

CONSIDERATION OF MANDATORY FORTIFICATION WITH IODINE

**A short guide to the development of a food standard
for Australia and New Zealand**

August 2006

Summary

FSANZ is developing a new food standard for mandatory fortification of the food supply with iodine. This complex issue requires wide consultation throughout the community.

Our proposed approach seeks to...

Reduce the prevalence of iodine deficiency in Australia and New Zealand, especially in children

We want to reduce iodine deficiency in the Australian and New Zealand populations as much as possible, especially among children up to three years of age, and women of child bearing age. We can achieve this by increasing the iodine content of the food supply through mandatory fortification. While this will benefit everyone with an iodine deficiency, some damage caused by the deficiency is irreversible in very young children. This is why we need to act now to fortify our food supply, and prevent further harm caused by iodine deficiency.

The new measure...

Mandates replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits

We prefer the mandatory replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits as an effective means of addressing iodine deficiency in Australia and New Zealand. Mandatory addition of iodine to salt in a range of between 20–45 mg per kg of salt in key cereal-based foods will increase the iodine intakes of the Australian and New Zealand population, particularly infants, children and women of child bearing age. We have chosen these foods for mandatory fortification because they are usually eaten on a daily basis and many are manufactured with salt as an ingredient. Our preferred approach is consistent with international research and recommendations of the World Health Organization, the International Council for the Control of Iodine Deficiency Disorders and the United Nations Children's Fund.

Retains current voluntary permissions for iodised salt

We want to retain the current addition of iodine to salt in conjunction with mandatory fortification. This will provide an alternative iodine source for people who do not consume salted cereal-based foods. It will also allow manufacturers to voluntarily add iodised salt to other commercial foods. However, FSANZ is proposing to reduce the concentration of iodine in iodised salt from 25-65 mg per kg to 20-45 mg per kg so it is the same as the proposed mandatory requirement.

Supports additional mechanisms to ensure women receive enough dietary iodine

Mandatory fortification of the food supply with iodine will benefit everyone with an iodine deficiency. However, it cannot deliver sufficient iodine to many pregnant and breastfeeding women without also increasing the iodine intakes of a proportion of

young children above upper safe levels of intake. Public health messages and advice from medical practitioners and other health professionals about dietary iodine will continue to be important for these women.

Supports the Australian and New Zealand national nutrition guidelines¹

National nutrition guidelines for Australia and New Zealand for all age groups recommend choosing foods low in salt, particularly pre-prepared foods, drinks and snacks. Mandatory replacement of non-iodised salt with iodised salt in key cereal-based products is not intended to promote increased salt intake. Iodised salt will replace non-iodised salt currently used in manufactured foods.

Given the low iodine intakes of New Zealanders, the New Zealand nutrition guidelines also state that if using salt choose iodised salt. The proposal to mandate replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits allows for the continued iodisation of salt for discretionary use.

Provides for consumer choice

We understand that some people may want to avoid iodised products. We recognise that there is a need for non-iodised alternatives and adequate information to ensure consumers can make informed choice about their food intake. The availability of some salt-free options among the key cereal-based foods, particularly breakfast cereals and unleavened breads, will provide non-fortified options for those who want them.

And includes...

Labelling requirements to guide and inform consumers

General labelling requirements require all ingredients of a product to be identified in the ingredient list. This will help consumers to choose products fortified with iodine or to avoid them, depending upon their individual choice.

Monitoring the effectiveness and safety of mandatory iodine fortification

We have prepared a plan to measure the ongoing effectiveness and the safety of mandatory iodine fortification in addressing iodine deficiency in Australia and New Zealand, consistent with Ministerial policy guidance. The plan includes ongoing monitoring of any changes in voluntary fortification of foods, as well as any changes in consumption of fortified foods and consumers' attitudes and behaviour towards these foods. The plan is attached to the Draft Assessment Report. As our responsibilities under the *Food Standards Australia New Zealand Act 1991* (FSANZ Act) are limited, we plan to work closely with health and regulatory agencies at the Commonwealth, State and Territory level in Australia and the New Zealand Government on this activity.

¹ NHMRC. Dietary Guidelines for Australian Adults. Commonwealth of Australia, 2003; Ministry of Health. Food and Nutrition Guidelines for Healthy Adults: A background paper. Wellington. Ministry of Health, 2003.

Communication and education

We have prepared a strategy to guide communication and education initiatives to raise awareness and understanding of the proposed standard for mandatory iodine fortification and its implementation. We recognise that improving the iodine status of the Australian and New Zealand populations relies on implementation of a range of strategies beyond our regulatory role. We will collaborate with other organisations to increase public awareness of the proposed standard and fortification issues, ensure consistency of information, and maximise the effectiveness of available resources.

A phase-in period

We are recommending a **12-month transition period** for implementation after the standard becomes law. This will give industry time to make the required changes to manufacturing and labelling, and to alert consumers to the new rules.

Commonly Asked Questions

What is iodine?

Iodine is an essential nutrient found in many foods. Iodised salt, dairy products, seafood, kelp, fruits, vegetables, eggs, meat and cereals can all contribute to the dietary iodine intake. Of these, certain seafood and kelp can contain very high levels of iodine. Iodine containing supplements and medicines can also be major contributors of iodine intake for some people. However, as some of our soil is low in iodine, some of our food products contain a low concentration of iodine.

Who needs iodine and why is it important in our diet?

We all need iodine. It is essential to the production of thyroid hormone, which regulates body temperature, metabolic rate, reproduction, growth, blood cell production, and nerve and muscle function. The thyroid produces the thyroid hormone. Iodine is very important for the normal development of the brain and nervous system during pregnancy, in infants and young children in the first 2-3 years. In particular, pregnant women, breastfeeding mothers and young children should have an adequate dietary iodine intake.

What are the effects of iodine deficiency?

Iodine deficiency can affect people of all ages, but infants and young children are most at risk.

Mild iodine deficiency during pregnancy and early years can result in slower reaction times and lead to a small reduction in mental performance which is irreversible if deficiency occurs before the age of 2-3 years.

Moderate iodine deficiency can lead to impaired visual and verbal information processing and fine motor control. It can reduce ability to concentrate, lower learning capacity and reduce intelligence quotient (IQ). It may also result in hearing impairment and increased risk of attention deficit and hyperactivity disorders.

Prolonged iodine deficiency can lead to adverse changes in the thyroid, including various forms of goitre (enlargement of the thyroid gland), which can predispose affected individuals to thyroid disease later in life.

What is the extent of iodine deficiency in Australia and New Zealand?

Over the past decade, several studies and surveys have revealed a re-emergence of mild-to-moderate iodine deficiency in parts of Australia and New Zealand. New Zealand and some parts of Australia, notably Tasmania, have a longstanding history of iodine deficiency which have been addressed by previous programs, and in Tasmania's case, current programs.

In Australia

In 2003-04, the National Iodine Nutrition Study (NINS) examined iodine status in primary school children from five Australian states. Mild iodine deficiency was found in New South Wales and Victoria, borderline iodine deficiency in South Australia, and adequate intakes in Queensland and Western Australia. Data were not

collected in Tasmania because of their public health intervention instigated in 2001 to address mild iodine deficiency.

Recent studies in Melbourne and Sydney suggest that many pregnant women border on moderate iodine deficiency. Compared to school age children, pregnant women appear to be more deficient.

In New Zealand

According to the results of the 2002 New Zealand Children's Nutrition Survey, New Zealand school children are mildly iodine deficient, but show signs of approaching moderate iodine deficiency. Other research also indicates a high proportion of New Zealand children have enlarged thyroid volumes, consistent with a degree of dietary deficiency. Available research also indicates that breast fed infants may have the poorest iodine status of any group. This suggests that mothers as a group are iodine deficient.

Why are we iodine deficient?

Historically, New Zealand and some parts of Australia, notably Tasmania, had low iodine intakes due to the low soil iodine content in these areas. The reasons for the current deficiency in South Eastern Australia are not fully understood but may be related to one or more of the following possibilities:

- decreased consumption of iodised salt, due to greater use of non-iodised salt and a reduction in total salt intakes;
- the dairy industry stopping the use of iodine-based sanitisers, leading to lower concentrations of iodine in milk; and
- variations in iodine levels in drinking water.

Can we get enough iodine from a healthy diet?

No. The food supply provides insufficient iodine for a wide range of the population. The most concentrated iodine content in food is found in seafood, kelp, and iodised salt. Moderate contents are found in dairy foods (although contents have reduced in recent years) and eggs. Through their widespread and regular consumption, milk and milk substitutes are a major contributor to dietary iodine intake. However seafood is not widely consumed, and the advocacy of greater consumption of salt is not consistent with national nutrition recommendations to reduce salt intake. The natural iodine content of salt, including sea-salt, is minimal.

How will iodine be added to our food supply?

Iodised salt will replace non-iodised salt in breads, breakfast cereals and biscuits as the preferred approach to address the re-emergence of iodine deficiency in Australia and New Zealand. The salt iodisation level is to be in the range of 20-45 mg of iodine per kg of salt. This approach is consistent with international experience of fortifying salt with iodine, and recommendations of the World Health Organization, the International Council for the Control of Iodine Deficiency Disorders and the United Nations Children's Fund.

Are there any risks in increasing the iodine content of the food supply?

Populations with long standing iodine deficiency are at an increased risk of iodine-induced hyperthyroidism if iodine intake increases. However, the degree of risk depends on the duration of deficiency, with those over 40 years of age who have been

iodine deficient since birth being the most vulnerable. These people will most likely be already under medical supervision and should consult their medical practitioner.

The current re-occurrence of iodine deficiency in the population is believed to be a relatively recent phenomenon that has emerged in the last 10-15 years. So, in the Australian and New Zealand context, any adverse effect is likely to be minimal and transient.

What will happen if we do nothing?

If we do nothing, the current levels of iodine deficiency may become more serious and widespread in Australia and New Zealand, especially among pregnant and breastfeeding women, infants and young children. This will increase the risk of impairments occurring during early brain and neural development of unborn children, infants and children up to three years of age. This cannot be reversed by an adequate supply of iodine later in life.

What is the expected impact of mandatory iodine fortification?

Mandatory iodine fortification will contribute considerably to alleviating the consequences of existing iodine deficiency, and prevent it from becoming even more widespread and serious in the future. Most importantly it will reduce the risk of mothers becoming progressively more iodine deficient through successive pregnancies. This, in turn, will reduce the risk of children being born with serious impairment from iodine deficiency.

We have selected the level of iodisation in salt to ensure the general population get enough iodine while vulnerable groups, such as young children, do not get too much.

Will pregnant and breastfeeding women get enough iodine through fortification of the food supply?

No. Mandatory fortification of the food supply with iodine cannot deliver sufficient amounts to pregnant and breastfeeding women without also increasing the iodine intakes of a proportion of young children above the Australian and New Zealand Nutrient Reference Values upper level of intake. Although the upper level for children is approximately one fifth the adult upper level, the estimated total salt, and therefore iodine, intake for children is comparatively similar to that of women's intakes. Even after fortification, many pregnant and breastfeeding women would benefit from taking an iodine supplement. FSANZ will refer this need for education to relevant health authorities and health professionals.

What does industry have to do to implement this proposal?

FSANZ has undertaken intensive consultation with the salt industry in both Australia and New Zealand. The salt industry has indicated their willingness and ability to produce greater amounts of iodised salt, noting that this would require a small expansion to the existing infrastructure.

For the processed food industry, the main impact would be replacement of iodised salt for non-iodised salt as an ingredient. It is technologically feasible to add iodised salt to most foods at the concentration being considered. The ingredients list on food labels, however, would need to be changed to reflect the addition of iodine as iodised salt to key cereal-based foods.

Guide to the proposed food standard

Food Standards Australia New Zealand (FSANZ) is an independent bi-national agency responsible for setting food standards for Australia and New Zealand, which appear in the *Australia New Zealand Food Standards Code*.

This guide provides individuals and organisations with an interest in fortification of food with information on the approach being proposed by FSANZ and our recommendations for the content of the standard.

Underpinning this document is a report that details why new regulations are needed, options that we considered during the development of the standard and a draft standard for incorporating into the Code. The report also includes the policy guidelines from the Australia and New Zealand Food Regulation Ministerial Council to be taken into account in developing the standard. It also contains our responses to issues raised by the public, industry, government and public health groups during our first period of public consultation in 15 December 2004 to 23 February 2006.

Having your say

We welcome your views on the issues and approaches outlined in this guide to the development of a food standard for mandatory fortification with iodine. We invite you to examine the rationale and content of the proposed food standard and to comment on our approach.

This second period of consultation will be open from **18 August 2006 until 18 September 2006**.

To make a written submission, please see the FSANZ website www.foodstandards.gov.au where you will find:

- Draft Assessment Report for Consideration of Mandatory Fortification with Iodine (Proposal P230). This report contains a summary of submitters' comments from the first round of consultation.
- Ministerial Policy *Guideline on the Fortification of Food with Vitamins and Minerals*.
- Information for individuals and organisations intending to make a submission.

Your views are important to us.

They will help shape new regulations for the fortification of food in Australia and New Zealand.

We must receive your submission by
**6pm AEST on
Monday 18 September 2006.**

Background

Mild-to-moderate iodine deficiency is re-emerging in New Zealand and in parts of Australia as a result of inadequate iodine intake. Iodine deficiency is associated with a wide range of health problems. In children iodine deficiency can damage the development of the brain and nervous system, from development in the womb to three years of age. In adults iodine deficiency increases the risk of thyroid dysfunction in later life. Both adults and children are at risk of developing goitre (enlargement of the thyroid gland).

In May 2004, the Australia and New Zealand Food Regulation Ministerial Council asked us to consider how mandatory iodine fortification of the food supply can address the re-emergence of iodine deficiency in Australia and New Zealand. We released an Initial Assessment Report about this issue in December 2004, followed by extensive consultations.

We have now prepared a Draft Assessment Report which focuses on mandatory fortification with iodine as a means of reducing iodine deficiency in Australia and New Zealand.

Our preferred approach

The mandatory replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits is the preferred approach to address the re-emergence of iodine deficiency in Australia and New Zealand. The salt iodisation level is to be in the range of 20-45 mg of iodine per kg of salt.

The voluntary permission for iodine in iodised salt and reduced salt will be retained, but will be adjusted from the current range of 25-65 mg per kg to 20-45 mg per kg, to be consistent with the mandatory requirement.

Reasons for our preferred approach

The reasons for our preferred approach are:

- the replacement of non-iodised salt with iodised salt in breads, breakfast cereals and biscuits would contribute considerably to alleviating the consequences of existing deficiency, and prevent it from becoming even more widespread and serious in the future;
- the use of iodised salt to reduce the prevalence of iodine deficiency is consistent with international guidance and experience. Internationally, at least 100 countries have adopted salt iodisation to address emerging iodine deficiencies;
- in Tasmania, the recent use of iodised salt in bread was a successful initiative to increase the iodine status of a mildly deficient population;
- on the available evidence, including overseas experience with mandatory

fortification, the proposed level of fortification does not pose a risk to general public health and safety. The level has been set to minimise any potential health risks. In groups that are generally more sensitive to increases in iodine intake, e.g. individuals with existing, thyroid conditions, the risk of a negative impact on health is still considered to be very low.

- the replacement of salt with iodised salt in key cereal-based food is effective and technologically feasible;
- FSANZ considers that the proposal would deliver net-benefits to Australia and New Zealand:
 - while quantifying the dollar values of the benefits proved extremely difficult, the identified benefits are considered to be valuable, especially in relation to the small cost likely to be incurred by the community;
 - the cost to industry and government in the first year would be \$A15.8 million and \$NZ0.7 million in Australia and New Zealand respectively, but would be lower in each subsequent year at \$A3.3 million and \$NZ0.4 million respectively;
 - these costs may be passed on to consumers and in the first year would amount to A\$0.79 per person in Australia and NZ\$0.16 per person in New Zealand, but in each subsequent year would fall to A\$0.17 per person in Australia and NZ\$0.11 per person in New Zealand;
- consumers will be provided with information through ingredient labelling to identify the presence of iodised salt in the key cereal-based food; and
- it is consistent with Ministerial policy guidance on mandatory fortification.

How mandatory iodine fortification will work

If the FSANZ Board approves the proposed draft variations to *Australia New Zealand Food Standards Code* (the Code) following the completion of a Final Assessment, the Ministerial Council will be notified of that decision. Subject to any request from the Ministerial Council for a review, the proposed draft variations to the Code are expected to come into effect 12 months from gazettal.

It is proposed that this 12-month transitional period will allow time for the salt industry to increase the production of iodised salt and for manufacturers of the key cereal-based foods to make the required changes to manufacturing and labelling. This will also allow time for consumers to be informed about the changes.

As detailed above, we will also:

- monitor implementation in collaboration with health and regulatory agencies at the Commonwealth, State and Territory level in Australia and the New Zealand Government; and
- undertake communication and education activities in collaboration with other organisations to raise awareness of the standard and its implementation.