANZ has not demonstrated that mandatory fortification with iodine is the most effective public health strategy, and that there is insufficient data to make such a determination. <li data-bbox="448 784 1394 873">• Principle 3: Considers the use of all biscuits and all cereals as suitable food vehicles is contrary to the national nutrition guidelines, as some of these products are high in fat, sugar or salt. <li data-bbox="448 891 1394 981">• Principle 4: Considers that the preferred approach will be likely to result in excess or imbalance for some population groups, though accepts that these excesses or imbalances are unlikely to be detrimental. <li data-bbox="448 999 1394 1084">• Principle 5: Considers that with available data it is impossible to assess whether the proposed mandatory fortification will deliver effective amounts of iodine with specific effect to the target population. <p data-bbox="448 1102 751 1133"><i>Monitoring and compliance</i></p> <ul data-bbox="448 1151 1394 1995" style="list-style-type: none"> <li data-bbox="448 1151 1394 1209">• Comments that international experience shows that a monitoring system is vital to ensure the sustainability and effectiveness of the program. <li data-bbox="448 1227 1394 1317">• Notes that the WHO/IDD recommend that a monitoring program should involve both process and impact evaluation to ensure a robust and sustainable monitoring framework. <li data-bbox="448 1335 1394 1393">• Considers the cost advocated in the Cost-Benefit Analysis will not allow for more than a meagre monitoring program. <li data-bbox="448 1411 1394 1469">• Considers that the proposed framework needs to be further detailed in order to transfer it into a workable initiative, and will be more costly than identified. <li data-bbox="448 1487 1394 1948">• Additional aspects to be included in the framework include: <ul data-bbox="528 1536 1394 1948" style="list-style-type: none"> <li data-bbox="528 1536 1394 1572">- committed Federal and State funding for these initiatives; <li data-bbox="528 1581 1394 1639">- a nationally coordinated body responsible for managing the monitoring and evaluation program; <li data-bbox="528 1648 1394 1706">- a commitment to review the legislation and its effectiveness on the basis of monitoring and evaluation results; <li data-bbox="528 1715 1394 1796">- baseline and post fortification data on iodine status in different geographical locations and for pregnant women; <li data-bbox="528 1805 1394 1863">- coordination and cooperation with the salt industry to ensure the mandated levels are adhered to; and <li data-bbox="528 1872 1394 1948">- the contribution of supplements to overall iodine intake in all groups, particularly young children. <li data-bbox="448 1957 1394 1995">• Considers a descriptive timeline must be in place to guide the monitoring process.

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	<ul style="list-style-type: none"> • Proposes that monitoring commence within two years of mandatory fortification with ongoing review every five years, and needs to continue for a minimum of two generations. • Requests that a benchmark for safety be established, which would stipulate the acceptable proportion of the population exceeding the upper limit based on current recommendations. If monitoring determines that this benchmark has been exceeded, the food vehicles and level of fortification would then need to be reconsidered. • Considers it unlikely that mandatory fortification with iodine would be proactively enforced without substantial Government funding, due to the multitude of food products being fortified and the lack of direct and immediate risk to public health. • Considers ‘reactive enforcement’ would also be unlikely as consumers would be unable to determine if a product contained less or more iodine than that mandated. • Comments that within Victoria it is expected that monitoring of iodine levels in food would be a low priority for Local Government surveillance programs, and hence would rely on good manufacturing practice within industry. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Suggests that the communication and education strategy be clear for each State, including consideration of the potential geographical differences in iodine levels/intakes within each state. This would require further studies to be completed in States thought to be replete to discount geographical anomalies. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • Considers the dietary modelling undertaken by FSANZ to determine the appropriate fortification level is ‘fundamentally flawed’, and does not enable an accurate and valid determination of population based risk assessments: <ul style="list-style-type: none"> - Incomplete or data not available on current intakes of iodine in the Australian population from food, supplements, water or via commercial cleaning processes; - No accurate data on the intake of salt; - The proposed food vehicles are based on the last 1995 NNS; - Assessments of fortification on replete states were based on water even though it is unclear what sources/factors are contributing to the iodine status in those states, and that the small number of water samples used were not representative of available water; and - The proposed level of fortification is different to the level modelled, and therefore the proportion of people exceeding the UL is underestimated. • Requests the collection of a range of ‘useful’ baseline data, to assist in the selection of the most appropriate food vehicles and level of fortification. <p><i>Alternative option</i></p> <ul style="list-style-type: none"> • Victoria proposes the following alternative for mandatory fortification with iodine: <ul style="list-style-type: none"> - mandatory fortification using iodised salt only in those bread, breakfast cereals and biscuits that are consistent with the national dietary guidelines; - voluntary permissions for the use of iodine in salt and reduced sodium mixtures to be allowed for discretionary purposes only; and - the level of fortification to be in the range of 15-35 mg iodine per kg salt for both mandatory and voluntary fortification permissions.

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<p>NSW Health & NSW Food Authority Australia Bill Porter & Stephen Corbett</p>	<p>Generally supports Option 2 – Mandatory fortification with iodine</p> <p>Generally supports the preferred approach, and agrees with recommendations that any change must be accompanied by appropriate education programs and a monitoring framework.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Provides a summary of the forecasted impact of mandatory iodine fortification, and concludes that the proposed addition of iodine to salt in NSW is likely to reduce the risk of sub-clinical hypothyroidism, and in the longer term the risk of overt hypothyroidism in their community. • Considers the possible adverse health affects were adequately addressed in the report, and agrees these can be addressed through community education and monitoring. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Notes that the level of fortification for the voluntary permission of salt iodisation will need to be revisited if biscuits are removed from the list of food vehicles. • Considers the option of removing biscuits from the foods to be fortified has some merit in view of the problems associated with imports, clarifying the interface between biscuits, cakes, pastries and confectionery, and the limited ability to make iodine claims on biscuits. • Notes the argument raised by Tasmania that removing biscuits would result in only a marginal improvement in iodine intake in that State. • Suggests that if it is not feasible to substitute biscuits with another food, such as potato chips, then the shortfall could be addressed by increasing the iodine level in salt for the remaining food vehicles. • Notes there are some indications from industry normal salt will be replaced with iodised salt in all products, and the potential for this to increase the iodine intake in some individuals more than intended. • Notes that preliminary advice from the bread industry confirms use of iodised salt does not pose any technical difficulties, however industry has not generally conducted storage trials to determine the stability of the iodine over the storage life of the product. • Appreciates that the mandatory fortification of iodine to table salt alone, as adopted by other countries, may miss significant sections of the population. • Considers the experience in Tasmania supports a mandated rather than a voluntary approach to iodine fortification. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Considers it inequitable to require all biscuits to use iodised salt in lieu of normal salt, but only allow some biscuits to make a claim (i.e. as allowed under Standard 1.3.2 for biscuits containing not more than 20% fat and not more than 5% sugars). • Notes that an entry in the Nutrition Information Panel for iodine would be regarded as a claim and would be subject to the limitations of Standard 1.3.2. • Considers on balance that the inclusion of iodine in the Nutrition Information Panel is warranted and requests that FSANZ reconsiders its position on this matter. <p><i>Trade</i></p> <ul style="list-style-type: none"> • Considers the report may understate the significance for imported products such as biscuits into Australia, and assume that this issue will be addressed in the WTO notification.

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	<p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> Notes that manufacturers could use the current voluntary permissions and add iodised salt to bread, biscuits and breakfast cereals at a higher level up until the end of the transition period, which could impact on the assessment of health risk from increased iodine intake. Considers that it may be worthwhile to consider limiting the addition of iodised salt only to foods with specific permissions, i.e. bread, breakfast cereal and biscuits. This would simplify the monitoring framework and decrease the risks of excessive intake. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Considers the categorisation of biscuits will be difficult, and may have significant implications for enforcement by the jurisdictions and the monitoring framework. Anticipates there will be difficulties in measuring outcomes in relation to iodine contents of fortified foods as there will be no specified range of iodine in the end product. Instead the iodine level will correspond to the level of added salt and be subject to losses during processing and storage. Notes that to determine iodine levels, where they are not declared, it will be necessary to rely on analysis of formulations on a case by case basis. Notes that end product levels are not readily enforceable without determining the level of added salt as opposed to total salt, providing allowance for iodine degradation over the life of the product, and differentiating between added salt and salt present by carry-over from another ingredient. Notes that both monitoring and enforcement will require significant resources, which they consider have not been allowed for in this process. Considers a combined monitoring approach for a variety of additives should be considered, rather than iodine alone, and in particular efficiencies be sought in relation to biological and nutritional monitoring. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Considers communication and education initiatives an essential component of the Proposal, however there needs to be a commitment for funding. To be undertaken for both the public and for the food industry, including importers and small businesses. Strategies should take into account the sectors of the population that do not eat bread or breakfast cereals, such as coeliacs and some ethnic groups.
<p>New Zealand Food Safety Authority (NZFSA) New Zealand Carole Inkster</p>	<p>Partial support for the preferred approach</p> <ul style="list-style-type: none"> Partial support for the preferred option, but does not support the inclusion of biscuits or breadcrumbs in the Standard. Committed to mandatory fortification as the most effective option for addressing iodine deficiency across the population at this time. Submission sets out the views of the NZFSA, the Ministry of Health, the Ministry of Foreign Affairs and Trade, the Ministry of Economic Development and the Ministry of Consumer Affairs. <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> The proposed level of iodine fortification is limited by concerns about the number of 1-3 year olds expected to exceed the UL. Fortification may be safe for children at higher levels than currently proposed, and higher levels would achieve higher iodine intakes for pregnant and breastfeeding women.

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	<ul style="list-style-type: none"> • Highlights uncertainties around the intake of iodine in children aged 1-3 years, and subsequently the importance of monitoring. • The Ministry of Health is generally supportive of the Proposal, noting the beneficial health outcomes. However, expresses concern regarding potential adverse health outcomes, particularly in relation to young children exceeding the UL. • The Ministry of Health considers pregnant and breastfeeding women are at higher risk of inadequate intakes compared to the total population, and notes that the proposed approach does not meet the RDI for iodine for these women. Agrees that a single nutrient supplement of 100-150 mg of iodine should be made available as a registered medicine, and the iodine level in the supplement needs to be consistent between Australia and New Zealand. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Supports the iodisation of salt as the preferred vehicle for addition of iodine to food, as this is in line with international recommendations, and international experience has shown this to be technically feasible. • Supports the option of requiring salt in cereal-based foods to be iodised rather than all processed foods, as it achieves an acceptable outcome in terms of increasing iodine intakes of the general New Zealand population, and it places fewer burdens on industry. • Considers that by not requiring salt to be iodised in all processed foods, this allows choice for those who wish to avoid iodine fortified foods. • Considers it important that it is made clear at Final Assessment that all cereal-based products included in the Standard, including unpacked bread, made with salt as an ingredient must use iodised salt. • Notes that there are likely to be further reductions in the salt content of processed foods, as promoted by Government and public health initiatives, and therefore the level of fortification may need to be reconsidered in the future if reductions in the salt content of processed foods mean that the population does not reach expected intakes of iodine. • Recommends that biscuits, both sweet and savoury, be excluded from the Standard for the following reasons: <ul style="list-style-type: none"> - many biscuits are high in fat, salt and sugar and the promotion of regular consumption of such foods is not consistent with the food and nutrition guidelines; - the dietary modelling indicates that biscuits contribute only a minimal amount of iodine; and - significant volumes of biscuits are imported into New Zealand from outside Australia and requiring iodised salt in these would pose significant problems. • Considers the range 20-45 mg of iodine per kg of salt reasonable. However, suggests the Standard should specify that the target should be 30 mg iodine per kg of salt so that this is used as the mid-range figure and becomes the average level of addition across the food supply. • Requests that FSANZ considers prescribing the term ‘iodised salt’ when used in the ingredient list. Does not support the use of other phrases such as ‘salt with added iodine’. • Recommends that consideration be given to removing breadcrumbs from mandatory requirements, for trade purposes.

SUBMITTER	SUBMISSION COMMENTS
	<p data-bbox="448 255 635 284"><i>Labelling/claims</i></p> <ul data-bbox="448 304 1390 423" style="list-style-type: none"> • Recommends that iodine content claims be prohibited for all foods, as the purpose of the Proposal is to add iodine to the food supply and as a consequence of this they do not want claims about iodine on foods that are not consistent with the food and nutrition guidelines. <p data-bbox="448 443 517 472"><i>Trade</i></p> <ul data-bbox="448 492 1390 1223" style="list-style-type: none"> • Notes trade implications for food produced in New Zealand for export as currently these foods must comply with the Food Standards Code. Therefore, all foods covered by this Proposal would contain iodised salt, which could be trade positive or trade negative depending on the receiving country's position on foods with added iodine. • Understands that unbaked doughs and bread mixes for export are not required to comply with the Food Standards Code, as they do not meet the definition of bread as they are not baked. • Notes the export of crumbed meat and fish products is an issue, and recommends removing breadcrumbs from the mandatory requirements. • The Ministry of Foreign Affairs and Trade requests that every effort is made to minimise the number of products requiring fortification to minimise trade implications. • Notes that New Zealand imports approximately \$150 million per annum of bread, breakfast cereals and biscuits, with over 75% of these imports coming from Australia. • Notes the trade impacts on those products imported from outside Australia, particularly for biscuits. • Notes that if the regulation is challenged by trading partners, New Zealand will need to demonstrate that it is the least trade restrictive measure to address iodine deficiency. <p data-bbox="448 1243 719 1272"><i>Current salt permissions</i></p> <ul data-bbox="448 1292 1390 1375" style="list-style-type: none"> • Supports the retention of iodised salt for discretionary use as it is a source of iodine for consumers with low consumption of cereal-based foods, and also if removed, consumers may find this a confusing and contradictory health message. <p data-bbox="448 1395 995 1424"><i>Removal of voluntary permission of salt iodisation</i></p> <ul data-bbox="448 1444 1374 1505" style="list-style-type: none"> • Supports retaining current voluntary permissions, but the potential increase in the range of foods containing iodine must be monitored by FSANZ. <p data-bbox="448 1525 624 1554"><i>Implementation</i></p> <ul data-bbox="448 1574 1382 1693" style="list-style-type: none"> • Recommends that consideration be given to the inclusion of separate but mirror standards in the Food Standards Code for Australia and New Zealand, to ensure that should Australian jurisdictions require further work on the proposed Standard that implementation in New Zealand can proceed. <p data-bbox="448 1713 751 1742"><i>Monitoring and compliance</i></p> <ul data-bbox="448 1762 1390 2027" style="list-style-type: none"> • Considers it imperative that monitoring, especially of at risk groups, is in place prior to implementation, and that the level of fortification is reviewed in relation to the outcomes of monitoring, to ensure that the program is effective and safe. • Acknowledges that monitoring is outside FSANZ's mandate and is the responsibility of the New Zealand Government, however believes that FSANZ plays a vital role in determining the overall monitoring framework. • Notes that the Ministry of Health will monitor the health and nutritional status of the population and NZFSA will monitor the food supply.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> • Considers it is important that a monitoring system is in place prior to fortification with iodine. • Notes monitoring activities likely to be conducted in New Zealand are: <ul style="list-style-type: none"> - National Nutrition Surveys; - Additional surveys on iodine status of specific groups e.g. pregnant and breastfeeding women, and children; - Involvement of the primary care sector, particularly for the early detection of iodine-induced hyperthyroidism; - The New Zealand Total Diet Survey; - Continuation of the Manufactured Food Database; and - Enforcement activities e.g. though proposed Food Control Plans. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> • Will consider the communication strategy when it becomes available, and will work with FSANZ to implement the necessary communication to New Zealanders. <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> • Agrees with the conclusion that there is a large degree of uncertainty surrounding the calculation of net benefits for the Proposal. • Disagrees with the suggestion that it may be worth considering an alternative proposal to deliver the health outcome, and is committed to mandatory fortification as the most effective option for addressing iodine deficiency across the population at this time. <p><i>Assessment of iodine status</i></p> <ul style="list-style-type: none"> • Believes that the assessment of the iodine status of New Zealanders in the Draft Assessment Report accurately reflects the mild iodine deficiency of the general population. • Notes the thyroid hormone results from the 2002 National Children's Nutrition Survey reported by Skeaff in 2005 confirms FSANZ's assessment. • Cites results from the recent Thyromobile and Iodine in Pregnancy study, which indicates that pregnant women as a group are moderately iodine deficient. <p><i>Dietary modelling</i></p> <ul style="list-style-type: none"> • The Ministry of Health has concerns about information on the iodine intakes for 1-3 year olds derived from the simulated diets, which suggests that a portion of 1-3 year olds is exceeding the UL. Notes that these results are not consistent with iodine status results for 230 South Island children aged 6-24 months which indicate mild iodine deficiency. • Requests FSANZ review the upper limit of iodine in Formulated Supplementary Foods for Young Children (FSFYC), as recently approved under Application A528. Does not agree with the data used in the dietary exposure assessment for children aged 1-3 years, noting that one serving per day is used. Also considers that the risk assessment should be conducted on the worst case scenario i.e. toddlers consuming two or three servings per day of FSFYC. • Considers that the number of young New Zealand children exceeding the UL for iodine would be greater than stated in the Draft Assessment Report. • Provides results of dietary modelling for New Zealand children as conducted by the University of Otago. The results indicate that a proportion of children aged 5-14 years are unlikely to meet the EAR for iodine following mandatory fortification.

SUBMITTER	SUBMISSION COMMENTS
	<ul style="list-style-type: none"> Notes that the discretionary salt intake of children used in the Proposal is likely to be an overestimate, and that discretionary salt will still be subject to voluntary fortification, thus reducing the potential exposure to iodine.
<p>Environmental Health Unit of Queensland Health Australia Gary Bielby</p>	<p>Supports a Modified Option 2 – Mandatory iodine fortification</p> <p>Supports a modified Option 2. Does not support the addition of iodised salt to biscuits.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> Concern about the lack of detail on how iodine will be made available to those who do not eat bread, bread products, breakfast cereals and salt. For example, those consuming a low carbohydrate diet, those consuming a low iodine diet for medical reasons, those ethnic groups who mainly consume other sources of carbohydrate. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> Recommends labelling of iodine be mandated in the nutrition information panel. Notes that the proposed mandatory fortification will not ensure adequate intakes for pregnant and breastfeeding women, and this would allow these consumers to calculate their iodine intake from fortified foods to inform their decision regarding the necessity for and strength of iodine supplements. Recommends that highly sugared breakfast cereals not be able to make nutrient content claims about iodine. <p><i>Current salt permissions</i></p> <ul style="list-style-type: none"> Recommends retaining voluntary permission for iodised salt as mandating the fortification of all salt would mean all processed foods would be fortified. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> Supports mandatory fortification on the understanding that: <ul style="list-style-type: none"> jurisdictions commit to the financial and other obligations of ensuring adequate monitoring and surveillance of dietary intake, nutritional status and health outcomes; adequate lead in time is allowed for the collection of baseline data, particularly up-to-date dietary intake data; and commitment to regular monitoring needs to be agreed upon by jurisdictions before implementation. Seeks clarification on the costs of monitoring and surveillance activities, noting that information given in the Draft Assessment Report appears to differ substantially. <p><i>Communication and education</i></p> <ul style="list-style-type: none"> Seeks clarification on the proposed communication and education strategy, including what it entails, who are the target groups, what is the role of jurisdictions, what is the approximate cost, how will GPs and other health professionals be informed, and is it more than a brochure and web page? <p><i>Cost/benefit analysis</i></p> <ul style="list-style-type: none"> Concern that the impact analysis does not include the costs to government of health promotion, education, monitoring and surveillance, and notes that it cannot be assumed that these activities are already happening in all jurisdictions. <p><i>Dietary modelling</i></p>

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	<ul style="list-style-type: none"> • Concern about the lack of baseline nutrient intake data with which to compare future monitoring and surveillance activities. • Concern about the lack of data on dietary supplement and discretionary salt intake. • Concern whether the National Iodine Nutrition Study had adequate representation of Indigenous groups and whether it is representative of the number of regional variations in iodine intake that may exist in a large decentralised state like Queensland.
<p>South Australia Department of Health Australia Joanne Cammans</p>	<p>Supports Option 2 – Mandatory fortification with iodine</p> <p>Supports the preferred approach for mandatory fortification with iodine, however raises some issues for consideration at Final Assessment.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Concerned that the level of iodine proposed will deliver insufficient iodine to those populations who are deficient, as discussed at the Jurisdictional Forum Teleconference in September 2006. It was considered that there exists more of a health risk by not delivering sufficient iodine than if iodine levels surpassed upper limits. • Supports consideration of increased iodine fortificant levels and/or ongoing monitoring, to establish good data on the outcomes of the program. • Notes the need for young children with limited intake of processed foods and women who consume little of the proposed food vehicles to be specifically targeted with education campaigns. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • It appears likely that manufacturers will use iodised salt in <i>all</i> products, not only those selected food vehicles. Therefore, there is potential for oversupply of iodine in the food system. Notes that this should be considered further at Final Assessment. <p><i>Labelling/claims</i></p> <ul style="list-style-type: none"> • Notes that the proposed Standard would regulate the level of iodine in iodised salt and not in food. There is potential for manufacturers to add excess salt/iodine to make a health claim. They recommend an upper limit be imposed for iodisation. <p><i>Implementation</i></p> <ul style="list-style-type: none"> • Asks if manufacturers can consistently fortify salt with iodine within a prescribed range. <p><i>Monitoring and compliance</i></p> <ul style="list-style-type: none"> • Considers ongoing monitoring of iodine levels in salt and processed foods, and via blood and urine testing, is imperative to the success and evaluation of the fortification program. • Supports the need for a coordinated monitoring program post fortification. • Considers the role of monitoring should be referred to the Ministerial Council/Food Regulation Standing Committee for consideration of a coordinated approach.

SUBMITTER	SUBMISSION COMMENTS
<p>Department of Health and Human Services, Tasmania Australia Judy Seal</p>	<p>Supports Option 2 – Mandatory fortification with iodine</p> <p>Supports the proposed approach for mandatory fortification with iodine, however expresses strong preference for mandatory USI.</p> <p><i>Safety and efficacy</i></p> <ul style="list-style-type: none"> • Comments that voluntary fortification has not been considered a realistic regulatory response to this important public health issue. • Notes that while some short term modest improvement in iodine status was achieved in Tasmania with an interim voluntary fortification program at a population level, they have concern about the reach of the program to sub-population groups, the sustainability of the program, and the ongoing costs of maintaining industry commitment. • Concerned that the proposed option, which involves a reduced level of salt iodisation, may result in a reduction in iodine intake in Tasmania compared with current intake under their interim voluntary program. • Dietary modelling conducted by Tasmania shows that the proposed approach will only achieve marginally more (i.e. 6 µg iodine per day) than the current Tasmanian interim program. • Considers the proposed approach will be inadequate to meet population iodine needs and the range of foods will need to be extended in the future. • Notes that the intention is to achieve a marginal increase in iodine, and that the needs of pregnant and lactating women are unlikely to be met without additional supplementation. • Comments on the apparent reluctance to increase the level of iodine fortification in Australia beyond what has been proposed so as to minimise the proportion of individuals who exceed the UL, particularly young children. • However, notes that the ULs do not <i>represent absolute thresholds for toxicity</i> and there is a <i>wide margin of safety associated with the ULs</i> and that intakes in young children above the UL are <i>unlikely to represent a health and safety risk</i>. • Notes advice from their Thyroid Advisory Committee that there is a risk that cautious language about exceeding the UL implies toxicity (without good justification) and this may lead to misunderstanding by the general public, and may compromise the fortification program. <p><i>Food vehicle</i></p> <ul style="list-style-type: none"> • Disappointed that mandatory USI has not been supported as the preferred option. Believes USI would be more effective, simplify communication with manufacturers, simplify enforcement, simplify the monitoring of food composition, result in a more sustainable solution and be consistent with international recommendations. <p><i>Voluntary fortification</i></p> <ul style="list-style-type: none"> • Concerned that voluntary permissions lead to uncertainty about the level of iodine in food in Australia and New Zealand, noting public health expert advice to AHMC. • Notes that until the proposed Standard is fully implemented it will be hard to predict how many additional foods will contain iodised salt using the voluntary permissions. • Notes the German experience combining voluntary and mandatory iodine fortification has been criticised, with the conclusion that without appropriate legislative measures to enforce USI the insufficient iodine status in Germany could become a never-ending story.

SUBMITTER	SUBMISSION COMMENTS
	<p data-bbox="448 271 751 300"><i>Monitoring and compliance</i></p> <ul data-bbox="448 320 1398 651" style="list-style-type: none"> <li data-bbox="448 320 1398 405">• Notes that appropriate monitoring needs to be implemented to complement the program, including health outcomes, nutritional status, nutrient intake, food composition and industry compliance. <li data-bbox="448 427 1398 517">• Considers a urinary iodine survey of school children should be conducted during 2008, to compare baseline data and determine if the proposed mandatory requirements need to be extended to a greater range of processed foods. <li data-bbox="448 539 1398 651">• Considers the monitoring of iodine status and iodine intake should be integrated into a broader nutrition monitoring and surveillance system so that monitoring is ongoing and sustainable, and the information could be used to refine the mandatory fortification program in the future.