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FIRST REVIEW REPORT

APPLICATION A528

MAXIMUM IODINE LIMIT IN FORMULATED SUPPLEMENTARY FOODS FOR YOUNG CHILDREN

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Executive Summary

In September 2005, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) requested a First Review of Application A528 – Maximum Iodine Limit in Formulated Supplementary Foods for Young Children. This Application seeks 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 35 to 70 micrograms (μg) per serving in formulated supplementary foods for young children.

Formulated supplementary foods for young children are products intended for children aged 1 – 3 years.

The Ministerial Council requested its review on the grounds that the Application does not protect public health and safety. In support of this position the Ministerial Council has raised a number of issues as listed in the following table.

MINISTERIAL COUNCIL ISSUE		ASSESSMENT OF ISSUE
Dietary Modelling Issues	The iodine concentration used in the dietary modelling has been based on an assumption of 45.5 μg iodine per serve.	The 45.5 μg per serve iodine concentration allocated to formulated supplementary foods for young children was based on information provided by the Applicant about the natural variation of iodine levels in the product.
	The market for formulated supplementary foods for young children is specialised and brand loyalty is strong. The use of market share data is not valid where a particular consumer is likely to use one brand. A significant number of high consumers already consume approximately 10% above the Upper Level for iodine. Not using the 45% market share methodology would raise this number considerably.	<p>It is appropriate to use market share data in this case because:</p> <ul style="list-style-type: none"> • There is natural variation in iodine levels within a brand and thus a distribution of iodine levels within the brand. Therefore a child will not consume all drinks at of the maximum iodine level per serve even if brand loyal. Therefore, the market share model is valid for a brand loyal consumer. • The dietary modelling process has used an Upper Level that is based on long-term intakes of iodine, assuming that a child will not consume a particular brand, or even multiple brands over a long period of time, as the products are directed to a limited range of ages (1-3 years). • Within the market share model, the variation in the iodine content across various brands was small. Therefore, a separate assessment of brands would not produce a significantly different outcome. • Given that the modelling methodology may have overestimated the proportion of children with intakes above the Upper Level, the omission of market share data from the modelling would not significantly increase the estimated risk to 1-3 year-old children of excessive iodine intakes. Note that a level of iodine inadequacy also exists within the 1-3 year-old population.
	The recommended number of serves used in the modelling was one/day, yet 10-15% children consume 2-3 serves/day.	The dietary modelling assumes one serve per day is the average consumption of formulated supplementary foods for young children over a long period of time. This means children consuming two to three serves per day for a short period of time (~ 1 year) will be accounted for using this model.

MINISTERIAL COUNCIL ISSUE		ASSESSMENT OF ISSUE
Safety Issues	A child could reach the Upper Level of 200 µg per day with just three serves per day (containing up to 70 µg per serve).	This is an unlikely scenario, as data provided by the Applicant indicates that formulated supplementary foods for young children contain iodine concentrations higher than 35 µg per serve only 30% of the time, with a maximum concentration of 56 µg per serve. The Upper Level also reflects long-term intakes, and occasional excursions over this limit do not pose a health risk.
Addition of Iodine to the Maximum Limit	Raising the maximum level from 35 to 45 µg iodine per serve would allow for high compliance with the standard and discourage manufacturers from adding iodine to levels up to 70 µg per serve.	The maximum <u>claimable</u> level is proposed to remain at 35 µg per serve, thereby acting as a disincentive for adding iodine beyond what can be claimed on the label.
	It is inappropriate that a single supplementary food provides the complete nutritional requirements for given nutrients.	A manufacturer could <u>theoretically</u> add iodine to formulated supplementary foods for young children at an amount that would supply all of a 1-3 year-old child's RDI in a single serve. However, the inability to claim such an addition would make the practice commercially unviable and therefore highly unlikely.
The Maximum Iodine Content	Data clearly shows that 99.7% of the time, endogenous levels of iodine will not actually exceed 44.8 µg per serve. There is no need therefore to set the maximum at 70 µg per serve, as 45 µg per serve will be satisfactory from a regulatory point of view.	<u>Data on iodine levels from other manufacturers are not available and therefore the maximum iodine levels found in these products are not known. FSANZ did assess the safety of iodine concentrations up to 70 µg iodine per serve at Final Assessment, concluding that there is no change in the risk to public health and safety if the permitted iodine levels are increased to 70 µg per serve. The higher level also allows industry greater flexibility in sourcing ingredients that are safe and meet regulatory requirements.</u>

Following these considerations, FSANZ remains confident that the findings of the Final Assessment remain applicable at First Review, and that the public health and safety of Australia and New Zealand has been accommodated within the assessment processes of this Application. Therefore FSANZ has reached the following decision in this First Review:

DECISION

FSANZ re-affirms its approval of the draft variation to Standard 2.9.3 of the *Australia New Zealand Food Standards Code* (at Attachment 1) as notified to the Ministerial Council. This decision permits an increase the maximum permitted level of iodine for formulated supplementary foods for young children from 35 to 70 µg per serving.

The reasons for this decision are that:

1. the resultant minor increase in potential iodine intake that occurs with an increase in the maximum permitted quantity of iodine in formulated supplementary foods for young children, identified in the dietary modelling for the Final Assessment, does not raise any public health and safety concerns for the target population;
2. the proposed draft variation to the Code is consistent with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991*. Specifically, FSANZ has addressed the protection of public health and safety by undertaking a risk assessment using the best scientific data available;

3. the proposed draft variation to the Code will increase compliance with the Code, reduce manufacturing costs, and prevent unnecessary trade barriers; and
4. the regulation impact assessment at Final Assessment concluded that the benefits from increasing the maximum permitted quantity of iodine in FSFYC outweigh any potential costs to affected parties.

1. Introduction

In September 2005, the Ministerial Council requested a First Review of Application A528 - Maximum Iodine Limit in Formulated Supplementary Foods for Young Children. This Application seeks 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 35 to 70 micrograms (µg) per serving in formulated supplementary foods for young children.

Formulated supplementary foods for young children are products intended for children aged 1 – 3 years.

2. Objectives of the Review

The objective of the First Review is to reconsider the draft variation notified to the Ministerial Council by Food Standards Australia New Zealand (FSANZ) in July 2005 in light of the Council's concerns as outlined in Section 3.

3. Grounds for the Review

A First Review was requested on the grounds that approval of the draft variation does not protect public health and safety. In support of this position, the Ministerial Council raised the following issues:

- concerns were expressed about a number of the assumptions and data used in the dietary intake assessment provided at Final Assessment;
- the potential for population intakes to exceed the Upper Level for iodine (the maximum safe level of intake);
- the potential for manufacturers to add iodine up to the proposed maximum iodine content limit; and
- whether it is necessary to increase the maximum iodine content limit to 70 µg per serve, and that a 45 µg per serve maximum iodine limit would be satisfactory from a regulatory viewpoint.

4. Background

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 Code to increase the maximum permitted quantity of iodine from 35 to 70 µg per serving in formulated supplementary foods for young children. The Applicant requested an increase in the maximum permitted quantity of iodine in formulated supplementary foods for young children to accommodate levels of naturally occurring¹ iodine in ingredients used in their manufacture.

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.

In July 2005, the FSANZ Board approved the Final Assessment of this Application, including the draft variation to Standard 2.9.3, and notified the Ministerial Council of its decision.

The main outcomes of the Final Assessment were that: there were no safety issues with increasing the maximum quantity of iodine to 70 µg per serve; sections of the 1-3 year old Australian and New Zealand populations have sub-optimal iodine intakes; and the maximum claimable quantity of iodine (35 µg per serve) be retained.

5. Assessment of the Ministerial Council Grounds for a Review

5.1 Protection of Public Health and Safety

The reason cited by the Ministerial Council for requesting a review of Application A528 was that it did not protect public health and safety.

For this Application, the main public health and safety concerns are associated with the risk to consumers from increasing the maximum permissible iodine content in formulated supplementary foods for young children from 35 µg per serve to 70 µg per serve. The specific risk in this situation is the potential for excessively high iodine intakes, which may have adverse health effects.

FSANZ considered this risk at Final Assessment by conducting a full risk assessment, including dietary modelling. At First Review this risk, and the risk assessment, have been reassessed through a review of the specific issues that formed the basis for the Ministerial Council's concerns on public health and safety. The assessment of these issues is detailed in the following sections.

5.2 Dietary Modelling Issues

Dietary modelling is a part of the risk assessment process and may also be used to inform risk management decisions. In this case, it was used to determine the potential impact of granting permission to increase the maximum permitted quantity of iodine in FSFYC from 35 µg/serve to 70 µg/serve on the iodine intake of the target population.

Concerns were raised about several aspects of the dietary modelling that was presented at Final Assessment, namely:

- the iodine concentration used,
- market share assumptions used, and
- the recommended number of serves used.

5.2.1 The Iodine Concentration Used in the Dietary Modelling

It was commented that FSANZ has based the dietary modelling and risk assessment on a figure of 45.5 µg iodine per serve, derived from the median level of iodine in the milk plus three standard deviations.

However, the figure of 45.5 µg iodine per serve was not derived from the median level of iodine in milk plus three standard deviations. The iodine concentration of 45.5 µg per serve used in the dietary modelling was a weighted figure, based on the Applicant's inability to comply with the 35 µg per serve maximum limit 30% of the time. Therefore, formulated supplementary foods for young children were assigned a maximum iodine concentration of 35 µg per serve 70% of the time, and a maximum iodine concentration of 70 µg per serve for the remaining 30% of the time (70% of 35 µg + 30% of 70 µg = 45.5 µg).

The modelling therefore accommodated the natural distribution of iodine content in products. The baseline model that used 35 µg iodine per serve is not intended to necessarily reflect iodine levels in currently available formulated supplementary foods for young children, and is instead a theoretical model based on current permissions.

5.2.2 *Market Share Assumptions*

A number of issues were raised on FSANZ's use of market share assumptions. These issues included:

- whether the assumption of a market share of 45% for the Wyeth brand of formulated supplementary foods for young children accommodates potentially strong brand loyalty of consumers;
- that market share assumptions may not be valid where a particular consumer is likely to use one brand for long periods of time;
- consumers who make up the 45% market share for Wyeth may not consume any other brands; and
- a significant number of high consumers were identified in the Final Assessment as already consuming approximately 10% above the Upper Level for iodine, and excluding considerations on market share could raise this number considerably.

5.2.2.1 Accommodating Brand Loyalty

The use of market share data in the dietary modelling is highly appropriate for the risk assessment as it assesses iodine intakes of the population over a period of time, and in this case includes brand loyalty considerations.

Natural variation within a brand means that there will be a distribution of iodine levels within the brand, and a child will not consume all drinks at 70 µg of iodine per serve even if brand loyal. Based on information provided by the Applicant, iodine levels exceed 35 µg iodine per serve in only 30% of products. The 30% of products over 35 µg iodine per serve represent the upper end of the distribution, and 70 µg of iodine per serve is considered an absolute maximum. The data supplied by the Applicant indicates that maximum iodine values generally do not exceed 56 µg per serve.

5.2.2.2 Long-Term Intake

It is not expected that children will be using formulated supplementary foods for young children (either single or multiple brands) for long periods of time. The Code defines formulated supplementary foods for young children (Standard 2.9.3) as products intended for children aged 1-3 years. Consumption data provided by the Applicant also reaffirms that formulated supplementary foods for young children are predominantly used during the 1-3 year age period.

The risk assessment at Final Assessment, including the market share modelling, compares estimated intakes to an Upper Level that represents a maximum daily intake over a lifetime. The risk assessment was therefore conservative given that formulated supplementary foods for young children are not used over a lifetime. However the modelling did ensure that long-term risks were represented through comparison of the estimated intakes with a reference health standard that relates to a longer period of intake.

5.2.2.3 Exclusive Brand Consumption

When formulated supplementary foods for young children are made up with water, the Wyeth brand has a mean iodine content of 208 µg per kilogram, and other brands have a similar mean iodine content of 211 µg per kilogram. When these values are weighted to take into consideration Wyeth having a 45% market share, the weighted mean concentration across brands is 210 µg per kilogram (45% of 208 µg/kg + 55% of 211 µg/kg = 210 µg/kg). If the estimated intakes were calculated for each brand separately, the small 3 µg per kilogram differences in iodine content across brands would result in minimal differences in estimated iodine intakes.

As Wyeth is the only brand with directions on the label for preparing the product with milk, the dietary modelling undertaken at Final Assessment separately addressed this issue.

5.2.2.4 Impact of Market Share Data on Safety Outcomes

The dietary modelling results at Final Assessment showed some children exceed the Upper Level for iodine, even where the iodine concentration was based on the current permitted level of 35 µg per serve. However, from available urinary iodine studies reported at Final Assessment (Li *et al.*, 2001; Guttikonda *et al.*, 2003; McDonnell *et al.*, 2003; Ministry of Health, 2003; Skeaff *et al.*, 2002; Skeaff *et al.* 2005), FSANZ is aware that a proportion of Australian and New Zealand 1-3 year old children may not be consuming iodine at sufficient levels to meet their requirements. This information shows that the baseline distribution of iodine status within the childhood population of Australia and New Zealand is broad, with some people experiencing or being at risk of developing a mild iodine deficiency, and with others having very high iodine intakes.

The estimated intakes of iodine were not adjusted to take into account 'second day' food consumption data, because the model used in the DIAMOND software did not have this particular adjustment capability. It has been shown that consumption information over several days provides more accurate information about long term consumption patterns with the distribution of intakes of particular nutrients becoming narrower (Rutishauser, 2000). If estimated iodine intakes were adjusted to accommodate consumption over a longer period of time, the number of children exceeding the Upper Level would decrease.

As mentioned in Section 5.2.2.3 above, other brands of formulated supplementary foods for young children have similar iodine concentrations, and market weighting had little effect on the iodine concentrations that were imputed into the intake assessment.

Omission of the market share methodology would not significantly increase the estimated risk to 1-3 year-old children of excessive iodine intakes. Furthermore, the methodology used to conduct the modelling will overestimate the proportion of children with iodine intakes above the international health reference standard. Examination of urinary iodine data for children supports the observation that the intake assessment is conservative and is overestimating actual intake.

5.2.3 Recommended Number of Serves Used in the Dietary Modelling

It was stated that the dietary modelling is undertaken on one serve of formulated supplementary foods for young children per day. It is acknowledged in the Final Assessment Report that 10-15% of children consume 2-3 serves per day, and the packages state that the recommended number of serves per day is two.

The issue of the number of serves was investigated as a means of ensuring that the correct assumptions were made about milk substitution behaviours. In the initial considerations it was assumed that all milk consumption could be substituted for formulated supplementary foods for young children. However, this was considered to be unrealistic, especially over a long period of time. Consequently, FSANZ sought information from the Applicant at this point on actual consumption patterns of formulated supplementary foods for young children.

While the recommended number of serves of formulated supplementary foods for young children per day on product labels is specified as two, market research information provided by the Applicant showed that the mean number of serves consumed per day is one or less (approximately 80% of children use the products once per day or less).

The dietary modelling assumes one serve per day is the average consumption of formulated supplementary foods for young children over a long period of time. This means children consuming two to three serves per day will be accounted for using this model, assuming they will not consume this many serves every day for a period of three years. Even if a child did consume 2-3 serves per day, studies of sub-clinical indicators show that healthy children produce an adaptive response to an increase in iodine intake. Therefore, modelling on one serve per day is appropriate for risk assessment purposes.

5.2.4 Summary

The information shows that the baseline distribution of iodine status within the childhood population of Australia and New Zealand is broad, with some children experiencing or being at risk of developing a mild iodine deficiency and others having very high iodine intakes. Dietary modelling was used to determine the potential impact of granting permission to increase the maximum permitted quantity of iodine in FSFYC from 35 µg/serve to 70 µg/serve on the iodine intake of the target population. A number of different scenarios were examined in the dietary modelling and included considerations of market share, preparation methods, consumption patterns over a period of time and the natural distribution of iodine contents in FSFYC products.

Assumptions made in the dietary modelling process took account of consumers who are brand loyal. Estimated dietary iodine intakes were compared with a reference health standard, the upper Level for iodine, which represents the maximum iodine intake over a lifetime, noting that occasional excursions over this level do not present an appreciable health risk.

5.3 Safety Issues

It was stated that *with brand loyalty (i.e. consumption from the brand containing up to 70 µg iodine per serve) made up as directed, a child could reach the Upper Level of 200 µg/day with just 3 serves per day, not including iodine from all other sources.*

This scenario is possible if the consumer has 3 serves of formulated supplementary foods for young children from the same can containing 70 µg of iodine per serve. However, this is unlikely to occur. Data provided by the Applicant indicates that formulated supplementary foods for young children contain iodine concentrations higher than 35 µg per serve only 30% of the time, even within one brand.

Data indicate that the highest iodine concentration per serve is approximately 56 µg, an amount unlikely to be consumed everyday in the long term, given the natural iodine variations that occur in formulated supplementary foods for young children. Established safety limits for iodine intake do not represent an absolute threshold for toxicity, and children can tolerate natural iodine fluctuations for a short period of time without any appreciable health risk.

5.4 Maximum Iodine Content

It was stated that *the sole reason stated to raise the level of iodine in formulated supplementary foods for young children from 35 µg per serve to 70 µg per serve is to accommodate the variation in iodine levels in milk. The data clearly shows that 99.7% of the time, the endogenous levels of iodine will not actually exceed 44.8 µg per serve (page 22, second paragraph of the Final Assessment Report). There is therefore no need to set the maximum at 70 µg per serve, given the potential public health issues that arise, as 45 µg per serve will be satisfactory from a regulatory viewpoint.*

The 44.8 µg per serve value was based on data provided by the Applicant for their product range. This value represents a mean iodine concentration (28.9 µg) per serve plus 3 standard deviations, and was derived on the basis of the general understanding of the relationship between the mean and high percentiles of distributions of data.

This information was provided at Final Assessment to show the likely distribution of iodine concentrations across currently available products. However, the actual maximum iodine concentrations provided by the Applicant show iodine levels up to 56 µg per serve, depending on the manufacturing location. The Applicant has also stated that they cannot meet the 35 µg per serve limit 30% of the time.

Another manufacturer has also indicated that at times they fail to meet the current 35 µg per serve maximum iodine limit using milk sourced from Australia, which demonstrates that the problem is not unique to the Applicant. Data on iodine levels from other manufacturers are not available and therefore the maximum iodine levels found in these products is not known.

However, FSANZ did assess the safety of iodine concentrations up to 70 µg iodine per serve at Final Assessment. The assessment concluded that there is no change in the risk to public health and safety if the permitted iodine levels are increased. The higher level also allows industry greater flexibility in sourcing ingredients that are safe and meet regulatory requirements.

5.5 Addition of Iodine up to the Maximum Limit

The Ministerial Council made a comment that the change to Standard 2.9.3 should be to raise the level of iodine per serve from 35 µg to 45 µg. Two issues were raised in reference to this recommendation:

- A 45 µg per serve maximum iodine limit would allow for high compliance with the standard and discourage manufacturers from adding iodine to levels up to 70 µg per serve; and
- The Final Assessment Report quoted (page 9) the outcomes of P199 - Formulated Meal Replacements and Formulated Supplementary Foods, a project that produced Standard 2.9.3. The discussion at Final Assessment indicated that it is inappropriate for a single supplementary food to provide the all of the recommended daily intake for given nutrients (70 µg/day for iodine).

5.5.1 Compliance with Standard 2.9.3

The maximum level of iodine that can be claimed in these products will remain at 35 µg per serve even though the maximum iodine content will be permitted up to 70 µg per serve to accommodate the natural variation in iodine levels in ingredients. This is a deliberate measure that prevents manufacturers from making claims on iodine contents in their products above 35 µg per serve. The inability to claim above 35 µg per serve creates a disincentive to add iodine above this concentration, as such a practice would be an unnecessary expense (additional iodine imposes manufacturing costs) with little or no benefit to the manufacturer.

FSANZ is unaware of any commercial reason or industry trend that would suggest manufacturers add iodine up to the maximum content limit.

5.5.2 Supply of Complete Nutritional Requirements

It is recognised by FSANZ that under a 70 µg per serve maximum iodine limit, a manufacturer could theoretically add iodine to formulated supplementary foods for young children at an amount that would supply all of a 1-3 year-old child's RDI in a single serve. However, the inability to claim such an addition would make the practice commercially unviable and therefore highly unlikely.

It should also be noted that the Applicant has not requested that formulated supplementary foods for young children be permitted to provide 1-3 year olds with their complete nutritional requirements, nor have the objectives of Application A528 encompassed such an outcome.

5.6 Outcomes of the Review on Public Health and Safety

At Final Assessment, FSANZ carried out a full risk assessment and was satisfied that iodine intakes would not increase to hazardous levels. After having reviewed the issues raised by the Ministerial Council on this risk assessment process, FSANZ remains confident that the findings of the Final Assessment remain applicable at First Review. Therefore it is concluded that protection of public health and safety has been satisfactorily addressed within the assessment processes of this Application.

6. Review Options

Three options are considered in this review:

1. Re-affirm approval of the draft variation to Standard 2.9.3 of the Code as notified to the Ministerial Council; or
2. Re-affirm approval of the draft variation to Standard 2.9.3 of the Code subject to any amendments FSANZ considers necessary; or
3. Withdraw approval of the draft variation to Standard 2.9.3 of the Code as notified to the Ministerial Council.

7. The Decision

After consideration of the issues raised in Section 5 of this report, and the options presented in Section 6, FSANZ has reached the following decision:

FSANZ re-affirms its approval of the draft variation to Standard 2.9.3 of the *Australia New Zealand Food Standards Code* (at Attachment 1) as notified to the Ministerial Council. This decision permits an increase the maximum permitted level of iodine for formulated supplementary foods for young children from 35 to 70 µg per serving.

The reasons for this decision are that:

1. The resultant minor increase in potential iodine intake that occurs with an increase in the maximum permitted quantity of iodine in FSFYC, identified in the dietary modelling for the Final Assessment, does not raise any public health and safety concerns for the target population;
2. The proposed draft variation to the Code is consistent with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991*. Specifically, FSANZ has addressed the protection of public health and safety by undertaking a risk assessment using the best scientific data available;
3. The proposed draft variation to the Code will increase compliance with the Code, reduce manufacturing costs, and prevent unnecessary trade barriers; and

4. The regulation impact assessment at Final Assessment concluded that the benefits from increasing the maximum permitted quantity of iodine in FSFYC outweigh any potential costs to affected parties.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*.

References

1. Guttikonda K, Travers C, Lewis P, Boyages S (2003). Iodine deficiency in urban primary school children: a cross-sectional analysis. *Med J Aust.* **179**: 346-348.
2. Li M, Ma G, Guttikonda K, Boyages S, Eastman C (2001). Re-emergence of iodine deficiency in Australia. *Asia Pacific J Clin Nutr.* **10**: 200-203.
3. McDonnell C, Harris M, Zacharin M (2003). Iodine Deficiency and Goitre in School Children in Melbourne, 2001. *Med J Aust.* **178**: 159-162.
4. Ministry of Health (2003). *NZ food NZ children: key results of the 2002 National Children's Nutrition Survey*. Ministry of Health, Wellington.
5. Rutishauser, I. (2000) *Getting it right:- how to use the data from the 1995 National Nutrition Survey*. Commonwealth of Australia, Canberra.
6. Skeaff S, Thomson C, Gibson R (2002). Mild Iodine Deficiency in a Sample of New Zealand Schoolchildren. *Eur J Clin Nutr.* **56**: 1169-1175.
7. Skeaff, S.A., Ferguson, E.L., McKenzie, J.E., Valeix, P., Gibson, R.S. and Thomson, C.D. (2005) Are breast-fed infants and toddlers in New Zealand at risk of iodine deficiency? *Nutrition* **21**(3):325-331.

ATTACHMENT 1

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

To commence: On gazettal

[1] *Standard 2.9.3 of the Australia New Zealand Food Standards Code is varied by omitting the entry in Column 2 of Table 3 of the Schedule for Iodine, substituting –*

70 µg (100%)