

CONSIDERATION OF MANDATORY FORTIFICATION WITH IODINE FOR AUSTRALIA AND NEW ZEALAND

SUMMARY OF SUBMITTER COMMENTS TO PROPOSAL P230 ISSUES PAPER

December 2007

Summary of Submitter Comments

In May 2007, FSANZ, received **48** responses to the Issues Paper for Proposal P230 – Consideration of Mandatory Fortification with Iodine, outlining the proposed changes under consideration for Final Assessment. The paper addressed the major themes that arose from submissions to the Draft Assessment and additional work undertaken. Six responses were received from government, 17 from industry, 19 from public health and academia and six from interested individuals and consumer groups. A summary of submitter comments is provided in the table below.

The Issues Paper outlined that at Draft Assessment, FSANZ proposed the mandatory replacement of salt with iodised salt in bread, breakfast cereals and biscuits. However, at Final Assessment, FSANZ proposed removing biscuits and breakfast cereals as food vehicles. The Issues Paper outlined the following proposed approach:

- the mandatory replacement of salt with iodised salt in bread as the preferred approach to address the re-emergence of iodine deficiency in Australia and New Zealand, with a salt iodisation range from 35-55 mg of iodine per kg of salt.
- retaining the *voluntary* permission for iodine in iodised salt and reduced sodium salt but adjusting it from the current range of 25-65 mg per kg to 35-55 mg per kg, to make it consistent with the mandatory requirement.

Key Issues Identified from Submitter Comments

1. Regulatory options

The majority of government stakeholders, public health professionals and consumer groups indicated qualified support for the Proposal. There was general acknowledgement among stakeholders on the inability of the Proposal to fully meet the substantially increased iodine requirements of pregnant and lactating women, and breast-fed infants. The need to address deficiency in non-bread eaters was also raised.

Some public health stakeholders viewed the current Proposal as an initial step and only part of the solution to addressing the current iodine deficiency. They noted that mandatory fortification is preferable to voluntary fortification as it provides greater certainty, sustainability, equity, and reach. However, a number of public health stakeholders believed that Universal Salt Iodisation (USI) would provide higher iodine intakes for pregnant and lactating women. Consumer organisations were generally supportive of the mandatory fortification option but noted the need for effective monitoring and education/health promotion strategies.

Most industry stakeholders opposed mandatory fortification, citing the increased regulatory burden, removal of consumer choice, and trade impacts as reasons for their opposition. They considered mandatory fortification is not the most effective public health strategy, preferring voluntary fortification, in conjunction with the promotion of iodine as a processing aid.

A Memorandum of Understanding (MoU) and an education campaign are also an integral part of this alternate approach. Industry considered international studies and the voluntary Tasmanian experience demonstrate the success of voluntary fortification in decreasing iodine deficiency.

Industry and some government stakeholder also argued that the current proposal is inconsistent with the Australian Government's Best Practice Regulation Requirements, and that to meet these requirements, all strategies for addressing iodine deficiency would need to be evaluated.

2. Food vehicles

Most stakeholders supported the decision not to include breakfast cereals or biscuits in the current mandatory fortification proposal. Some, however, expressed concern regarding the medicalisation of the food supply if bread is fortified with thiamin, folic acid and iodised salt.

Many considered that the addition of iodine should not legitimise the consumption of unhealthy foods and supported the addition of iodine to foods consistent with nutritional guidelines. Public health stakeholders expressed concern about the wide variation in salt and therefore iodine content of different bread, in particular, in low salt bread. Some expressed concern with salt as the food vehicle.

Industry stakeholders raised concern that many women in the target group are low bread eaters. Stakeholders identified the need to explore direct addition of iodine or additional food vehicles such as breakfast cereals, milk and water. However, others did not support direct addition of iodine to bread in Australia due to inadequate equipment and resources of small, in-store bakeries.

3. Safety and efficacy

Many stakeholders commented that the substantially increased iodine needs of pregnant and breastfeeding women, and therefore breast fed infants, were not fully met by the Proposal. They also noted that those who do not eat bread with iodised salt will not benefit from iodine fortification and considered that FSANZ should consider how iodine intake could be increased in these groups.

A small number of consumers, with a history of thyroid disorders, expressed concern about potential adverse effects from increased amounts of iodine in the food supply. These individuals viewed mandatory fortification as an infringement of their rights. They considered that there was limited data available on the adverse effects of mandatory fortification or on the number of people affected by hyperthyroidism. Government stakeholders requested age-related information on the extent of iodine deficiency in Australia.

Some health professional stakeholders questioned the relevance of the currently established Upper Level of Intake (UL) for iodine in young children. They noted that the UL was extrapolated from adult data on a metabolic body weight basis, with no regard to the relatively greater iodine requirement in early childhood. FSANZ was urged to ask the National Health and Medical Research Council (NHMRC) to consider reviewing the UL for iodine in children.

Public health and government stakeholders also recommended FSANZ review the availability of appropriate supplements, including pregnancy supplements containing iodine.

4. Consumer choice

Consumer choice was a major reason given by many stakeholders who did not support mandatory fortification. Organic, unleavened or gluten-free bread was not considered to provide 'real' choice. Some expressed the view that excluding organic bread from mandatory fortification created inequity, as these products are more expensive than non-organic bread.

5. Trade

Some industry stakeholders expressed concern about the potential impact of mandatory fortification on imports and exports, especially on crumbed products exported to Japan.

6. Labelling and Claims

Some consumers and groups expressed concern that using iodised salt could encourage manufacturers to increase salt levels to make health claims. Mandatory requirements should not discourage the food industry from reducing the amount of salt in bread.

A number of public health and consumer groups supported including iodine in the nutrition information panel (NIP). In contrast, industry did not support the inclusion of iodine in the NIP. There was general agreement for the inclusion of 'iodised salt' in the ingredient list to inform those wishing to avoid iodine fortified foods.

Some public health professionals did not support the use of nutrition and related claims on fortified foods. However, industry stakeholders requested a review of the current restrictions on iodine content claims and supported the development of a general level health claim. Industry considered that the proposed wording of the current health claim statement was not meaningful for consumers and put forward alternate wording.

7. Implementation and Transition Period

The majority of stakeholders supported the proposed two-year implementation period. Industry sought clarification of the definition of bread and the requirement for fortification of breadcrumbs, seasonings and toppings and associated labelling provisions. Government stakeholders raised concern regarding the lack of resources for Local Government Agencies who will have responsibility for enforcement activities.

Industry questioned the feasibility of iodised salt use by a very small number of bakeries that use a brining system to add salt to bread. It was recommended that FSANZ investigate this matter further. One major salt manufacturer reported that their quality control data indicated that the salt iodisation range of 35-55 mg of iodine per kg of salt could not be achieved 100% of the time. They requested the current range of 25-65 mg/kg be maintained.

There was general support among stakeholders for the exemption of 'organic' bread, although some questioned the lack of a FSANZ definition of 'organic' or 'heavy health bread'. New Zealand recommended a more specific provision to exempt bread made under or aligned with an organic certification agency to assist with compliance and enforcement.

New Zealand industry requested clarification of the definition of 'natural' to ensure the addition of iodised salt to these products would still allow this claim.

Industry stakeholders requested sufficient time to align packaging changes to minimise the write off of existing stock. Some government stakeholders recommended a stock-in-trade provision to allow industry to manage content and label changeover within the phase-in period. Development of a Users' Guide was also supported.

8. Costs

A number of stakeholders considered the lack of quantitative estimates for ascertaining the health benefit of the Proposal makes it difficult for FSANZ to rationalise the costs imposed by the proposed fortification. One public health stakeholder considered that the economic cost of a decrease in IQ caused by iodine deficiency had been underestimated in the report. Industry recommended FSANZ commission a cost effectiveness analysis which addresses restriction of consumer choice, potential adverse effects, costs of monitoring intake and health outcome, and complementary policies necessary, but outside the purview of FSANZ. Some stakeholders questioned the industry costs included in the report. The risk of litigation and possible compensation for losses by manufacturers as a result of mandatory fortification were raised by a small number of stakeholders.

Some individuals with thyroid related medical conditions noted that mandatory fortification would increase the cost of monitoring their condition through extra medical consultations, pathology tests and time spent attending appointments. They also considered that these costs and purchasing more expensive non-iodised alternatives had not been taken into account in the cost benefit analysis. Those with low socio-economic status or who live in rural areas would be disadvantaged by the proposed mandatory fortification approach.

Government stakeholders suggested FSANZ include the costs of introducing further regulatory changes if the current proposal proves unsuccessful e.g. increasing iodine concentration in salt, or trade impacts arising from using iodised salt in breakfast cereals.

9. Monitoring and Compliance

There was general agreement on the need for an effective and integrated Trans-Tasman monitoring program to assess iodine in the food supply and the impact of iodine fortification on the population. While acknowledging that monitoring is not wholly within FSANZ's remit, many comments noted the lack of a national framework and a firm commitment to fund and coordinate such a program by the Commonwealth, state and territory governments. The collection of baseline data on food and water was identified as a priority, along with the need to monitor the impact of salt reduction programs.

Stakeholders supported monitoring at-risk individuals to determine any increase in the incidence of iodine-related conditions. They also supported monitoring groups who do not eat fortified bread. Some industry stakeholders recommended a sunset provision to enable a review of compliance, safety and efficacy data for mandatory fortification.

10. Communication and Education

Most stakeholders acknowledged the need for an effective communication and education strategy, including at-risk groups. Several stakeholders expressed concern regarding inconsistent messages, as consumers are encouraged to moderate salt intake.

Public health professionals recommended integrating advice to pregnant women, for example, including information on iodine, folic acid and mercury, supplements, and advice for non-bread eaters. Messages should be developed in collaboration with target groups. Many stakeholders supported collaboration between industry, government, medical, health and consumer organisations to develop and implement the strategy.

11. Dietary Intake Assessment

Some industry stakeholders expressed concern regarding the lack of data on bread consumption (total consumption and by population group), estimates of total salt consumption and the iodine content of Australian and New Zealand foods. Government stakeholders requested additional dietary modelling scenarios to compare outcomes with those presented at Draft Assessment. They also requested information on the iodine content of infant formulas. Industry stakeholders questioned the dietary modelling undertaken by FSANZ on the alternate voluntary approach proposed by industry and supported reconsideration of this approach promoting iodine as a processing aid.

12. Consistency with Policy Guidelines

A number of stakeholders who did not support the preferred option, stated that they believed it was inconsistent with the FSANZ Act and the Policy Guidelines on fortification. They specifically questioned whether mandatory fortification is the most effective public health strategy and requested FSANZ include a comprehensive assessment of all options for improving iodine status in the Final Assessment.

13. Voluntary Permission for Iodine in Iodised Salt

The majority of stakeholders supported retaining the voluntary permission for iodised salt as it allows industry to add iodised salt to a broader range of foods. It also provides a source of iodine for those who do not eat bread for medical or cultural reasons. Removal of this permission would restrict consumer choice and create confusion, especially in New Zealand where currently 74.5% of discretionary salt it iodised.

SUBMITTER	SUBMITTER COMMENTS
Australian Consumers'	Supports mandatory fortification with iodine, if commitment made to monitoring and evaluation
Association (ACA)	Food vehicle
Australia	Iodine should be added to foods consistent with the nutritional guidelines.
Clare Hughes	The addition of iodine should not legitimise the consumption of unhealthy foods.
	The use of iodised salt should not encourage manufacturers to increase the salt level in order to make a health claim.
	The mandatory requirements should not discourage the food industry from reducing the amount of salt in bread.
	Supports the decision not to fortify breakfast cereals or biscuits.
	Safety and efficacy
	Concerns that those who do not eat bread will not benefit from iodine fortification.
	Concerns that many pregnant and lactating women will not eat enough bread to get adequate iodine.
	FSANZ should consider how iodine intake could be increased in these groups.
	Monitoring and compliance
	Monitoring should assess iodine in the food supply and the impact of iodine fortification on the population.
	Appreciates that a monitoring and evaluation program is not wholly within the scope of FSANZ responsibilities.
	Not aware of any firm commitment from the Commonwealth, state and territory governments of funding or other resources for monitoring or evaluation.
	Monitoring of individuals is essential to assess the impact of the intervention and determine if there has been an increase in the number if individuals with excessive iodine consumption.
	Communication and education
	Any intervention to fortify the food supply should be accompanied by a public awareness campaign outlining the health benefits of iodine and food sources of iodine.
	It should also explain why foods are fortified and how consumers can increase consumption of iodine through fortified foods.
Ellen McEwen	Does not support mandatory fortification with iodine
Private Australia	Considers the justification for mandatory fortification is expediency. Believes that mandatory fortification tramples on the rights of minorities for the benefit of the majority.
Austrana	Safety and efficacy
	Monitoring those people with existing thyroid conditions will not help those who have not yet been diagnosed with an overactive thyroid.
	Hyperthyroidism may be difficult to diagnose and is similar to general fatigue.
	Monitoring and compliance
	Does not include tracking the impact of iodine fortification on those at risk of hyperthyroidism.

SUBMITTER	SUBMITTER COMMENTS
	Communication and education
	 Need to educate those in retail and hospitality sector about the needs of those with hyperthyroidism. Difficult to select foods without iodine fortification, especially if uptake of voluntary permissions is widespread.
	Costs
	There would be increased costs for those with hyperthyroidism:
	- extra doctors consultations;
	- more pathology tests;
	 time lost from work and family sitting in doctors' waiting rooms;
	 extra cost of organic or yeast free bread; and
	- those with Graves disease will be forced to choose from a limited range of bread.
	The above will disadvantage those with low socio-economic status and /or living in rural areas.
Alison Joy	Supports mandatory fortification with iodine
Mace Private	Concerns about the reliance on iodised table salt when many health conscious people are using less table salt.
New Zealand	Believes that mandatory iodisation may assist in correcting inadequate iodine status in the South Island of New Zealand.
Peter	Preference not specified
Chamberlain	Believes the alternatives to mandatory fortification are:
Private	- a major public education campaign, which has worked in the past; and
Australia	 voluntary fortification of bread or other staple foods.
	Safety and efficacy
	Many people are concerned with the level of sodium in their diet. They may choose organic bread and therefore miss out on iodisation.
	States there are many people who will be eating bread that is not iodised i.e. bread without yeast or organic bread.
	No attempt has been made to quantify the numbers of people who will miss out on iodine fortification. Many more people are eating organic bread now.
	Monitoring and compliance
	• FSANZ should monitor those people who do not eat bread that is fortified with iodine.
Patricia St	Does not support mandatory fortification with iodine
John Private	Mandatory fortification should only be undertaken when the deficiency is severe and other alternatives have been tried and failed.
New Zealand	Safety and efficacy
	A 'significant proportion' of the population has autoimmune thyroid disease and would be adversely affected by fortification of bread with iodine.
	Iodine fortification may create (new) thyroid problems in the population.
	Adequate alternatives must be provided for those who will be adversely affected by iodine fortification.
	Access Economics said data presented in draft proposal was based on unconvincing and

SUBMITTER	SUBMITTER COMMENTS
	uncertain evidence.
	 Clinical effects of mild iodine deficiency are uncertain but cannot result in iodine deficiency diseases which are only a result of severe iodine deficiency, starvation and lack of variety of food choices. Even as population iodine status decreases to marginal 'there is no clear evidence of impaired intellectual function or growth retardation' (referenced in comments).
	• FSANZ's claims that increased motor skills, cognition skills and concentration would ensue from iodine fortification are misleading, as the benefits are unquantifiable (Access Economics).
	 High iodine intakes are undesirable especially for children under eight whose safe maximum intake is half that of adults.
	 Approach to improve iodine status should be cautious to avoid iodine induced hyperthyroidism (IIH).
	• Data is lacking on the effects of IIH.
	 Many health problems identified in the Access Economics report are ignored in the Issues Paper.
	• There is no Australian or New Zealand data on adverse effects of Proposal.
	• The majority of children are not iodine deficient and eat more bread than adults.
	• No data on the number of people affected by hyperthyroidism. Community surveys show an incidence from 7-22%. A larger proportion can have latent or subclinical disease, and up to 36% of adult women are estimated to have thyroid antibodies. The Proposal used data from the Wickham Survey showing 9% could have hypothyroidism or hyperthyroidism.
	 Thyroid medications are increased with caution, as increasing thyroid hormones can cause sudden death from heart failure in those with thyroid and heart conditions.
	• The problem of insufficient iodine intake for pregnant and lactating women is outside the scope of this Proposal and it should be for health professionals to assess the need for supplementation.
	• Many thyroid problems of pregnancy are not simple thyroid deficiency but are the result of latent thyroid disease.
	 Believes the recent problem with insufficient dietary iodine stems from increased cost of fish and milk, decreased consumption of table salt, decreased awareness of the importance of adequate dietary iodine and an increase in the consumption of soy products which are goitrogenic.
	• Does not know whether current iodine status reflects a steady state or is decreasing over time.
	Implementation
	• Considers clarification is needed on definitions for organic bread and bread.
	• Questions if aerated frozen dough will be exempt.
	 A New Zealand bakery does not use a yeast leavened process. If their product is not defined as bread they will maintain their markets and have a cost advantage over competitors, however if defined as bread this will impact on trade especially to USA and Japan.
	• Suggests bread from small niche bakeries should not be iodised to give more consumer choice, as this would only affect 5% of the market.
	Concerns that producers may increase the level of iodine in bread to make a good source

SUBMITTER	SUBMITTER COMMENTS
	claim, which would lead to an increased level of salt in bread.
	Considers health warnings on the label will be necessary.
	Costs
	Access Economics report refers to a lack of data on health costs of the Proposal.
	Cost estimates for monitoring population health were not covered.
	FSANZ need to include the increased costs for those with autoimmune disease for alternative organic bread.
	Monitoring and compliance
	Concerns that FSANZ does not propose to monitor iodine in bread, only in salt and the use of iodised salt.
	Concerns that FSANZ considers monitoring the effects of iodisation on population health as a government responsibility.
	Dietary modelling
	Data used is poor and old (Australia 1995 and New Zealand 1997 National Nutrition Surveys). No urine excretion tests were carried out.
Susan	Does not support mandatory fortification with iodine
McGahan	Requests that FSANZ reconsider adding iodine to bread as it is already difficult for those
Private	sensitive to iodine to avoid iodine in other foods, medications and supplements.
Australia	
Australian	Does not support mandatory fortification with iodine
Food and	Preferred approach
Grocery Council (AFGC) Australia David Roberts	Recommends a voluntary approach, led by industry, to promote iodine as a processing aid, together with the AFGC proposed Memorandum of Understanding (MoU) – attached to response. The MoU with industry for voluntary use of iodised salt in food manufacture could be applied regionally, as only some parts of Australia are iodine replete.
	• States that new evidence of the effect of voluntary fortification in pregnant women from Tasmania supports the AFGC proposal to utilise a wide variety of voluntary permissions under a MoU, and suggests that a mandatory focus on a single food vehicle will not deliver an effective outcome (referenced).
	Recommends FSANZ reconsider the likely uptake of a voluntary scheme based on the outcome from Tasmania and the likely incentive of a general level health claim.
	States that most countries where iodised salt is recommended do so under a voluntary scheme.
	Considers FSANZ has failed, on the evidence before them and contained within the expert report commissioned by Australian Health Ministers Advisory Council (AHMAC), to develop a regulatory measure that satisfies the requirements for effectiveness. Considers FSANZ has also failed to meet the requirements of the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC) for mandatory fortification. Therefore, suggests that FSANZ withdraw the Proposal.

ommends amending Standard 2.10.2 to allow iodised salt to make an iodine content in indicating the amount of iodine per 100g without this triggering the need for a full rition Information Panel (NIP). Ommends that products containing iodised salt be allowed to make iodine content ins. Siders the proposed pre-approved general level claim will not be understood by sumers. Ommends the following general level health claims be permitted: iodine is necessary for normal/active metabolism; iodine is necessary for normal/active brain development; and iodine is necessary for normal/active metabolism, growth and brain development. siders that current restrictions on vitamin and mineral claims in Standard 1.3.2 ricts the role the food industry can play in communicating iodine content to sumers. Per choice In the content of the content of the content of the content of the content to commend the content to sumers. In the content of the conte
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s not consider that exempting organic bread retains consumer choice as:
not all consumers value organic bread;
organic bread are limited in offering and availability; and
organic bread is more expensive and therefore the consumer will incur a price penalty.
ommends that FSANZ commission a cost effectiveness analysis that includes riction of consumer choice; potential adverse effects; costs of monitoring intake and th outcome; and complementary policies necessary but outside the purview of NZ, to complement the analysis that has been undertaken to date.
modelling
stions the dietary modelling undertaken by FSANZ on the proposed AFGC ntary approach, and supports reconsideration of this approach promoting iodine as a essing aid.
ntation
ommends the draft Standard be reviewed to clarify the intent that all salt added to d dough must be fortified, and therefore salt added as a topping is excluded.
ing and compliance
andatory approach is adopted, recommends that the Standard should lapse after 4 s if:
no measurement of the health effect has been undertaken; or
if measurement has occurred, such measurement fails to demonstrate a significant
improvement in health effect.

SUBMITTER	SUBMITTER COMMENTS
	 Additional comments Does not believe that FSANZ will consider issues raised by submitters in response to the Issues Paper in the same manner as if a Preliminary Final Assessment Report (PFAR) was released.
Campbell Arnott's Asia Pacific Australia Michael Depalo	 Does not support mandatory fortification with iodine Supports voluntary fortification with iodised salt or other iodine source. Safety and efficacy Concerns regarding mandatory fortification across a broad range of foods and impact on individuals with hyperthyroidism. Costs Concerns regarding underestimation of education, monitoring and enforcement costs. Trade Concerns regarding potential impact of mandatory fortification on imports and exports (especially to Japan). Consumer choice Concerns regarding impact of mandatory fortification on consumer choice. Supports removal of biscuits as a vehicle for mandatory fortification. Communication and education Supports education campaigns promoting benefits of iodine and natural sources which are consistent with nutrition guidelines. Concerns about inconsistent messages, as consumers are being encouraged to moderate salt intake.
Cerebos Foods Australia Patricia Verhoeven	Does not support mandatory fortification with iodine Supports the AFGC comments and a voluntary approach with a MoU. Reasons for not supporting mandatory fortification include: not the most effective public health strategy; removes consumer choice; exemption of organic bread does not address consumer choice (limited availability and increased cost); impact on select population groups e.g. coeliacs, those with Grave's disease; and international studies indicate voluntary fortification is successful (further supported by results of Tasmanian MoU – decrease in iodine deficiency from 21% to 10.5% in four years). Voluntary permissions Supports retention of voluntary permission for iodised salt as: demonstrated as an effective strategy internationally; retains consumer choice; allows industry to select most suitable food vehicles for target group; retail salt scan data indicates consumers are choosing more iodised salt, but this is not resulting in growth of overall discretionary salt sales;

SUBMITTER	SUBMITTER COMMENTS
	 readily available and economical source of iodine for at risk groups;
	 removal of permission would restrict consumer choice and create consumer confusion, especially in New Zealand where currently 74.5% of discretionary salt is iodised;
	- source of iodine for those with coeliac disease; and
	 allows manufacturers to legally add iodised salt to manufactured foods.
	Implementation
	• Recommends redrafting the proposed variation to Standard 2.1.1 to clearly indicate FSANZ intent that salt added to bread dough must be iodised while salt used as a seasoning on top of focaccia-style bread is exempt.
	Labelling/claims
	Food labels are an important communication medium, providing consumers with information on the iodine content of foods.
	Supports development and introduction of a general level health claim to use on a variety of foods containing iodised salt.
	 Considers FSANZ proposed wording for a health claim statement is not meaningful for consumers and proposes preferred alternate wording or modification of the FSANZ wording.
	Seeks a review of current restrictions on iodine content claims to enable food manufacturers to use food labels to communicate education messages to consumers on a wider range of manufactured foods.
	No incentive for manufacturers to voluntarily add iodised salt to products unless they can promote awareness of the importance of iodine on labels. (includes products such as gravies and gravy mixes, sauce and sauce mixes, meal bases, salad dressings and cooking aids).
	Recommends amendment of Standard 2.10.2 to permit iodised salt to make a content claim per 100g salt without triggering a NIP to encourage use of iodised discretionary salt.
	• Recommends amendment of Standard 1.3.2 to allow products containing iodised salt to make iodine content claims when a serve of the food has 10% RDI.
	No evidence to suggest that allowing health claims would impede attempts to lower the salt content of foods.
	Seeks assurance that comments regarding health claims will be considered despite being after the closing date for submissions on Proposal P293.

SUBMITTER	SUBMITTER COMMENTS
Cheetham Salt	Supports mandatory fortification with iodine
Australia	Costs
John Murray	Costs spread over a smaller volume with removal of breakfast cereals and biscuits.
	Level of fortification
	• States that the reduced fortification range of 35-55 mg/kg is unachievable and recommends retaining current level of 25-65 mg/kg (2 standard deviations).
	Advised that testing showed that calculated mean of 44 mg/kg, but standard deviation was 9.9.
	Three standard deviations is the normal measure of process capability.
	Iodine is added as milled potassium iodate (solid), but not sure of practice of other manufacturers.
Food	Preference not specified
Technology Association of	Consumer choice
Australia	Considers mandatory fortification does not give consumers a choice.
Australia	Food vehicle
Tony Zipper	Why only fortify bread which will also be fortified with thiamin and folic acid - bread will have 'medical connotations' rather than be a staple food.
	• Should other methods of addition of iodine be permitted in other foods e.g. add directly to breakfast cereals or to water, milk?
	Concerns with exempting organic and 'heavy health' (New Zealand) bread as FSANZ has not defined organic/heavy health bread.
	Consumer choice
	People who can't tolerate salt or iodine will have choice of a staple food restricted.
	Labelling/claims
	Allowing claims would be some compensation to manufacturers.
	Would crumbed foods require labelling with 'iodine' if less than 5% crumbs?
	Level of fortification
	Will salt reduced bread have a higher level of iodine fortification?
	Implementation
	A two year introduction will mean more people will suffer from iodine deficiency.
	Will gluten free bread be exempt?
	Monitoring and compliance
	Enforcement to start upon gazettal to better track fortification effects.
	Bread manufacturers will be legally liable for any associated litigation.
	Who will pay for follow-up surveys?
	Communication and education
	Will an education program on iodine lead to increased iodised salt in foods which would lead to consumption of more salt and a negative health outcome?
	Who will pay for education?

SUBMITTER	SUBMITTER COMMENTS
	Costs
	It will be difficult for manufacturers to justify the recovery of extra costs of iodisation.
	Questions if Government compensation is available for industry for this enforced action?
	Industry will have to increase analytical work to ensure uniformity etc.
Coles Myer	Does not support mandatory fortification with iodine
Limited	Preferred approach
Australia	Supports:
Kim Tikellis	Extending voluntary provisions.
	Education campaign to promote:
	 increased supplement use by target group;
	 voluntary fortification of table salt and naturally occurring sources of iodine.
	• Retaining voluntary permission for iodised table salt, but adjusting range to 35-55µg iodine per kg, consistent with mandatory requirement.
	• If mandatory fortification is the preferred option, supports fortification of salt in bread, subject to an active salt reduction policy across the food supply.
	Food vehicle
	Supports voluntary fortification of bread and milk with iodine.
	Opposes the direct addition of iodine to bread in Australia due to inadequate equipment and resources of small in-store bakeries.
	Implementation
	Suggests documentation of minimum tolerance level of 20% in the user guide to the Standard for enforcement purposes.
	Include position in relation to 'natural', 'organic' and 'no added salt' claims in the explanatory notes and user guide.
	Recommends availability of a User Guide at gazettal.
	Monitoring and compliance
	Willing to assist in the development of a national enforcement approach.
	Recommends a sunset provision for review to examine compliance, safety, dietary intake and efficacy data for mandatory fortification.
	Labelling
	Does not support iodine in the NIP for mandatory iodine fortification, but supports mandatory iodine NIP declaration for voluntary iodine fortification or foods making nutrition or health claims about naturally occurring iodine.
	Costs
	Requests consideration of cost effects of adding 'iodised salt' to the digi-labels in instore bakeries where space is limited.
	Communication and education
	Welcomes opportunities to support health promotion initiatives via range of methods e.g. in store signage, check-out screens, newsletters, catalogues, sponsored magazine articles etc.

SUBMITTER	SUBMITTER COMMENTS
Food and Beverage Importers Australia Australia A J Beaver	Does not support mandatory fortification with iodine Believes a MoU for voluntary use of iodised salt in food manufacture should be tried before mandatory iodisation is implemented.
	 Food vehicle Supports removal of biscuits as a food vehicle because of the impact on trade. Cost Concerns that the proposal will still have trade implications as some products defined as bread may be imported into Australia.
Flour Millers Council of Australia	Does not support mandatory fortification with iodine Does not support mandatory fortification with iodine as a public health strategy to address a health problem that is not shared by the whole population.
Australia Graeme Lukey	 Food vehicle With more research we will know whether the iodine deficiency would be better addressed with fortifying food or by modifying agricultural practices. Consumers should be able to choose whether or not their food is iodised.
	 Safety and efficacy Reasons for the current deficiency are not fully understood. The necessary data should be available to government for research so that best decisions can be made. Monitoring and compliance Ongoing monitoring and surveillance of dietary intake should be a key element of
Dairy Australia Australia	Does not support mandatory fortification with iodine Is unconvinced that mandatory fortification is the best solution based on available information.
Jacinta Orr	 Strongest contemporary evidence of successful population intervention in Australia is voluntary iodine fortification program in Tasmania. Unaware of information suggesting voluntary fortification is less effective than mandatory. Considers statement on the re-emergence of iodine deficiency correlating with changes in dairy industry practices distracts attention from the current determinants of poor
	 iodine status. Interested in developing innovative iodine enriched food products providing technical and safety issues are adequately addressed. Safety and efficacy No basis for prediction in Issues Paper regarding 'current levels of iodine deficiency
	 will become more serious'. Concerns regarding the lack of understanding and speculative explanations of regional differences in iodine status. Monitoring and compliance Supports appropriately resourced research via the iodine monitoring strategy to identify nutrition issues which may be masked by mandatory fortification.
	Supports assessment based on health improvement not dietary intake.

CHDMITTED	CHIDANITEED COMMENTS
SUBMITTER	SUBMITTER COMMENTS Supports a 'support along a' to received the Standard if the interpretation is not shown to be
	• Supports a 'sunset clause' to rescind the Standard if the intervention is not shown to be effective on direct health parameters.
	Labelling/claims
	Supports a general level health claim to encourage 'on pack' information about the nutritional need for iodine.
Dominion Salt	Supports mandatory fortification with iodine
New Zealand	Level of fortification
Brett Hobson	Supports an iodine range in bread salt equivalent to voluntary permissions.
	Iodine range of 35-55 mg/kg is achievable.
	Technical issues
	Iodine delivered in a brine solution – variation could be due to difference in solubility between salt and potassium iodate.
	Iodide is more soluble, but less stable - may release free iodine gas under certain circumstances.
	Technical solution may be batch mixing of iodised salt containing iodate or iodide in a brine, ensuring all solids are dissolved before use.
	Implementation
	One or two year implementation is achievable.
George	Does not support mandatory fortification with iodine
Weston Foods Australia and	Accepts that the use of iodised salt in place of non-iodised salt can be an effective strategy to address iodine deficiency in affected populations.
New Zealand Fiona Fleming	Believes that this is an opportunity for industry, Government and FSANZ to work together to achieve a successful outcome in Australia and New Zealand.
	Does not support the Mandatory Fortification Proposal as it:
	 fails to meet the policy requirements which support an assessment of alternative strategies prior to choosing mandatory fortification;
	- removes consumer choice from those products;
	 fails to be an effective solution for those with coeliac disease, those who are wheat intolerant or who do not consume wheat based products;
	 fails to be an effective solution for pregnant and lactating women who will still require a supplement to reach their needs; and
	 places the burden of responsibility of a public health issue on the food industry. Also:
	 iodine deficiency appears regionally rather than nation-wide; and
	 it is not mandatory in most countries where the salt has been adopted as the delivery vehicle for iodine.
	Preferred approach
	Strongly supports the recommendations of the AFGC to:
	 develop a MoU with industry for voluntary use of iodised salt in food manufacture;
	- promote the use of iodine as a processing aid;
	 develop and maintain an industry awareness campaign of the need to use iodised

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SUBMITTER	SUBMITTER COMMENTS
	salt in food manufacture;
	 retain the current permission for iodised salt for discretionary use, and promote substitution of iodised salt for non-iodised salt for such use;
	 develop and maintain a consumer education campaign aimed at the target population about the importance of iodine in the diet; and
	 develop and maintain a trans-Tasman monitoring program for urinary iodine status in the target population to estimate prevalence of iodine deficiency disorders (IDD).
	Also supports a clause in the legislation, if mandatory fortification is implemented, such that the Standard should lapse after 4 years if:
	 no measurement of the health effect has been undertaken; or
	 if measurement has occurred, such measurement fails to demonstrate a significant improvement in the health effect. Supports the AFGC's recommendation of an agreed MoU with industry to voluntarily use iodised salt in food manufacture because it:
	 has evidence of effectiveness in the Australian market;
	- retains consumer choice;
	 it allows for those with coeliac disease to be reached through use in non wheat based products; and
	 has been shown to be effective internationally. Also supports the AFGC recommendation to promote iodine as a processing aid (permitted for use for fruits, vegetables and eggs under Standard 1.3.3) as:
	 it is in line with national nutrition guidelines to increase consumption of fruits and vegetables; and
	 it has the potential to improve the reach of iodine to those who do not consume bread.
	Consistency with policy principles
	Requests that FSANZ adequately assess other options for increasing iodine intakes in line with the policy principles for mandatory fortification.
	Food vehicle
	Requests that FSANZ discuss the issue of fortification of the water supply as a possible way of alleviating iodine deficiency with the appropriate authorities.
	Dietary modelling
	Questions whether the use of dietary supplements including iodine was included in the modelling.
	Questions whether the average salt content of bread was updated in FSANZ's latest dietary modelling since at draft assessment this was over estimated (1.36%) and therefore over estimated the effectiveness of the proposal.
	Costs
	Questions costs not included in the Access Economics CA dated April 2007:
	 potential adverse health effects from excess iodine intake;
	- costs of monitoring;
	- restriction of consumer choice; and
	 complementary policies required alongside fortification but outside the purview of FSANZ.

SUBMITTER	SUBMITTER COMMENTS
	Also questions the discrepancy in industry costs in the report.
	Questions how the ongoing costs for the voluntary program in Tasmania differ from costs associated with mandatory fortification.
	Implementation
	Recommends outcome-based standards to allow industry flexibility in meeting the Standards.
	Labelling/claims
	Questions whether the inability of most bread to make a 'good source' claim will confuse consumers who will be advised to consume bread for iodine.
	Requests FSANZ decides on a specific iodine health claim prior to Final Assessment. Suggests wording for claims.
	Monitoring and compliance
	• Notes that in the editorial note to Standard 1.3.3 of the Food Standards Code, FSANZ states they will review the extent of the use of iodine as processing aid three years from inclusion in the Standard. It is imperative that this be reviewed as part of Proposal P230.
	Questions if FSANZ will monitor the number of yeast-free bread using iodised salt?
	Communication and education
	Recommends that the MoU and promotion of iodine as a processing aid occurs in conjunction with an education campaign that encourages consumers to seek out products naturally high in iodine or fortified with iodine and is specifically targeted to different population groups depending on their needs, including women of child-bearing age and people who don't consume bread.
	Suggests that non-written material such as radio advertisements could play an important role in an education campaign.
Go Grains	Does not support mandatory fortification with iodine
Australia	Considers the proposed approach is inconsistent with policy guidelines as:
Trish Griffiths	it will not deliver sufficient amount to the target group; and
	no monitoring system is in place to monitor and review mandatory iodine fortification.
	If mandatory fortification proceeds Go Grains seeks commitment from FSANZ and other agencies regarding:
	 actively promoting the consumption of grain-based foods; and
	 monitoring consumption of grain based foods.
	Food vehicle
	Recommends a consistent approach to food vehicle selection.
	• Concerns that issues raised by other food groups take priority over bread e.g. breakfast cereals.
	Safety and efficacy
	Questions the safety of mandatory fortification, and raises concerns regarding the unacceptably high rates of thyrotoxicosis following the introduction of iodine fortification in Tasmania in the late 1960s which lead to its discontinuation in 1976.
	Monitoring and compliance

SUBMITTER	SUBMITTER COMMENTS
Goodman Fielder Baking Australia	SUBMITTER COMMENTS Supports implementation of monitoring prior to mandatory fortification. Identifies general lack information on iodine status of pregnant and breast-feeding women. Dietary modelling Considers data missing in relation to: bread consumed – total consumed and segmented by population group; quantitative estimates of total salt consumption; and the iodine content of Australian and New Zealand foods. Consumer choice Considers mandatory fortification compromises consumer choice and organic and salt-free bread are not adequate alternatives. Vulnerable groups Considers mandatory fortification will not reach specific population groups e.g. those who avoid or limit bread consumption due to coeliac disease, wheat intolerance or allergy, personal preferences and cultural influences. Communication and education Supports an education campaign targeting at risk groups. Does not support mandatory fortification is medication of the food supply. Considers mandatory fortification is inconsistent with policy principles regarding
Fielder Baking	Considers mandatory fortification is medication of the food supply.
	Cost

SUBMITTER	SUBMITTER COMMENTS
	 Recommends FSANZ commission a cost analysis on the cost of restriction to consumer choice, potential adverse health effects from excess iodine intake; monitoring nutrient intake and urinary iodine concentration and complementary policies required alongside fortification but outside the purview of FSANZ.
	A regulatory impact statement which complies with the Office of Best Practice Regulation should include a cost effectiveness analysis.
	Encourages FSANZ to include cost of labelling changes required for products containing more than 5% of breadcrumbs in cost benefit analysis.
	Estimates a cost of changing packaging at \$1.4 million in Australia and New Zealand.
	Trade
	Majority of breadcrumbs are made from bread (6,000 tonnes per year by Goodman Fielder).
	Considers mandatory fortification of breadcrumbs will have a significant impact on imports and exports especially of crumbed products to Japan.
	Implementation
	Requests any changes to packaging to incorporate new mandated ingredients be transitioned at the same time, to allow for minimal write off of existing stock.
	Labelling/claims
	Considers wording of the proposed general level health claim is not suitable for consumers e.g. thyroid hormones. Provides alternate wording.
	Dietary modelling
	Considers FSANZ has not used best available evidence and should seek from stakeholders information on current consumption patterns relevant to the application or proposal. If none is forthcoming, then FSANZ can justifiably state that they have used the best available evidence in their dietary modelling, albeit with severe limitations.
	Communication and education
	Supports national education campaign of promotion of fortified foods.
	Supports industry awareness campaign re the use of iodised salt and iodine as a processing aid.
	Supports promotion of naturally occurring sources of iodine such as seafood, milk and eggs. These foods also contribute omega 3 oils and calcium.
	Recommends modifying and expanding the New South Wales Food Authority's education campaign on safe mercury levels in fish to develop a communication campaign for women planning pregnancy and pregnant women, promoting seafood as a source of iodine.
	Monitoring and compliance
	• Supports trans-Tasman monitoring program for urinary iodine status in target population to estimate prevalence of IDD.

SUBMITTER	SUBMITTER COMMENTS
New Zealand	Does not support mandatory fortification with iodine
Association of Bakers	Considers the proposed approach is excessive and impacts on consumer choice.
(NZAB) New Zealand	Supports alternative proposal with MoU - to be overseen by joint committee of Government, industry and health representatives. Benefits include:
Annette	- addresses this public health issue;
Campbell	- preserves consumer choice;
	 industry and government working together;
	 allows targeted and focused campaign for at risk groups; and
	 government funded and industry supported education campaign.
	Organic/natural
	Considers organic bread do not provide consumer choice.
	Requests clarification of the status of natural products so that any addition of iodised salt would still allow this claim.
	Labelling/claims
	Industry would need permission to highlight claims on packaging and at point of sale within current health claims legislation.
	Suggests alternate wording as proposed wording is not helpful for consumers.
	Consumer choice
	Suggests that FSANZ consider Prof. Segal's report to understand the importance and economic value of consumer choice.
	Technical issues
	Suggests that a member of New Zealand Association of Bakers (NZAB) uses brine system technology and that system is used widely internationally.
	• NZAB has not had time to research this issue and suggests that FSANZ 'investigate this further'.
	Communication and education
	Supports independent validation from health authorities to ensure consumer buy-in.
	Supports a government funded and industry supported education campaign.
New Zealand	Does not support mandatory fortification with iodine
Food and Grocery	Supports voluntary fortification with MoU.
Council	Proposal is unreasonable, inequitable and excessive.
New Zealand	• Considers extending use of iodine as a processing aid as can produce similar outcome to mandatory fortification in conjunction with a MoU.
Brenda Cutress	Mandatory fortification is a last resort.
	Benefits of voluntary fortification approach:
	Same objective can be achieved as mandatory fortification approach.
	Maintains consumer choice (80% of New Zealand population oppose mandatory fortification.
	Those who need to avoid high intakes of iodine would have choice.
	The 12-13% who do not eat bread would have access to other food choices.

SUBMITTER	SUBMITTER COMMENTS
	Women of child bearing age are not high consumers of bread, so a wider variety of products than just bread would increase the chance of raising the iodine level of women of child bearing age, pregnant and breast-feeding women.
	Fulfil same criteria as mandatory fortification i.e. effectiveness, equity, efficiency, certainty, feasibility and sustainability that are required for an effective public health strategy.
	Other comments:
	It would have been helpful if the dietary intake assessments for the industry MoU were included in the Issues Paper for review and comment. The range of foods could be amended to ensure the required levels of iodine are obtained.
	Consumer choice
	Raises the option of fortification of water with iodine, especially in Australia where iodine deficiency is not a problem in some states.
	Unleavened bread and organic bread do not provide 'real' choice.
	Costs
	Suggests undertaking a cost benefit analysis of the removal of consumer choice.
	Labelling and claims
	Suggests that the wording of proposed health claim would not be understood by the majority of consumers. Proposes alternate wording.
	Communication and education
	Supports a communication strategy.
	Monitoring and compliance
	Considers monitoring is essential.
Salt Institute	Supports mandatory fortification with iodine
USA	Advises that providing iodised salt is relatively simple and inexpensive.
Richard Hanneman	Believes the proposal would be strengthened by including a strong statement that the Government is committed to protecting and enhancing the mental development of the next generation through the iodisation of salt and that this proposal is the first step to carry that policy into effect.
	This will put the public and the food industry on notice that an extension of the use of iodised salt would be in order if the current intervention falls short of its expected achievement of adequate iodine intakes for the population.
Unilever	Does not support mandatory fortification with iodine
Australasia	Supports AFGC approach with MoU.
Australia Julie	Considers mandatory fortification to be an impost on industry and restricts consumer choice.
Newlands	Questions reasons for the release of an Issues Paper rather than a PFAR.
	Considers evidence from Tasmanian MoU approach does not support mandatory fortification of a single food vehicle.
	Technical issues
	Supports use of iodine as a processing aid.

SUBMITTER	SUBMITTER COMMENTS
	Communication and education
	Supports a communication program.
New Zealand	Provisional support for mandatory fortification with iodine
College of Midwives	Support dependent on wider consultation with public and with their members.
New Zealand	Proposal is well researched and provides a comprehensive risk benefit analysis.
Lesley Dixon	Safety and efficacy
	Accepts evidence and is concerned with the re-emergence of iodine deficiency.
	Understands that dietary iodine intake is especially limited in pregnant women because they are advised not to eat large predatory fish.
	Health risk from increased salt in diet.
	Reassured that FSANZ has considered health risk from hypertension and to those with existing thyroid conditions.
	States that fortification of bread with iodine is unlikely to fully meet needs of pregnant and lactating women.
	Could alleviate existing conditions and provide improved iodine stores at the beginning of pregnancy.
	Communication and education
	Suggests consultation with public before decision on mandatory fortification.
	• Information on the health benefits and RDI of iodine should be provided for the public and health professionals.
National Heart	Supports mandatory fortification with iodine
Foundation of Australia	Supports mandatory fortification in core foods including bread but has reservations with the use of iodised salt.
Australia	Food vehicle
Barbara Eden	If iodisation of bread alone does not improve iodine status adequately then believes that other core foods should be fortified, e.g. breakfast cereals and milk, not biscuits.
	Believes that using salt as food vehicle conflicts with public health messages, evidence based nutrition and their 'Tick Program'.
	Adding a nutrient (iodine) with positive health benefits to a food via a nutrient (salt) with negative health effects may confuse consumers.
	This may be a disincentive for the food industry to reduce salt levels and food industry need incentives to reduce salt in products.
	Seeks clarification regarding the process of increasing the proportion of iodine in salt if manufacturers wish to reduce sodium content of bread.
	• Believes that lower sodium bread fortified with salt iodised at 35µg iodine/100g will not meet the conditions to make a 'good source' claim.
	The Heart Foundation encourages FSANZ to explore other methods of iodine fortification e.g. direct addition of iodine in bread, iodised feed for cows (Finland) and in animal feed and other foods in Finland, Norway and Sweden and Germany.
	Monitoring and compliance
	Urges FSANZ funded by government to ensure adequate monitoring of dietary intake of iodine.

SUBMITTER	SUBMITTER COMMENTS
	 Monitoring should focus on those at most risk of deficiency e.g. pregnant and lactating women or those at risk of exceeding the upper limit e.g. young children.
	Communication and education
	Believes that an education program on achieving adequate iodine intake and possibility of supplements is FSANZ's responsibility.
National	Supports mandatory fortification with iodine
Council of Women of New Zealand	Most members agree that mandatory preferable to voluntary and would be concerned if universal salt iodisation (USI) were adopted.
New Zealand	Safety and efficacy
Christine Low and Jan Brown	• Some members have concerns with the increased level of fortification: that people who use iodised salt and consume iodised salt in bread may exceed the upper limit for safety. Most members were reassured that studies have shown addition of iodine is safe.
	 Need to ensure that those with thyroid conditions or intolerances are monitored regularly.
	 Agrees that iodisation of salt in bread would contribute to alleviating existing iodine deficiency.
	Food vehicle
	Supports exemption of organic bread to provide consumer choice.
	• Fortifying bread with iodised salt was preferable to iodising milk.
	• Most members did not support iodisation of other processed foods (USI).
	Labelling/claims
	 Labelling must be changed to reflect any changes and needs to be easily read by consumers.
	Monitoring and compliance
	 Monitoring to ensure ongoing effectiveness and safety of the mandatory fortification program.
	Formal reviews are essential.
	Communication and education
	• Education initiatives to raise awareness and understanding of the Proposal.
	• Collaboration with other organisations that educate consumers.
	• Ensure that target groups in the population e.g. those with thyroid conditions should receive advice to avoid iodine rich foods or additional use of iodised salt.
	• Ensure that pregnant and breastfeeding women are advised that they will need additional iodine supplements. This group will need specific messages.
New Zealand	Supports mandatory fortification with iodine
Dietetic Association	The New Zealand Dietetic Association supports:
New Zealand	- the removal of biscuits;
Ms Jan Milne	 use of salt in bread as the best vehicle;
1715 Juli 1711IIIC	 that the most cost effective fortification is to use iodised salt only in bread rather than require all salt to be iodised; and
	- the exemption of organic bread.

SUBMITTER	SUBMITTER COMMENTS
	Food vehicle
	Accepts the reasons for removing cereals from proposal but requests that if fortification is inadequate, direct addition of iodine to cereals be considered.
	Safety and efficacy
	Aware that some groups, especially pregnant and lactating women, will still be at risk of iodine deficiency. Is concerned that supplementation will not reach all women.
	Multivitamin supplements (Elevit and Pregnacare) available for pregnant and lactating women do not contain iodine. The Ministry of Health and Pharmac should make iodine supplements available for pregnant and lactating women as is done in Europe.
	• Supports use of general practitioner or specialist for those people at risk of high iodine intakes, suggest that registered dietitians be added to list of health professionals that can provide individuals with dietary advice.
	Communication and education
	Pregnant and lactating women are poorly informed about the need for iodine and extensive education will be required. The New Zealand Dietetic Association is willing to be involved in this.
	Publicity and education will be required for those people who do not eat bread. Education on other sources of iodine for non-bread eaters should be consistent with the advice regarding mercury in fish.
	Dietitians and midwives should be included as key professional groups that can target population groups at risk e.g. pregnant and lactating women. Children should also be added to the list of target groups that need advice regarding iodine.
	Labelling/claims
	Supports labelling bread to list iodised salt.
	Accepts health claims regarding source and good source provide a method of consumer education.
	Monitoring and compliance
	Would like FSANZ to have a detailed plan regarding review of the level of iodine fortification and foods to be fortified if the current proposal proves inadequate for pregnant and lactating women.
	Would like New Zealand national food composition tables to be updated.
New Zealand	Supports mandatory fortification with iodine
Nutrition Foundation	Supports mandatory fortification as a starting point but believes it does not meet the needs of pregnant and lactating women and consumers who don't eat bread.
New Zealand	Food vehicle
Ms Kelsey Woodcock	Food vehicles need to be broadened beyond bread, especially important to have wheat or gluten free food vehicles.
	Recommends FSANZ reconsider USI.
	Some consumers may choose to reduce salt in their diet while still consuming adequate iodine. This reinforces the need for further research into food vehicles other than salt.
	Communication and education
	Education campaign should raise awareness of iodine rich foods, iodised salt and multivitamins containing iodine for those with wheat/gluten intolerance.

SUBMITTER	SUBMITTER COMMENTS
	Essential that health professionals and women of child bearing age are targeted to increase awareness of the requirement for iodine rich foods, iodised salt and multi vitamins containing iodine.
	The general public should be advised to avoid using extra salt during cooking or at the table but to use iodised salt when they do. Increased use of salt is not consistent with current health messages re sodium and hypertension.
	Safety and efficacy
	Iodine supplements are not currently available in New Zealand.
	Elevit, a commonly recommended supplement in pregnancy contains no iodine.
	FSANZ should investigate methods to make oral supplements available in New Zealand.
	Suggests liaison with manufacturers of vitamins used during pregnancy and lactation to include iodine in appropriate amounts to their multivitamins.
	Suggests that FSANZ explores the use of iodised oil for pregnant and lactating women as suggested by Trevor Beard.
	Labelling/claims
	Allowing health claims may encourage food manufacturers to maintain or increase the amount of salt in their products.
	Policies need to ensure that this does not happen and also to prevent manufacturers being disadvantaged if they reduce sodium in their products.
	Iodised products need to be appropriately labelled, as some consumers need to avoid iodine.
	Monitoring and compliance
	Ongoing monitoring and evaluation of the iodine status of the population is essential.
	The iodine content of foods should be monitored.
Asia-Pacific	Supports mandatory fortification with iodine
Region ICCIDD and Australian	Supports mandatory fortification as effective for the majority of population but considers level of fortification inadequate for pregnant and lactating women and small infants.
National Iodine	Considers this unfortunate because 'the worst expression of iodine deficiency is seen in these groups'.
Steering Committee	Food vehicle
Australia Creswell Eastman, Phillip Harding, Basil	Believes that USI would provide higher iodine intake, for those with higher requirements i.e. pregnant and lactating women.
	Safety and efficacy
	Developing foetus, (mother) and infant will need iodine supplements to avoid iodine deficiency.
Hetzel, Mu Li	Adverse effects of undesirable salt and/or iodine intake were adequately addressed by proposal.
	Costs/benefit analysis
	Notes industry opposed to mandatory fortification because of cost of implementation and to regulation on principle.
	Negative reactions to mandatory fortification might be based on a poor understanding of the issues involved, including the potential health benefit.

SUBMITTER	SUBMITTER COMMENTS
	Communication and education
	Believes that a consultative approach to industry explaining the benefits of mandatory fortification to community health.
	 Manufacturers should be encouraged to view mandatory fortification positively, as portraying their products to the public as conducive to good health.
	 Scientists and clinicians should be in dialogue with industry representatives and regulators working towards a collaborative rather than adversarial process.
	Monitoring and compliance
	• Concerns that only process and some aspects of impact monitoring have been outlined.
	Believes that the most important monitoring should be outcome based.
	 Need baseline data for pregnant and lactating women in both Australia and New Zealand.
Meniere's	Supports mandatory fortification with iodine, but in foods other than salt
Support Group of NSW	Salt exacerbates their condition. They cannot eat commercial produced bread as it is too high in salt and therefore would not receive the benefits of iodisation.
Australia	Food vehicle
David Brigden	• Salt is not an appropriate vehicle for iodine fortification.
	• Prefer direct fortification of all flour (for home use and in processed foods) with iodine and folic acid.
	 Notes current salt intake in Australia is too high and would exacerbate several medical conditions including hypertension.
	• Fortifying salt would encourage the perception of salt as healthy and people may choose more highly salted bread. This may lead to an incorrect belief that all highly salted foods are healthy.
Australian Division of	Supports mandatory fortification with iodine, as an interim measure
World Action	Food vehicle
on Salt and Health	 Believes that there is a public confusion and administrative difficulty with having conjoined food additives with opposite health messages – iodine (you need more because it is good for you) and salt (you need less because it is bad for you).
(AWASH) Australia	 Wide variation in the amount of salt in bread will produce different doses of iodine from different bread products.
Jacqui Webster	• Increasing the level of iodine in salt as the sodium level in bread decreases is not a good response as the bread with the lowest salt content will still have the lowest iodine content.
	• The absolute difference between 2 breads with different iodine contents will be even greater as the iodine level increases.
	• Plan with clear timelines to replace iodised salt with a better alternative such as iodised flour in bread perhaps in conjunction with folic acid.
	Safety and efficacy
	• Iodised bread is unlikely to provide sufficient iodine for the most vulnerable groups i.e. young children 9 months to 3 years who do not eat much bread.
	• Considers whether an alternative approach to iodisation is required to target high risk groups.

SUBMITTER	SUBMITTER COMMENTS
	Communication and education
	Use iodised bread initially but make sure that the importance of reducing salt intake is communicated clearly as a priority.
	Monitoring and compliance
	A monitoring program should assess the impact on iodine status of the population.
The Australian	Offers qualified support for current mandatory fortification proposal
Thyroid Foundation	Believes that all processed foods should be iodised.
Australia	Food vehicle
Beverly Garside	Pregnant women are at particular risk for inadequate iodine as they often watch their weight and may not eat bread regularly and because they are advised not to eat large fish.
	• Iodine should be mandatory in all food sources to ensure that every mother and baby has enough iodine in their diet.
	Safety and efficacy
	Research from the MJA shows that iodisation of bread in Tasmania does not provide adequate iodine for pregnant women.
	Many doctors and obstetricians do not advise pregnant women to take iodine despite the paper by Creswell Eastman informing them of the importance of iodine supplements and the results of the NINS.
	ADD and autism are steadily increasing. This may be due to iodine deficiency.
	Those who suffer from coeliac disease or do not eat bread will be not benefit from the iodisation of salt in bread and will be discriminated against.
	Those who do not eat bread should not have to pay for supplements. Some people cannot afford to buy supplements.
	FSANZ should ensure that supplements contain adequate amounts of iodine.
	The supplement 'Elevit' is often recommended by obstetricians as a multivitamin for pregnant women but it does not contain any iodine and is twice as expensive as other multivitamins. FSANZ should review 'Elevit'.
	Cost
	Cost to society of autism and ADD if proved that they are caused by iodine deficiency.
	It is discriminatory that some people who do not eat bread will need to pay for supplements. Many of these people may not be able to afford supplements.
	Communication and education
	Educate the medical profession about the importance of iodine for the mother and her developing foetus and the need for iodine supplements in pregnancy.
	Monitoring and compliance
	A monitoring system needs to be in place before implementation of mandatory iodisation and follow up research is necessary after implementation.

SUBMITTER	SUBMITTER COMMENTS
Australian	Supports mandatory fortification with iodine, but would prefer USI
Medical Association	Food vehicle
Australia	Supports USI the preferred approach of WHO, ICCIDD and UNICEF.
Margaret	Mandatory will only have an impact on those people who eat bread.
Chirgwin	• In Tasmania 10% of children surveyed continued to have low iodine levels. Suggested this is due to their families' not consuming bread.
	Safety and efficacy
	• The current level of fortification is unlikely to meet the needs of pregnant and breastfeeding women as well as children. They will still need supplementation, which is not the preferred public health approach.
	Monitoring and compliance
	Monitoring should be included as part of an updated NNS and should include collection of blood and urine samples. This will support ongoing monitoring of micronutrient levels in population.
	Prefer urinary iodine concentration (UIC) across a representative sample of the population. Used by WHO and ICCIDD.
	Communication and education
	Doctors and other medical professionals are well placed to provide information on iodine fortification to their patients.
	Doctors will be the first point of inquiry for those with thyroid disorders who are concerned with iodine fortification.
	• FSANZ will need to work closely with the medical profession in development of the communication strategy. Should include take home resources which doctors can provide to their patients.
	Implementation
	Believes that one year is an adequate implementation time.
Dietitians	Supports mandatory fortification with iodine
Association of Australia Australia	The benefits of mandatory fortification will be compromised if not supported by a public health program included targeted monitoring and education of groups most at risk of iodine deficiency
Kate Poyner	Food vehicle
	• Concerns with salt as the vehicle. Bread is the major contributor of salt to the Australian diet. Communication should focus on iodine in bread not salt.
	Concerned that reduced salt bread will have reduced iodine levels.
	Seeks clarification whether good source claims would be available for bread fortified with iodine.
	Would prefer consideration of an alternative method of fortification such as 'iodised kilojoules.'
	Safety and efficacy
	Many pregnant and lactating women will have difficulty reaching sufficient iodine intakes consistent with NRVs and may need iodine supplementation.

SUBMITTER	SUBMITTER COMMENTS
	Implementation
	Changing the fortification level needs to be technologically easy so that as sodium is reduced in bread, iodine levels can be raised.
	Monitoring and compliance
	Details of the monitoring framework have not been announced. Concern that safety and efficacy of the proposed mandatory fortification cannot be evaluated without appropriate monitoring in place.
	Monitoring and review is desirable for all age groups. WHO recommends schoolchildren be used as an indicator of the population iodine status. But this would not give an accurate indication of the iodine status of pregnant and lactating women. The Dietitians Association of Australia asks that women of childbearing age, and children under 3 years, particularly those in iodine depleted areas, be monitored.
	A monitoring program should consider; i) Health status, ii) Urinary iodine excretion in school aged children, women of child bearing age and children under 3. iii) Nutrient intake and food consumption patterns as assessed by food frequency questionnaires. iv) Food composition data on iodine from major dietary sources v) Compliance monitoring for industry
	Monitoring is a core government responsibility.
	Labelling should be monitored, especially for those with thyroid conditions.
	Communication and education
	There is a need for a public health program to highlight the importance of adequate iodine during pregnancy, lactation and childhood as present levels of fortification will not provide adequate iodine for many women.
	Women may incorrectly believe that the fortification of bread will provide them with adequate iodine.
	Some women will not consume bread due to allergies or food intolerance.
	Suggest human development programs at secondary schools provide an opportunity for targeting adolescent girls.
	The number of people exceeding the UL will be greater in Queensland and Western Australia. They might need a specific education program.
Centre for	Supports mandatory fortification (with a few concerns)
Public Health Nutrition	Food vehicle
University of Sydney Australia	Pleased that biscuits have been removed
	Acknowledges FSANZ's intention to reconsider breakfast cereals as a fortification vehicle if current approach is inadequate.
Vicki Flood and Jimmy Louie	Acknowledge that FSANZ has considered the question of reducing salt in the diet and reassured by i) modelling that even with a 30% reduction in salt bread can still make a nutrition content claim ii) that manufacturers reduce the level of salt in bread iodine levels can be raised in salt.
	Safety and efficacy
	• Concerns that a substantial minority of people do not eat bread (14% from a New South Wales survey in 2002).

SUBMITTER	SUBMITTER COMMENTS
Salt Matters of	Supports mandatory fortification with iodine, as a short-term solution
Australia and New Zealand	Food vehicle
Australia and New Zealand	• It was true in the past and it is still true for 3rd world countries that using salt as a vehicle for iodine is the best way to 'combat IDD'.
Trevor Beard	Using salt as the vehicle for iodine will create an epidemic of hypertension.
Trevor Beard	Australia should only use salt as an interim measure and should plan now for a change to a safe vehicle such as iodised dough improver or iodised bread flour.
	Public confusion and administrative nightmare result from a marriage of two food additives with opposite health messages.
	Salt Matters of Australia and New Zealand recommends adding iodine directly to bread flour. This could be managed with the same equipment as folic acid additions.
	Safety and efficacy
	The whole population approach is no longer adequate: those most in need of iodine, pregnant and lactating women, will not receive adequate iodine from mandatory fortification.
	This special subgroup requires special prescriptive measures e.g. supplements, iodised oil etc.
	Iodised oil could be used in clinics as part of primary health care.
	Implementation
	It will be difficult to increase the iodine content of salt if salt content of bread decreases because different bread manufacturers will not reduce salt content uniformly unless salt reduction in bread is mandatory.
	• Salt Matters of Australia and New Zealand recommends that when iodine fortification is implemented there should be a mandatory reduction of salt in all bread to 400 mg/100 g.
	 Health conscious consumers will choose bread with the highest iodine content if they listen to International Council for the Control of Iodine Deficiency Disorders and bread with the lowest salt if they listen to Salt Matters of Australia and New Zealand. This is a conflict for those trying to control their salt intake and provides an excuse for those who do not want to reduce salt intake.
	Bread with the 'Tick' for low sodium will also contain the lowest iodine.
Taranaki	Supports mandatory fortification with iodine
District Health Board, New	Believes a voluntary approach would not work but there are too many exemptions e.g. flat, organic, homemade and gluten free bread for it to be truly effective.
Zealand New Zealand Amanda Brien	Food vehicle
	Supports removal of biscuits but believes cereals would be a good vehicle for mandatory iodised salt as they are a major food group that the population is encouraged to eat. In the New Zealand nutritional guidelines cereals are the same category as bread and can be considered a substitute for bread.
	Support FSANZ exploring direct addition of iodine to cereals.
	Believe that it is better to add salt to a staple than to advise people to add iodised salt to food.
	Disappointed that the decision on the food vehicle was based on non nutritional considerations (trade, cost to industry).

SUBMITTER SUBMITTER COMMENTS Is it possible to add iodine to the water supply? This would eliminate health inequalities and regional variation. For this strategy to be effective nearly all bread would have to be iodised. Yeast free bread are becoming more common in the food supply and this would decrease the effectiveness of the proposal. Safety and efficacy The proposal is still inadequate to address needs of pregnant and lactating women and their children. Less than one quarter of pregnant and lactating women will obtain enough iodine. Elevit a supplement currently recommended during pregnancy does not contain iodine. Most pregnancies are undetected in the early stages when critical growth and neurological development occurs so would not be taking supplementation at the most crucial time. The UL is not an issue and more study needs to be done in this area. Toxicity is not a problem for Asian countries, in fact seems to contribute to this population's higher average intelligence quotient. If bread becomes considered an iodine rich food will people with existing thyroid conditions be advised to reduce bread intake? This will have other nutritional implications: folic acid, fibre and carbohydrate intake. Females tend to eat less food than males, especially if on 'low carbohydrate' diet. Will be difficult for women to obtain enough iodine from other dietary sources particularly as pregnant women are advised to avoid seafood. Those of Middle-Eastern and Asian descent and those with coeliac disease will be disadvantaged because they do not eat bread as a staple food. Supports the use of potassium iodate rather than sodium iodate due to the consequences of hypertension that result from increased dietary sodium. Labelling/claims Most bread manufacturers would be able to make a source claim for iodine but the less expensive brands may choose not to. This would lead consumers to believe that the cheaper breads had less iodine. Manufacturers may see this as an opportunity to increase the cost of bread. Monitoring and compliance Supports monitoring iodine in the food supply so that the need for additional food vehicles can be reconsidered. Questions data that indicates that 88% of Australians 2 years and over are consuming bread. Is this at a level to meet nutritional recommendations? A recent study in New Zealand Medical Journal by Theodore et al, found that only 7% of pre-school aged children in Auckland are meeting daily bread and cereal requirements. Communication and education Those of low socioeconomic status will be disadvantaged, as lack of education/ knowledge and or income means this group is less likely to obtain iodine supplements. Health education alone does not result in complete compliance. A study in Germany found that only 59% of pregnant women and 21% of lactating women are taking the recommended supplementation following 13 years of public health efforts. Health education of naturally rich sources of iodine will not ensure that minority groups not eating bread will get sufficient iodine. This increases disparities as there are few

alternatives of iodine rich foods that are readily available or affordable.

SUBMITTER	SUBMITTER COMMENTS
	Maori and other at risk ethnic and socioeconomic groups have been overlooked in the communication policy. Key messages need to be tailored for these groups and stakeholders need to be consulted to ensure that the messages are appropriate and effective.
	Any education campaign would have to be sustained to ensure future mothers are aware of the matter.
Massey	Supports mandatory fortification with iodine
University New Zealand	Supports mandatory fortification with iodine, but the level is not sufficient for pregnant and lactating women.
Louise	Safety and efficacy
Brough, Jane Coad, Gary	The level of fortification is based on an UL that is calculated on extrapolation of adult data based on body weight that is not appropriate.
Mendoza and	There is no documentation of iodine toxicity from supplemented food in children.
Janet Weber	 In the UK median iodine intakes for children aged 11/2 - 41/2 were 100 μg/day with the 97.5 percentile being 322 μg/day with no adverse effects seen or concern regarding children being above the UL for iodine.
	The Expert Group on Vitamins and Minerals in the UK state there is insufficient data to establish a safe upper level and state that children may consume high levels of iodine but there are compensatory mechanisms that alleviate concerns.
	Acknowledges the difficulty of ignoring the UL but other countries have done so, and urge FSANZ to ask NHMRC to reconsider the UL.
	Food vehicle
	Agrees with the decision to exempt organic bread.
	Disappointed that iodisation of table salt is not mandatory.
	Labelling/claims
	Iodine content should be displayed on the NIP.
	Communication and education
	 Should highlight importance of actively choosing iodised salt whenever salt is purchased.
	Nutrition and related claims should not be allowed as a claim of high iodine will also signal high sodium level. This may confuse consumers. If level of iodine in salt is such that all breads can make a claims it should be mandatory to on all breads.
	All bread manufacturers could be involved with a public sector education campaign to promote generic bread which would help to offset the costs of implementation.
	A communication strategy should make it clear that iodine content is linked to salt.
	The outline of the communications is appropriate but no indication of level of resources available.
	The main message needs to come from the health food/standards sector not just the food industry to ensure credibility.
	• Special attention must be given to health professionals who might be sceptical about the use of fortified foods.
	Important to address the needs of pregnant women and the health professionals who work with them.
	Appropriate, low cost/free supplements must be available for this group.

SUBMITTER	SUBMITTER COMMENTS
	The difficulty of promoting a supplement for pregnancy has been illustrated by the lack of success with folate supplementation.
Aidan	Supports mandatory fortification with iodine
McElduff Private	Supports mandatory fortification but considers the proposed level of fortification inadequate for the most vulnerable group pregnant women and their infants.
Australia (Poyal North	This strategy is least effective in targeting the most vulnerable group and iodine supplements will still be necessary.
(Royal North Shore	Safety and efficacy
Hospital, Sydney)	 Pregnant women and infants are a major subgroup vulnerable to serious consequences of iodine deficiency.
	 Pregnant women present to medical care late in 1st trimester when developing foetus may have suffered damage due to iodine deficiency.
	 Women should commence a supplement prior to pregnancy for effective prophylaxis against iodine deficiency.
	Communication and education
	• Pre-pregnancy counselling is not particularly effective.
	 Unlikely to improve iodine intake through supplement use without specific targeted education programs.
	Difficult to reach the most vulnerable.
	Monitoring and compliance
	Should ensure adequate intake and guard against excess.
	 Dietary modelling would be a useful adjunct to monitoring the use of voluntary permissions.
	 Understands FSANZ role in monitoring but there must be a financial commitment to monitoring.
Sheila Skeaff	Supports mandatory fortification with iodine
Private	Food vehicle
New Zealand	• Disappointed biscuits and cereals removed because 10% of the population who do not eat bread will not receive additional iodine.
(Otago University,	Safety and efficacy
New Zealand)	• The additional iodine from fortification will not meet the requirements of the most important group; pregnant women.
	Monitoring and compliance
	• Iodine status of the New Zealand population will need to be monitored.
	Assume iodine monitoring will occur through National Nutrition Surveys.
	Implementation
	• Two-year implementation period seems more than generous.
	• Hope iodine fortification will not be delayed if there are problems with folic acid.
	Communication and education
	Would like to see the communication and education strategy.
	Strategy to inform pregnant women about iodine deficiency should already have been

SUBMITTER	SUBMITTER COMMENTS
	implemented.
Eugen Kriener	Supports mandatory fortification with iodine
Private Germany	Supports mandatory fortification but believes that it is inadequate and would support direct addition of iodine to breakfast cereals.
(Wurzburg	Food vehicle
Board of Health,	Suggest including direct iodination of breakfast cereals as the percentage of people not eating bread is too high.
Germany)	Safety and efficacy
	Believes that the UL for iodine is false.
	• There is hypothyroidism that is normally not detected in the foetus during pregnancy in areas with moderate iodine deficiency. This has been shown to impact on the babies IQ.
	• Authors of Spanish study (referenced in comments) claim 1.42 times the risk for an IQ below the 25th percentile when urinary levels are below 100 μg/L.
	• An Italian study (referenced in comments) showed moderate iodine deficiency caused a cognitive deficiency in 9.5% of children.
	• There is a dose-effect relationship between iodine supply and the risk of an IQ below the 25 percentile. With iodine intakes (for mothers?) increased to 150 µg/d (aligning with the EAR for pregnancy) the risk for an IQ below the 25th percentile can be reduced by 20%. It can be further reduced by another 20% when intakes increase to 225 µg/day.
	• Increasing the daily iodine intake of a population with an MUIC of 42 μ g/L to 92 μ g/L doesn't alter the intelligence distribution very much.
	• Mild iodine deficiency can lead to a high incidence of autonomous thyroid nodules with hyperthyroidism in the older population. This can lead to severe osteoporosis, and heart damage with heart failure and atrial fibrillation atrial thrombosis and atrial embolism causing apoplectic stroke. Switzerland solved this problem by raising the MUI excretion from 90 μ g/L to 150 μ g/L.
	• Austria had a mandatory salt iodation at 7.4 ppm iodine which resulted in an estimated average increase of 65 μg iodine per day. This increment only prevented visible goitre and the total goitre rate of children remained at 11.8%. Fortification was increased to 15 ppm and iodine was also added to animal feed to give an extra 60 μg iodine per day.
	• Infants and children have a markedly higher T4 turnover relative to adults. In infants T4 production is estimated to be 5-6 µg/kg per day. This decreases over the first few years of life to about 2-3 µg/kg per day at ages 3-9 years. Adult production rate is only 1.5 µg/kg per day. This suggests that infants and young children would have a higher EAR for iodine relative to bodyweight. Supported by epidemiological evidence in Japan where intakes for children are 600-700 µg iodine per day at age 1-3 years without visible deleterious effects.
	Implementation
	There should be a tax on non-iodised salt.
	Monitoring and compliance
	It is urgent to monitor iodine in milk regularly and to make a legislation for iodine content in livestock feed. A change in iodine content of animal feed can have major effects on dietary iodine e.g. from milk, dairy food, meat etc.
	Iodine content of nutritional supplements needs to be monitored.

SUBMITTER	SUBMITTER COMMENTS
Ben Balzar	Supports mandatory fortification with iodine but would prefer USI
Private	Believes that the current proposal is inadequate and prefers USI.
Australia	Believes that FSANZ's inadequate recommendations are based on an invalid NHMRC upper level.
	Considers the Proposal is a sham program that will inevitably fail and require further modification and will damage the reputations of FSANZ, and nutritional and medical communities.
	Safety and efficacy
	The proposal will not address the emerging health problem adequately.
	• Fails to account for cultural diversity in Australia where some sub-groups may be more or less at risk of iodine deficiency due to different diets. The proposal may be in breach of general principles of multiculturalism and equality.
	Defies the advice of the WHO experts, the ICCIDD and ACCIDD and leaves Australia open to ridicule.
	The assumed UL for young children of 200-300 mmol/day is based totally on conjecture and is extrapolated from adult recommendations on a metabolic bodyweight basis.
	Over reliance on the UL has lead FSANZ to propose ridiculously low levels of iodine fortification and will definitely result in brain damaged children.
	Dietary modelling
	• The modelling of children's intake iodine may have overlooked that children get a very large proportion of their food as dairy products and thus fortification of bread may have a smaller impact on them than on adults.
	Cost
	The economic modelling seriously underestimates the economic costs of the definite injuries to IQ of Australian and New Zealand children from iodine deficiency.
	• The proposal and the economic modelling fails to acknowledge that a nation's greatest resource is the national IQ, and this is under direct threat by the current levels of iodine deficiency. Even small changes in IQ can cause a profound increase in the number of children with mild and severe developmental delay and decrease in the occurrence of genius and giftedness. A 1 point drop in IQ can result in a 2.3% drop in earnings. This 1 point drop in IQ in 250,000 children would add up to a loss of \$12 billion per annum.
	The proposal opens the door to medico-legal proceedings against GPs, obstetricians, midwives and nutritionists that could total millions of dollars for brain injury claims.
	The modelling used by Access Economics places an undue emphasis on EAR a level that is by definition inadequate as it will only make 50% of the population replete.
	Modelling severely underestimates the benefits of iodine supplementation.

SUBMITTER	SUBMITTER COMMENTS
New Zealand	Supports mandatory fortification with iodine
Food Safety Authority,	Key comments:
Ministry of Health,	Supports the mandatory replacement of salt with iodised salt in bread, with a salt iodisation range from 35-55 mg of iodine per kg of salt.
Ministry of Foreign Affairs and	Supports retaining the voluntary permission for iodine in iodised salt and reduced sodium salt at the new range of 35-55 mg per kg to make it consistent with the mandatory requirement.
Trade, Ministry of	Acknowledges that the voluntary use of iodised salt in manufactured foods may also be an important contributor of iodine to the diet of New Zealanders.
Economic	Safety and efficacy
Development and Ministry of Consumer Affairs	 Acknowledges that the proposed new approach to iodine fortification will not deliver enough iodine to fully meet the needs of pregnant and breast-feeding women, and some children.
New Zealand	Dietary modelling
Carole Inkster	Seeks a direct comparison of projected increase in average daily iodine intake of adults in the Issues Paper with the modelling done for the Draft Assessment Report. This should be presented in the Final Assessment Report.
	 Requests the % of adults at the lower end of the range of increase in average daily iodine intake (i.e. 30 μg/day) that will meet the RDI for iodine at 150 μg per day, especially in New Zealand.
	Recommend that FSANZ reflect the impact of such salt reduction programs in their dietary modelling because the review process is unlikely to detect the impact of such strategies on iodine status quickly enough.
	Costs
	Would like to see costs to Government of monitoring and communication included in the Final Assessment Report.
	Implementation
	Supports the exemption of bread represented as organic from mandatory iodine fortification to provide consumers with a greater level of choice if they do not wish to consume iodine fortified bread. However, would like FSANZ to be more specific in the provision to exempt bread made under or aligned with an organic certification agency or a recognised agency (recognised by the relevant competent authority). This would accommodate the range of certified standards available for organic produce in New Zealand and assist with compliance and enforcement issues.
	• Supports the proposal to implement iodine fortification over the same timeframe as folic acid fortification.
	Communication and education
	Recognises that iodised table salt will continue to play a role in meeting the iodine needs of some individuals and that careful consideration will need to be given to how best to communicate health messages associated with the consumption of salt.
	Seeks clarification from FSANZ as to whether the strategy to guide communication and education initiatives to raise awareness and understanding of the proposed Standard is a trans-Tasman strategy. If so, we recommend that New Zealand be involved in the development of the strategy to ensure that the New Zealand situation is adequately addressed and sufficient time and resource are available to implement the communication strategy.

SUBMITTER	SUBMITTER COMMENTS
	In the absence of a suitable iodine supplement for pregnant and breastfeeding women in New Zealand, thought will need to be given to how best to assist these women to achieve their RDI for iodine.
	Labelling/claims
	Acknowledges the potential role of iodine content claims in the promotion of iodine containing foods through voluntary fortification, but would be disappointed to see iodine content claims on foods inconsistent with Food and Nutrition Guidelines.
	Monitoring and compliance
	Recognises the need for on-going monitoring and the need for a review of the effectiveness of the Standard.
	 Acknowledges that industry may undertake programs to reduce the salt content of their bread. New Zealand Food Safety Authority and Ministry of Health are interested in the impact that salt reduction strategies may have on the iodine intake and status of the population.
	Acknowledges a FSANZ role for some components of an overall monitoring system, including the contribution to updating Australian national food composition databases. Suggests that work be undertaken to share food composition data between the two countries, particularly for foods that are the same, to avoid duplication.
	• Suggests need for a timeframe for review of the effectiveness of the Standard which will need to draw on health status data.
	Changes in fortification level, additional food vehicles or direct addition should be considered as part of any review process.
	• It will be important for industry to keep the Ministry of Health and New Zealand Food Safety Authority informed as to the timing of the change to iodised salt in bread making because any overlap with the 2008 New Zealand Adult Nutrition Survey will have implications for estimating iodine intake and interpreting urinary iodine results.
Department of	Does not support mandatory fortification with iodine
Agriculture, Fisheries and	Supports strategies to reduce iodine deficiency, providing initiatives impose minimal regulatory and financial burden on industry.
Forestry Australia	Costs
Richard Souness	 Acknowledges that FSANZ's revised approach to add iodised salt to bread as the food vehicle addresses previous technical and trade issues and reduces costs imposed by using breakfast cereals and biscuits.
	Acknowledges lack of empirical evidence in Australia to link an increase in iodine status with quantifiable health benefits.
	Review of alternate approaches to increasing iodine intake
	Considers that FSANZ needs to address the principles for good regulatory process that were recommended by the Report of the Taskforce on Reducing Regulatory Burdens on Business.
	Supports undertaking an evaluation of alternative approaches for increasing iodine intakes in Australia (consistent with Proposal P295 First Review Request).
	Monitoring and compliance
	Supports further consideration of the need for baseline data and implementation of an effective monitoring and evaluation framework to monitor health benefits over time and to prevent an unjustifiable regulatory burden being imposed on industry.

SUBMITTER	SUBMITTER COMMENTS
	Implementation
	Supports a stock-in-trade provision in the Standard that legally allows industry to manage the content and label changeover within the phase in period.
	Communication and education
	Supports a communication strategy to advise consumers of the possible inclusion of iodine without accompanying labelling during the changeover period.
New South	Preference not specified
Wales Food	Safety and efficacy
Authority/ New South Wales Health	Suggests that quantitative data on the extent of iodine deficiency in the Australian community be provided in the Final Assessment Report.
Australia	Recommends including percentage of each specific age group in the population below the RDI.
David Cusack, Bill Porter and	Food vehicle
Kerry Chant	Supports use of salt for bread-making as the vehicle for mandatory fortification with iodine.
	Dietary modelling
	Recommends including results in the Final Assessment Report of modified dietary intake assessment data using iodised salt at the proposed fortification level to determine the impact and appropriateness of this new approach.
	Concerns regarding the level of iodine in infant formula and the impact on exclusively formula fed infants and recommends this issue be addressed in the Final Assessment Report.
	Costs
	Requests FSANZ include the estimated cost of the current iodine deficiency to the Australian community and advise on the quantitative benefit delivered by iodine fortification in the final assessment report.
	Should the initial proposal prove unsuccessful in achieving the health outcome, suggests FSANZ carefully investigate the costs of raising the level of iodine in salt used for bread making or substituting salt used for making breakfast cereals with iodised salt before moving forward.
	Assumes that costs of non-compliance and subsequent investigations associated with non-compliance have been appropriately factored into cost estimates of this proposal on jurisdictions.
	Trade
	Suggests FSANZ thoroughly investigate trade implications arising from substituting salt used for making breakfast cereals with iodised salt.
	Labelling/claims
	• Suggests the eligibility criteria applicable to general and high level health claims under Standard 1.2.7 be extended to foods prepared with iodised salt using voluntary permissions. Concerns that retention of voluntary permissions for iodised salt may allow foods, by virtue of their iodised salt content, to make source claims where these claims that are not considered by nutritionists to be healthy (e.g. potato chips). Does not consider this appropriate.
	Implementation

SUBMITTER	SUBMITTER COMMENTS
	Suggests the removal of the proposed exemption for 'organic' bread until a standard definition of 'organic' has been determined.
	Requests FSANZ to provide an exhaustive list of breads that will be exempt under this proposal, by virtue of the definition proposed by FSANZ for bread.
	Suggests FSANZ provide guidance on the flexibility for a bread manufacturer to prepare their bread with iodised salt from the date of gazettal, or some other time in the transition period, but use up their old packaging stocks before changing to ones labelled with 'iodised salt' in the Final Assessment Report.
	Monitoring and compliance
	Monitoring programs for mandatory fortification will be addressed by AHMAC in mid- June.
	Communication and education
	Suggests FSANZ consult with health portfolios to ensure this Proposal is properly integrated into the health promotion framework and implemented in conjunction with other health initiatives.
	• Recommends inclusion of education programs targeting at risk groups in the population, people not receiving their daily iodine requirements from this initiative, and those that do not consume bread.
	• Considers it important that educational material be prepared identifying foods that will be fortified with iodine under this proposal and how much iodine will be in a standard serve of these foods (i.e.: two slices of bread). Also suggests education material be prepared for those sectors of the community not consuming these foods, identifying alternate dietary sources of iodine and promoting the use and availability of iodine supplements.
	Supports educational material targeted at those sensitive to iodine.
	Suggests the preparation of educational material informing the public on the re- emergence of iodine deficiency in Australia and the importance of consuming sufficient dietary iodine to meet daily requirements.
Department of	Supports mandatory fortification with iodine
Health and Human	Supports mandatory fortification, but considers USI more likely to achieve adequacy for pregnant and lactating women.
Services, Tasmania	Consistency with policy principles
Australia Jen Savenake	Considers there is no conflict with iodised salt as the food vehicle and the need for Australians to lower their salt intake.
Jen Savenake	Safety and efficacy
	• Considers voluntary fortification is inadequate as it does not provide certainty around the level of iodine in the food supply, reach across the population or sustainability of the program over time.
	Tasmanian experience shows a small increase in iodine status with iodised salt in bread.
	Proposed level of fortification is inadequate to meet the requirements of pregnant and lactating women. (data to be published in June MJA).
	USI is more likely to achieve an adequate intake in this target group.
	Recommend ongoing investigation of alternate sources of increasing iodine in the food supply e.g. fortification of breakfast cereals.
	Other comments

SUBMITTER	SUBMITTER COMMENTS
	Avoid further delays.
Queensland Health	Supports mandatory fortification with iodine Whole of Queensland Government Response.
Australia	Food vehicle
Gary Bielby	 Supports voluntary permission to be consistent with mandatory range.
	Consumer choice
	Supports exemption for organic bread and yeast-free bread.
	Implementation and transition
	Supports two year implementation period.
	Safety and efficacy
	 Expressed continuing concerns regarding vulnerable groups who are non-bread eaters e.g. people trying to lose weight through low carbohydrate diets, those on low salt diets and some ethnic groups.
	Costs
	 Concerns that cost of monitoring and surveillance as well as education and health promotion activities are not included in the cost assessment.
	Monitoring and compliance
	Concerns regarding lack of data on supplements.
	Collection of baseline data should include drinking water.
	• Lack of data of iodine status in rural and remote areas in Queensland.
	• Lack of date on iodine status of pregnant and breastfeeding women which has generally been shown to be lower than that of children.
	Lack of data on discretionary salt intake.
	 Expressed concern about the Food Regulation Standing Committee's proposal for monitoring framework for mandatory fortification and supports referral of the framework and draft monitoring systems for folic acid and iodine being referred to AHMAC for advice in relation to:
	 the integration of the proposed monitoring data collection with existing health collections for nutrition and health outcomes;
	- the appropriate bodies to oversee reporting and evaluation of data; and
	- the funding of these two monitoring systems.
Department of	Supports mandatory fortification with iodine
Human Services Victoria Australia Victor Di Paola	Support for mandatory fortification is contingent on development of comprehensive monitoring program.
	Consistency with policy principles
	 Concerns the proposal is inconsistent with the FSANZ Act and the fortification Policy Guideline.
	• The Specific Order Policy Principles 1, 2 and 4 for mandatory fortification have not been clearly demonstrated.
	• Policy Principle 2 has not been demonstrated in the following:
	- FSANZ hasn't reviewed the relevant research thoroughly, especially in relation to

SUBMITTER SUBMITTER COMMENTS analysing the costs and benefits of the proposal. Wishes to ensure the most cost effective strategy is introduced. Strategies other than fortifying the food supply have not been adequately assessed e.g. water fortification, soil enrichment, iodine added to animal feed or fertiliser. Policy Principle 1: justification for mandatory fortification has not been clearly demonstrated given the differing levels of severity and prevalence in the Australian population. Policy Principle 4 is contradicted for the Western Australia and Queensland populations who are iodine sufficient and would not benefit from iodine fortification. Monitoring and compliance A robust monitoring system is integral and should be developed in conjunction with mandatory fortification not as a separate adjunct. Support is contingent on establishment of a comprehensive national monitoring program. Monitoring is essential to ascertain the success of the strategy in reaching all population groups and the need for any adjustment in iodine levels or food vehicles used. Assumes that analysis of bread to determine final iodine levels will be done by Local Government Agencies. They have not been consulted and have not accepted the responsibilities. The may not have the resources to do this and must enforce issues with a public health priority. Food vehicle Supports the change from cereals, biscuits and bread to bread only. Safety and efficacy Concerned that people with coeliac disease and those from cultures who do not regularly eat bread will not obtain any benefit fro fortification of bread. Communication and education Needs to address those who do not eat bread and who will remain at risk of iodine deficiency. Costs The Access Economics Report is incomplete and does not include many key costs. These include costs associated with: - monitoring the restriction of consumer choice, and with complementary policies required alongside fortification but outside the purview of FSANZ. A comprehensive cost benefit analysis is imperative to inform decision making on the proposal. The cost benefit analysis needs to be consistent with the COAG Principles and Guidelines for National Standard Setting by Ministerial Councils and Standard Setting Bodies. The cost of monitoring has to be considered as a necessary and fundamental part of the proposal. Who will bear the cost has yet to be established. In Victoria, monitoring iodine will be competing with other immediate health resources

such as heart disease and diabetes. Costs to the government in the report include

SUBMITTER	SUBMITTER COMMENTS
	awareness raising amongst GPs which is based on an extrapolation from one jurisdiction.
	 Average costs to industry based on two samples is not robust. The average costs should be based on a larger sample size or there should be a range based on upper and lower costs.