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

2-04
17 March 2004

INITIAL ASSESSMENT REPORT

APPLICATION A528

MAXIMUM IODINE LIMIT IN FORMULATED SUPPLEMENTARY FOODS FOR YOUNG CHILDREN

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
28 April 2004
(See 'Invitation for Public Submissions' for details)

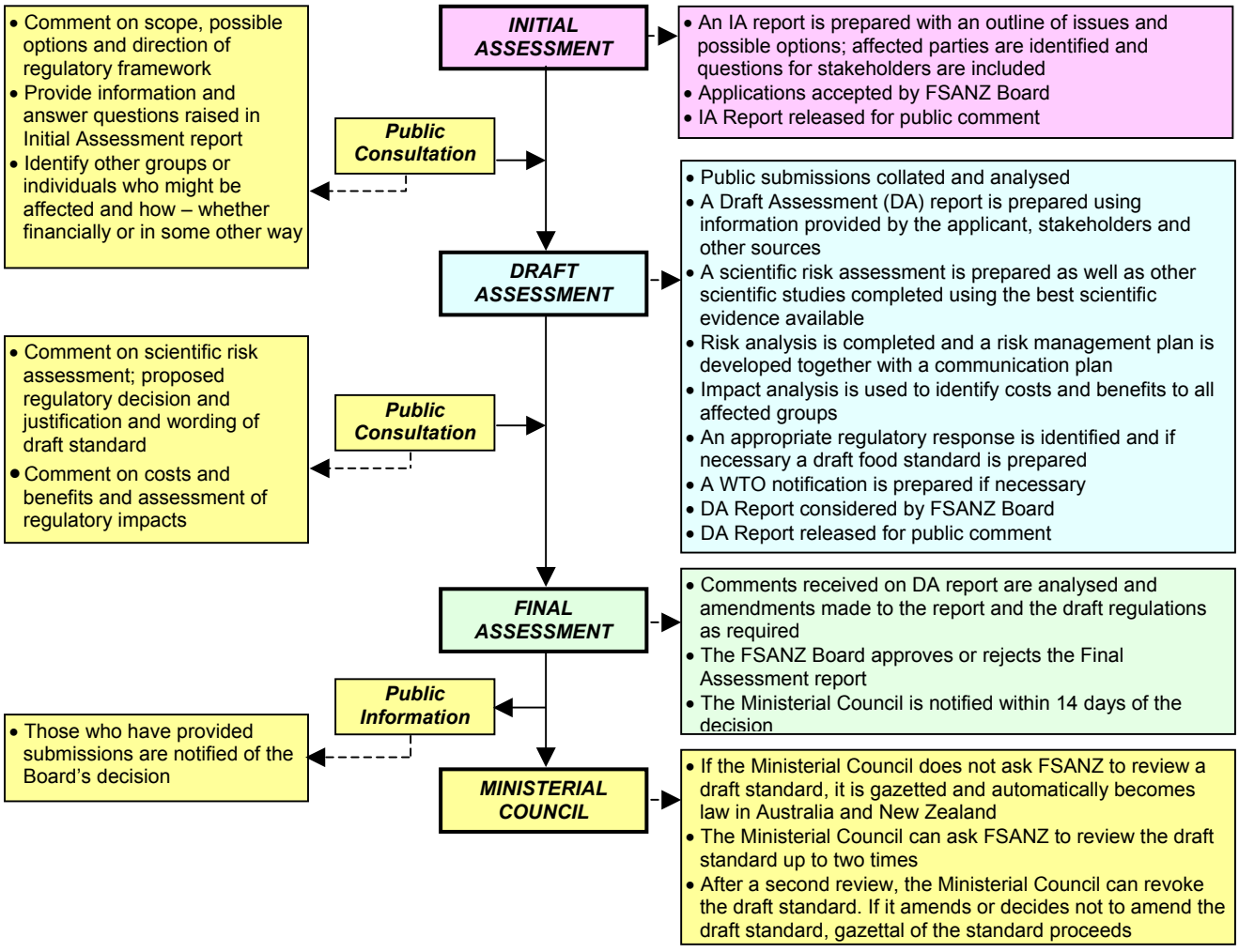
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Application A528, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment for this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 28 APRIL 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

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

Regulatory problem

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

Issues

Several issues have been identified as important in meeting the objectives of this Application, in particular:

- the variability of iodine found in ingredients used to manufacture FSFYC;
- the iodine status of young children in Australia and New Zealand; and
- safety issues including upper limits and toxicological assessment.

Regulatory options and impact analysis

Two options are being considered to progress this Application at Initial Assessment. These are:

1. Maintaining the *status quo* by not increasing the maximum iodine limit; or

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

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

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

Conclusion

This Application has been assessed against the requirements of section 13 of the FSANZ Act. Accordingly it is recommended that this Application should be accepted and progressed to Draft Assessment subject to payment of fees pursuant to section 66 of the FSANZ Act and the Regulations.

In assessing the Category for this Application, and taking into account the regulations under the FSANZ Act, FSANZ has come to the view that the Category for this Application should be set at Category 3 which is an application requiring only an updated risk assessment in relation to an existing standard.

Public submissions are now invited on this Initial Assessment Report. Comments are specifically requested on the scientific aspects of this Application, especially information relevant to the safety of increasing dietary iodine in the diets of Australian and New Zealand children who use FSFYC and the likely regulatory impact(s) of the proposed amendment.

1. Introduction

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

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

This Initial Assessment Report discusses the issues involved in the proposed amendment and seeks comment from stakeholders, particularly in relation to expected regulatory impact(s), to assist FSANZ in making an assessment of this Application.

2. Regulatory Problem

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

3. Objectives

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

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

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

- the need for standards to be based on risk analysis using the best available scientific evidence;

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

- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

Further, section 13 of the FSANZ Act provides:

(1) The Authority must make an initial assessment of the application.
(2) In making an initial assessment of the application, the Authority must have regard to the following matters:

(a) whether the application relates to a matter that may be developed as a food regulatory measure, or that warrants a variation of a food regulatory measure, as the case requires;
(b) whether the application is so similar to a previous application for the development or variation of a food regulatory measure that it ought not to be accepted;
(c) whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the measure or variation;
(d) whether other measures (available to the Authority or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the application;
(e) any other relevant matters.

This Application has been assessed against the above criteria and accepted for the following reasons:

- The Application relates to a matter that may warrant a variation to Standard 2.9.3, on the basis of information already obtained. The existing permission sets a level of iodine at 35 μg per serve. If the information provided by the applicant and the assessment of all relevant material supports the raising of that level to 70 μg then a variation to the standard will be required.
- This Application is not so similar to a previous application that it ought not be accepted.
- The potential costs and benefits are dealt with at Section 7 of this Report.
- There are no other measures available to permit that which the applicant is requesting.
- Regulation 12 prescribes 2 relevant matters which are the category of assessment that will be required for a matter to proceed to Draft Assessment, and whether any variation would confer an exclusive, capturable commercial benefit (ECCB) on the Applicant. This is dealt with in Section 4.5 of this report.

The specific objective of Application A528 is to ensure that the proposed amendment to Standard 2.9.3 is safe for consumers of FSFYC (i.e. young children aged 1 – 3 years) and achievable by manufacturers of FSFYC.

4. Background

4.1 Current regulation

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

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

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

Iodine is allowed to be added to FSFYC, in a permitted form, provided that the total quantity of both the naturally occurring and added amount does not exceed this prescribed maximum level (subclauses 6(2) and (3)). Where a permitted vitamin or mineral is added, a maximum claim limit of 50%RDI also applies (subclause 7(2)(c)). However in relation to this Application, the issue relates to iodine naturally present in raw materials used to manufacture FSFYC, not iodine added during manufacture. Therefore the declaration of iodine, in this case, is subject to the generic nutrition labelling requirements in Standard 1.2.8 – Nutrition Information Requirements of the Code.

4.2 Current market

The vast majority of FSFYC available in Australia and New Zealand are milk-based supplementary drinks known as 'toddler formula'. FSANZ is not aware of other products that are currently manufactured to the FSFYC provisions.

Toddler formula is generally promoted as a supplementary milk drink for children aged over 12 months of age and is usually prepared in water, although the Applicant has indicated that in most cases (approximately 70%) the product is made up in milk. In addition toddler formulas are sometimes promoted as being suitable as a replacement for milk in other foods e.g. custards.

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[3] In the Code 'total quantity' refer to both naturally occurring and added nutrients.

[4] Column 4 in the Schedule to Standard 1.1.1 – Preliminary Provisions – Application, Interpretation and General Prohibitions of the Code specifies the recommended dietary intake (RDI) for iodine in children aged 1 –3 years as 70 μg.

There are only a small number of manufacturers/importers of FSFYC in Australia/New Zealand and on the whole, the market for these products is relatively small and discrete.

4.3 Historical changes to regulations

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

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

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

4.3 International regulations

4.3.1 Codex Alimentarius

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

4.3.2 Other international regulations

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

4.4 Iodine in the diet

4.4.1 Sources

Iodine in food occurs mostly as inorganic iodides or iodates (COMA 1999) and its levels in food are dependent on the environment of the food's origin, particularly the levels of iodine in the soil. Australia and New Zealand have low levels of iodine in their soils, which can often expose sections of the population to low iodine intakes (Gunton et al 1999). Internationally, the major natural sources of iodine in the diet (i.e. excluding fortified foods) are seafood, milk and eggs (FAO/WHO 2002). Meat and cereal are secondary sources.

[5] Guidelines on Formulated Supplementary Foods for Older Infants and Young Children (CAC/GL 08-1991)
[6] National Standard of the People's Republic of China (GB 10767 – 1997) Foods for Infants and Young Children.

4.4.2 Role

Iodine is an essential component of the thyroid hormones thyroxine (T4) and tri-iodothyronine (T3). T3 and T4 are synthesised within the thyroid gland where iodine is removed from the blood and concentrated before being linked to the hormones. Thyroid hormones are essential for the maintenance of metabolic rate, cellular metabolism and the integrity of connective tissue (Gibson 1990).

4.4.3 Bioavailability

Dietary iodine is easily absorbed from the stomach and upper small intestine (Thomson 2002, Stanbury 1996), however this absorption can be reduced by the calcium, magnesium and iron content in food and water (SCF 2002). Additionally the utilisation of dietary iodine in the body is influenced by goitrogens. Goitrogens are found in the vegetables of the Brassica genus (Cruciferae family: cabbage, broccoli, turnips Brussels sprouts) and interfere with the biosynthesis of the hormones T3 and T4. Heat from the cooking of these vegetables will inactivate most of the goitrogens that are present.

4.5 Work Plan classification

This Application had been identified as Application A528 – Maximum Iodine Limit in Formulated Supplementary Foods for Young Children, rated as complexity Category 3, and placed in Group 3 on the FSANZ Standards Development Work Plan. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

In assessing the category for this Application, and taking into account the regulations under the FSANZ Act, FSANZ has come to the view that the category for this application should be set at Category 3. The Regulations, Schedule 3, Part 1 – Categories of Assessment defines Category 3 paid applications as *an application requiring only an updated risk assessment in relation to an existing standard.* By requesting an increase of maximum permissions in the Code, Application A528 is consistent with regulations for Category 3, as it requires an updated risk assessment and does not deviate from the requirements of this category.

5. Relevant Issues

Several issues have been identified that are relevant to this Application including:

- the variability of iodine in the milk used to manufacture FSFYC;
- daily requirements for dietary iodine;
- issues surrounding iodine deficiency in Australia and New Zealand;
- dietary modelling to assess the possible impacts of this Application; and
- upper limits and safety of higher levels of iodine in FSFYC.

5.1 Variability of iodine in the milk used to manufacture formulated foods for young children

The Applicant has made specific reference to the variability of iodine in the milk and in the milk-based ingredients that are of prime importance in the manufacture of FSFYC. It is therefore important to identify the status of iodine within the base milk ingredients of FSFYC, and to determine if there is sound rationale for amending the Code as proposed by the Applicant.

5.1.1 The impact of iodine variability in milk on formulated supplementary foods for young children

The Applicant has stated that because the iodine in milk is highly variable, the use of milk and milk components can result (the Applicant claims approximately 30% of the time) in some FSFYC that have total iodine content exceeding the maximum limit specified in the Code. These products may be currently available on domestic markets even though they are in breach of the Code abut the full extent of non-compliance with the maximum permitted quantity of iodine is unknown.

The milk used in the Applicant's FSFYC products is sourced from Ireland, United States / Canada, and Australia / New Zealand depending on the availability of milk at particular times of the year. The Applicant has not provided any information on the highest and lowest iodine concentrations that can result from the use of milk sourced from these regions.
To prevent iodine levels of FSFYC exceeding the maximum permitted amount without an amendment to the Code, manufacturers would need to screen the iodine content in all ingredients derived from milk. The Applicant has indicated that this is not logistically feasible for manufacturers to undertake, as other attributes of milk ingredients set the quality benchmark for their use; e.g. milk protein levels.

5.1.2 The extent of iodine variability in milk

The Applicant has mentioned that except for iodine, all minerals are contained within milk as components of micelles. As micelle production is regulated during milk formation, the concentrations of these minerals are consistent no matter where the milk is sourced from (United States Board on Agriculture 1988). However, iodine is present as a free form in milk and is therefore subject to external influences.

There are two main external influences on the free form level of iodine in milk: geographical variations and seasonal diets, in addition to the use of iodophores as sanitising agents of milking equipment. Geography influences iodine levels by producing variations in the soil iodine content of cattle grazing pastures. Seasonal variations occur when iodine rich stock feed is given to dairy cattle during winter to compensate for reduced access to grazing pastures (United Kingdom Food Safety Agency 2002).

Iodophores have been used in the past as sanitising agents for teats and milking equipment, and contributed significantly to the iodine content of milk. Australia, New Zealand and many other overseas countries have now moved away from the use of iodophores to other sanitising agents, resulting in a lowering of milk iodine contents.

However, some nations (e.g. United Kingdom) still maintain the practice of iodophore use, which contributes to the global variability in milk iodine contents (Eastman 1999, McDonnell 2001, Dunn 1998). The Applicant has provided data for iodine levels in United Kingdom (UK) milk, where iodine levels are relatively high compared to New Zealand and Australian milk.

Table 1 below demonstrates some of the variability that can exist in milk iodine concentration on a global scale; only a selection of countries are provided due to the lack of information on international milk iodine concentrations. New Zealand data has been obtained from the 1997/98 Total Diet Survey results, while information on Australia is only available for Tasmania where periodic monitoring is undertaken by two major milk producers.

Table 1: Annual Iodine Concentrations in Milk (μg/L)

	Minimum	**Maximum**	**Mean**
Australia (Tasmania) (Personal communications: Seal J, 2004)	110	440	265
New Zealand (Vannort R 2000)	44	184	85
United Kingdom (United Kingdom Food Standards Agency 2000)	184	426	315
Germany (Preiss 1997)	<100	150	115
International Mean (FAO/WHO 2001)	34	54	46

Questions:

Is the variability of iodine in milk of a sufficient magnitude to justify the amendments proposed by the Applicant?

- Are you aware of any data on the variability of milk iodine or iodine in general that can supplement the information provided above?
- Do you have any information on the highest iodine concentrations that can occur from the use of milk and milk components in FSFYC production from Australia and elsewhere?
- Are the regions that the Applicant sources milk from likely to reflect the variability that exists in milk on a global scale?

Can manufacturers readily modify the production of FSFYC to accommodate the iodine variability of milk?

- Is it unfeasible to screen macro-ingredients for iodine content as argued by the Applicant?
- What would be the costs to FSFYC manufacturers if the regulations were unchanged?

5.2 Nutritional aspects

5.2.1 Recommended dietary intakes of iodine

The current Australian and New Zealand RDI for iodine of 70 μg/day for children 1-3 years is at the lower end of other comparable international RDIs (Table 2). Dietary modelling[7] in Australia for this age group (2-3 years) indicates that approximately 39% of children have dietary intakes less than the Estimated Average Requirement (EAR)[8] of 65 μg/person/day.

Table 2: Current International Dietary Reference Intake Values for Iodine

Country	Age	Reference Intake
Australia and New Zealand[9]	1-3 years	70 μg/day
UK[10]	1-3 years	70 μg/day
WHO[11]	0-59 months (0-6 years)	90 μg/day
Germany/Austria[12]	1-3 years	100 μg/day
Switzerland[12]	1-3 years	90 μg/day
USA and Canada Reference Intake Values for Iodine[13]	1-3 years	90 μg/day

5.2.2 Current iodine status of the children in Australia and New Zealand

The International Council for the Control of Iodine Deficiency Disorders (ICCIDD) have determined criteria for assessing iodine status based on median urinary iodine concentrations in school age children. Many researchers have chosen to use these criteria in assessing their research population. Table 3 below describes the ICCIDD criteria, and Table 4 illustrates the results of several studies undertaken to examine the iodine status of school age children in Australia and New Zealand.

[7] The dietary exposure assessment was conducted using FSANZ's dietary modelling computer program, DIAMOND, and the intake data collected from the 1995 National Nutrition Survey.
[8] The EAR describes the average "intake requirement" and is the intake level below which the population may be at risk of having inadequate intake. The EAR is the amount of intake two standard deviations below the Recommended Dietary Intake.
[9] The National Health and Medical Research Council (NHMRC) is currently reviewing the RDIs for Australia and New Zealand in light of recent international recommendations.
[10] Report of the panel on dietary reference values of the committee on medical aspects of food policy. Dietary Reference values for food energy and nutrients for the United Kingdom 1991. Chapter 35 Iodine
[11] ICCIDD, UNICEF, WHO Assessment of Iodine Deficiency Disorders and Monitoring their elimination. 2nd Edition. Geneva: WHO publishing ,2001
[12] German Nutrition Society, Austrian Nutrition Society, Swiss Nutrition Society, Swiss Society for Nutrition Research. Reference values for nutrient intakes. Frankfurt am main: Umschau/Braus, 2000 (in Thomson 2002)
[13] Food and Nutrition Board IoM. Dietary reference intakes for vitamin A, vitamin K, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium and zinc. Washington, D.C.: National Academy Press, 2001

Table 3: Epidemiological Criteria for Assessing Iodine Nutrition based on Median Urinary Iodine Concentrations in School-aged Children.

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

Table 4: Results from Studies Investigating Iodine Status of Children in Australia and New Zealand

Author	Subjects	n	% < 50 μg/L	% <100 μg/L	Median urinary iodine concentration
	Australia				
Guttikonda 2003	Children 5 –13 years Central Coast, NSW.	301	14	69	82 μg/L
McDonnell 2003	Children 11-18 years Melbourne, VIC	577	27	76	
	Female	410	31	79	
	Male	167	17	69	
	New Zealand				
Skeaff 2002	Children 8 – 10 years	282	31.4	79.7	66 μg/L
NZ National Children's Survey 2002	Children 5-14 years	3275	28		66 μg/L 68 μg/L males 62 μg/L females

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

As illustrated above, studies have shown mild iodine deficiency in Victorian and New South Wales population groups. In Australia there have been no national nutrition surveys that have investigated the iodine status of children, although there is active monitoring in Tasmania but the results of these studies have not been published.

Iodine deficiency is also beginning to re-emerge in New Zealand. A number of studies in New Zealand, including the National Children's Survey have indicated mild iodine deficiency or risk of mild iodine deficiency. The ICCIDD suggest that no more than 20 percent of children in a population should have a urinary iodine level less than 50 μg/L, whereas as illustrated above, three of the four total study populations had a median urinary iodine concentration below this level.

Question:

Do submitters have any information on the iodine status of preschool children in New Zealand and Australia?

5.2.4 Nutrient interactions

Some nutrients are known to compete with others for absorption and bioavailability. There is no literature to suggest that iodine competes with, or inhibits the bioavailability of any other nutrient. This suggests that an increase in dietary iodine intake is unlikely to impact on the nutrient absorption of the consumers of FSFYC.

5.3 Dietary modelling

FSANZ is collecting information around the use of FSFYC to assist in dietary modelling which will be undertaken at Draft Assessment. The Applicant has provided information to suggest that approximately 72 000 children in Australia use their S-26 Toddler Gold milk formula, with research involving an older product that indicated the predominant level of use was one serve per day. The Applicants market research has also indicated that approximately 70% of consumers (i.e. young children) use the product made up with milk, and 30% with water. This information will be used for dietary modelling which will be available for submitter comments at Draft Assessment.

Question:

Are you aware of further information on the use of FSFYC that can be used in dietary modelling at Draft Assessment?

5.4 Safety issues

5.4.1 Upper Limits

Iodine overdose is rare. There are no reported incidences of antibody reaction to iodine although some people have shown sensitivities to intravenous iodine and iodine applied directly to the skin (www.megaheart.com/Beard/Leaflet_14html.htm). Thyroid disease is not uncommon in the New Zealand and Australian populations. Hyperthyroidism (or thyrotoxicosis) is caused by an over active thyroid gland resulting from an excess of circulating free T3 and free T4. Although iodine can cause thyrotoxicosis, a large amount of iodine must be ingested first. This is very uncommon and usually only seen in patients ingesting large iodine loads for radiological procedures such as a barium enema.

There have been a number of reviews on the toxicity of iodine and recommended safe levels as presented in Table 5 below.

Table 5: International Recommended Upper Safe Levels of Iodine Intake

Group	Safe Intake Level	Comments
WHO Joint Expert Committee on Food Additives (JECFA) 1989[14]	0.017 mg/kg bw/day	Level is a Provisional Maximum Tolerable Daily Intake (PTDI). Equivalent to 255 µg/day (for a 15 kg toddler). JECFA noted that this level might still cause adverse effects in some individuals, e.g., those with thyroid disorders or people who are particularly sensitive to iodine.
Agency for Toxic Substances and Disease Registry 2001[15]	0.01 mg/kg bw/day	Level is a Minimal Risk Level (MRL). The MRL is based on a no-observable-adverse-effect-level (NOAEL) of 0.01 mg/kg bw/day and a lowest-observed-adverse-effect-level (LOAEL) of 0.029 mg/kg bw/day for sub-clinical hypothyroidism in healthy human children.
Institute of Medicine 2001[16]	200 µg/day 1-3 years 300 µg/day 4-8 years	The levels are Tolerable Upper Intake Levels (ULs).
Scientific Committee on Food 2002[17]	200 µg/day 1-3 years 250 µg/day 4-6 years	The levels are Tolerable Upper Intake Levels (ULs). The levels are based on studies in adults that showed no adverse clinical effects before being adjusted on the basis of body surface area.
Food Standards Agency, United Kingdom Upper safe limits for vitamins and minerals[18] May 2003	0.015 mg/kg bw/day	The expert committee do not consider there to be sufficient data to establish a Safe Upper Level for iodine. This UL is based on an intake that would not be expected to create any adverse effects. It is expected that some population groups (children), may exceed this intake from normal dietary sources but that compensatory mechanisms exist and allay concerns for potentially vulnerable groups. Equivalent to 225 µg/day (for a 15 kg toddler)

5.4.2 Toxicological safety assessment

Iodine is a well-known chemical element and an extensive amount of literature is available on its toxicology. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) reviewed the toxicology of iodine in 1988. In this review, JECFA set a provisional maximum tolerable daily intake (PMTDI) from all sources of 0.017 mg iodine/kg body weight. However, JECFA also noted that while this level is considered safe for the majority of the population, it may not be fully protective for people with thyroid disorders or people who are particularly sensitive to iodine.

[14] WHO Evaluation of Certain Food Additives and Contaminants (Thirty-third report of the Joint FAO/WHO Expert Committee on Food Additives). WHO Technical Report Series. No. 776. 1989

[15] ATSDR (2001). Draft toxicological profile for iodine. U.S. Department of Health and Human Services, Agency for Toxic Substances and Disease Registry, Atlanta, GA. http://www.atsdr.cdc.gov/

[16] Institute of Medicine. *Dietary reference intakes: vitamin A, K, arsenic, boron, chromium, copper, iodine, iron, manganese, molybdenum, nickel, silicon, vanadium, and zinc*. A Report of the Panel on Micronutrients, Subcommittees on Upper Reference Levels of Nutrients and of Interpretation and Use of Dietary Reference Intakes, and the Standing Committee on the Scientific Evaluation of Dietary Reference Intakes. National Academy Press, Washington DC. 2001

[17] Scientific Committee on Food. Opinion of the Scientific Committee on food on the Tolerable upper intake levels of iodine, 7 October 2002. http://europea.eu.int/comm/food/fs/sc/scf/index_en.html

[18] Expert groups on Vitamins and Minerals. Upper safe limits for vitamins and minerals, May 2003. www.foodstandards.gov.uk/mulitmedia/pdfs/vitmin2003.pdf

A toxicological safety assessment will be provided in conjunction with the dietary modelling in the Draft Assessment Report, and will include JECFA considerations as well as an assessment of other relevant information.

5.2.3 Information from the Applicant

The Applicant has provided information in relation to the European Commission, Scientific Committee on Food (SCF) (SCF 2002) consideration of UK dietary survey data which has shown that intake of iodine in young children aged 1 ½ – 4 ½ years can vary between 87 and 309 μg/day, with the predominant source being milk. The SCF has agreed with the view of the UK Committee on Toxicity of Chemicals in Food, Consumer Products and the Environment (COT) that high iodine intakes in young children who consume high levels of milk are unlikely to pose a health risk, and note that an upper limit (UL) is not threshold of toxicity but may be exceeded for short periods without appreciable risk to the health of individuals.

However the SCF also noted that the UL should not be applied to iodine deficiency disorder (IDD) populations, as they are more sensitive to iodine exposure. Therefore, the implications of increasing the maximum iodine permissions in products aimed at young children may have little effect in the UK population, but a greater one in the Australian and New Zealand population where iodine intakes are lower and the prevalence of iodine deficiency is an emerging issue.

The Applicant contends that if the maximum quantity of iodine permitted in FSFYC was raised to 70 μg (100% RDI) and a child consumed the recommended 2 serves per day then they would receive 140 μg/day from this source which they believe, whilst recognising this to be higher than the currently accepted Australian RDI, is within internationally accepted ranges.

Questions:

Do submitters agree with the position of the Applicant that an increase in the iodine content of FSFYC is unlikely to pose a safety threat to the users of FSFYC in Australia and New Zealand?

Do submitters have any further information on levels of intake required to compromise the safety in populations with low iodine status?

Do submitters have any further information regarding thyroid disorders in young children?

5.5 Other FSANZ work plan items of relevance to this Application

FSANZ is currently assessing Application A493 – Iodine as a Processing Aid, (A493) which is requesting amendment to Standard 1.3.3 - Processing Aids, specifically Clause 12 which relates to permitted bleaching agents, washing and peeling agents. The Applicant is seeking permission to use elemental iodine as a washing agent for fruits, vegetables (including herbs), nuts and eggs with a maximum permitted residue level of good manufacturing practice (GMP).

Application A493 is currently at Draft Assessment and FSANZ expects to conduct another round of public comment on this Application in mid 2004. If this Application is approved, the iodine residue from the sanitising wash will contribute to dietary iodine intake to an unknown extent and potentially increase iodine intakes across the population. FSANZ would then be required to consider the increase of iodine in the food supply in conjunction with this Application.

6. Regulatory Options

There are two possible options to progress this Application:

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

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

7. Impact Analysis

7.1 Affected Parties

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

7.2 Cost Benefit Analysis

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

7.2.1 Option 1 – Status quo

7.2.1.1 Consumers

It is likely that maintaining the *status quo* will have minimal impact on consumers. Though if manufacturers are required to conduct regular batch testing of ingredients there may be increased costs associated with the manufacture of FSFYC which may be passed on to consumers via product price increases. In addition the inability of manufacturers to source suitable raw materials that allow compliance with the iodine limit may result in supply problems and consumers being unable to purchase FSFYC. To date however this situation has not been known to occur.

7.2.1.2 Industry

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

Retaining the *status quo* may require industry to undertake more frequent monitoring of iodine in raw material batches thereby increasing costs and possibly affecting product supply in the future.

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

7.2.1.3 Government

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

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

7.2.2.1 Consumers

An increase in the permitted maximum iodine content of FSFYC may benefit some consumers of FSFYC by providing additional iodine in their diet. Conversely however, there is a possibility that FSFYC consumers who have a low iodine status may be at risk of exceeding a safe intake, especially if powdered products are reconstituted with milk.

7.2.2.2 Industry

An amendment to the Code will have the most benefit for industry as there is likely to be fewer manufacturing costs, particularly in the testing of raw ingredients for iodine levels, for FSFYC and a greater opportunity for regulatory compliance. Furthermore by increasing the quantity of iodine permitted in FSFYC industry are less likely to be required to specifically manufacture FSFYC for New Zealand and Australian markets, thereby increasing trade opportunities.

7.2.2.3 Government

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

Questions:

Are there any other parties that are impacted as a result of this Application?
Are there any other costs or benefits for the affected parties listed above?

8. Consultation

This Initial Assessment Report is intended to seek early input on a range of specific issues known to be of interest to various stakeholders on the likely regulatory impact of this Application. At this stage FSANZ is seeking public comment to assist it in assessing this Application and is particularly interested in receiving further information on the:

- types and use of FSFYC;
- variability of iodine in milk;
- parties that might be affected by having this Application approved or rejected;
- arguments in support or opposition to permitting an increase in the iodine permission for FSFYC; and
- potential costs and benefits to consumers, industry and government.

8.1 World Trade Organization (WTO)

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

The impact on international trade will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on the proposed changes where these changes may have a significant impact on their markets.

9. Conclusion

This Application has been assessed against the requirements of s.13 of the FSANZ Act, and it is recommended that the application be accepted. Accordingly FSANZ now seeks public comment in order to proceed to Draft Assessment. If subsequently recommended by FSANZ and agreed to by the Ministerial Council, an amendment to the Code would permit an increase in the maximum permitted quantity of iodine in FSFYC from 35 μg to 70 μg per serve.

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