FORTIFICATION OVERAGES OF THE FOOD SUPPLY

Vitamin C, zinc and selenium

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by

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VITAMIN C, ZINC AND SELENIUM

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DISCLAIMER

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ABBREVIATIONS

AI	Adequate intake, used when an RDI cannot be determined. Is based on observed or experimentally-determined approximations or estimates of nutrient intake by a group (or groups) of apparently healthy people that are assumed to be adequate.
CV	Coefficient of variation, equal to the standard deviation of results divided by the mean of results, expressed as a percentage
IANZ	International Accreditation New Zealand
MFD	Manufactured Foods Database
NNS	National nutrition survey
NZFSA	New Zealand Food Safety Authority
RDI	Recommended dietary intake, the average daily dietary intake level that is sufficient to meet the nutrient requirements of nearly all healthy individuals in a particular life stage and gender group.
UL	Upper level of intake, the highest average daily nutrient intake level likely to pose no adverse health effects to almost all individuals in the general population.

SUMMARY

The aim of the project was to assess levels of vitamin C and zinc in a range of food types, and selenium in infant formulae; and to compare these to average levels claimed on product labels, and in the case of selenium in infant formula, to the mandatory minimum and maximum levels in the Standard 2.9.1 of the Food Standards Code. This information will assist in the development of food standards relating to nutrient fortification. The project follows similar projects assessing levels of folate and iron (2005) and vitamin A, vitamin D and calcium (2006).

Vitamin C and zinc

Approximately 225 samples from forty five different food products were purchased between November 2006 and March 2007 from Auckland, Christchurch or Wellington retail outlets and analysed for vitamin C or zinc. Vitamin C content was determined using an acid extraction, oxidation and derivatisation and analysis by high performance liquid chromatography with fluorescence detection. The variability between 5 batches of 25 food products, as measured in terms of CV, ranged from 1-60% with 40% of samples giving a CV of greater than 25%. Samples for zinc analysis were acid digested with nitric and hydrochloric acid and analysed by ICP-MS. The variability of zinc content between batches, as measured by CV, ranged from 3-42 %.

In assessing the data, an overage or underage was defined as being where the label claim did not correspond to the measured value after making an allowance for the measurement uncertainty associated with this value.

Mean vitamin C concentrations were 21-84% below the average label claim in 20% of the products tested (5/25) and exceeded the label claim in 52% (13/25) of products with overages of 19-529%. The mean concentration of twenty eight percent (7/25) of the products analysed for vitamin C met the average label claim. A single serving of the fruit based canned baby food with the highest overage of 529% would result in an intake of 227 mg of vitamin C contributing between seven to eight times the adequate intake of vitamin C for a 7-12 month infant and 23% of the prudent upper limit for vitamin C.

Mean zinc concentrations were 14-56% below the average label claim in 20% of the products tested (4/20) and exceeded the label claim in 30% (6/20) of products with overages of 18-83%. The mean concentrations of 45% (9/20) of the products analysed for zinc met the average label claim. High consumption of the product with the maximum zinc overage would result in an intake of up to 26% of the Upper Level of intake (UL).

The mean concentrations of 20 % (9/45) of the foods sampled were less than claimed, based on the criteria applied in this assessment. Consumers of these products are ingesting less of the added nutrients than they would believe, based on average label claims.

The mean concentrations of 42% (19/45) of the foods sampled were higher than claimed. None of the selected foods fortified with vitamin C or zinc appear to present a realistic hazard of a consumer exceeding the UL of any of these nutrients.

All analytical measurements have associated uncertainty arising from sampling, the analytical method and the manufacturing technique. For standard setting, consideration may be given to defining a range around the label claim that takes measurement uncertainty into account.

Selenium in infant formulae

Approximately 100 samples of 20 different infant formulae were analysed for selenium content. Samples were purchased between November 2006 and March 2007 from Auckland, Christchurch or Wellington retail outlets. Infant formulae, prepared as for consumption, were analysed for selenium content by atomic absorption following an acid digestion and conversion of the selenium to selenium hydrides. The variability of selenium content between batches, as measured by CV, ranged from 0-63% for different batches of the same product.

Mean selenium concentrations met the label claim in 60% of the infant formulae tested (12/20) and exceeded the label claim in 35% (7/20) of products with overages of 7-49%. One product made no claim for selenium content. Each of the infant formulae with a selenium label claim, complied with the maximum and minimum permissible amounts of selenium.

Consumption of the recommended three to four feeds per day, of the two follow-on formulae with the highest overages, would result in an intake of 128% of the Adequate Intake (AI) and 32% of the UL for a seven to twelve month infant, the target consumer for these products. None of the selected infant formuale appear to present a realistic hazard of a consumer exceeding the UL of selenium.

1 INTRODUCTION

Work is progressing on the development of food standards relating to nutrient fortification. The establishment of safe upper limits for nutrients added to foods and meaningful label claims relies on robust data of current intake, based on consumption data and concentration information of actual levels, for the foods of interest.

The Food Standards Code requires that most packaged processed foods must display a nutritional information panel (FSANZ, 2002, Standard 1.2.1). Where a food product claims to contain a vitamin or mineral, the label must state the average quantity of that vitamin or mineral (FSANZ, 2002, Standard 1.3.2) where "average" may be determined by (a) the manufacturer's analysis of the food, or (b) calculation from the actual or average quantity of nutrients in the ingredients used; or (c) calculation from generally accepted data to best represent the quantity of the substance that the food contains, allowing for seasonal variability and other known factors that could cause actual values to vary (FSANZ, 2002, Standard 1.1.1)

The Manufactured Foods Database (MFD) is a compilation of food ingredient and composition data voluntarily provided by New Zealand food manufacturers and compiled by Nutrition Services, Auckland Hospital, under contract to the New Zealand Food Safety Authority (NZFSA). The MFD includes data on fortificants which are derived from either measured amounts or calculated from recipes by manufacturers (Nutrition Services, 2005) and shows an increasing number of fortified foods available on the New Zealand market (Nutrition Services, 2005).

While there are sufficient data on the composition of unfortified foods, there are limited independent data on the actual levels of fortificants in fortified foods in New Zealand. International evidence suggests that actual levels of fortificants can vary significantly, by up to 320% of the claimed label value (Whittaker *et al*., 2001). For New Zealand foods fortified with folate, iron, vitamin A, vitamin D or calcium, overages of up to 296% have been found (Thomson, 2005, 2006).

There is a potential public health and safety issue associated with insufficient or over-consumption of some nutrients and interactions between nutrients if levels are too high. For this reason, Recommended Dietary Intakes (RDI)s and Upper Levels of Intake (UL)s have been estimated for New Zealand and Australia, for a range of nutrients including vitamin C, zinc and selenium (AG/MoH, 2006). Details for these nutrients are provided in Appendix 1.

Although most animals can synthesize vitamin C from D-glucose, humans lack the key enzyme, L-3 gulonolactone oxidase. Vitamin C has a role in several metabolic pathways including the synthesis of the connective tissue protein, collagen, the conversion of dopamine to the neurotransmitter noradrenaline and the biosynthesis of the amino acid carnitine, that has a fundamental role in fatty acid metabolism (Mann and Truswell, 1999). Vitamin C may prevent the formation of potentially carcinogenic N-nitroso compounds in the gut, and protect against free radical damage through anti-oxidant properties. Vitamin C deficiency causes scurvy (AG/MoH, 2006). The RDI of vitamin C for infants is based on the lower level found in breast milk and the fact that no incidences of scurvy have been reported for breastfed infants. For adult men, the RDI is based on a body content halfway between tissue saturation and the point at which clinical signs of scurvy appear. The RDI for women is based on the RDI for men. An UL for vitamin C has not been established because data are inconclusive but 1000 mg/day is a prudent limit (AG/MoH, 2006).

Zinc is a component of various enzymes that help maintain structural integrity of proteins and regulate gene expression. Although plasma zinc concentrations are not generally affected by mild deficiency, this can result in impaired growth rate, suboptimal pregnancy outcomes and an impaired immune response. In addition to impaired growth, severe zinc deficiency can result in hair loss, diarrhoea, delayed sexual development and impotency, eye and skin lesions and impaired appetite. There is no evidence of adverse effects from naturally occurring zinc in food but chronic intake of supplemental zinc may lead to suppression of immune response, decrease in high density lipoprotein cholesterol and reduced copper status. The UL for zinc is based on the impact of zinc on copper metabolism.

Selenium exerts its effects as a constituent of several selenoproteins with the most important being glutathione peroxidases, selenoprotein P, iodothyronine 5'-deiodinases and thioredoxin reductases. Selenium functions as an antioxidant and plays a crucial role in the metabolism of thyroid hormones that are essential for growth and metabolism (Mann and Truswell, 1999). Low selenium intake is associated with Keshan and Keshan-Beck diseases. Selenium deficiency in conjunction with iodine deficiency has also been reported to increase the risk of cretinism (AG/MoH, 2006). The Recommended Daily Intake (RDI) of selenium for adults is based on the assessment of glutathione peroxidase activity at varying intakes of supplemental selenium. The RDI for children was derived from the value for adults with adjustment for relative body weights. The AI for infants (0-6) is based on breast milk equivalents and is extrapolated to 7-12 months infants on a weight basis. The margin between an adequate and toxic intake of selenium is quite narrow. Over exposure to selenium can lead to loss of hair and nails as well as stomach upset, skin rash, fatigue, irratibility and nervous system abnormalities. The UL of selenium for adults is based on increased risk of cancer. For young infants, the UL is based on the absence of any observable adverse effects from the consumption of breast milk with a selenium concentration of 60 µg/L.

Selenium is mandatory in infant and follow-on formulae with minimum and maximum amounts of 0.25µg and 1.10µg per 100kJ respectively (Standard 2.9.1, Food Standards Code).

The aim of the project was to measure the actual levels of the fortificants vitamin C and zinc present in fortified foods, and selenium in infant formulae and to compare actual levels with average levels claimed on product labels. An analysis of actual levels of nutrients being present in fortified foods is essential for undertaking a robust risk assessment of the consequences of nutrient additions to foods, both mandatory and voluntary, and will used in the development of the relevant food standards.

2 MATERIALS AND METHODS

2.1 Selection of foods for inclusion in the study

Foods that are fortified with vitamin C, zinc or selenium were identified from the MFD and grouped into food types. Foods from each food group were selected for analysis with consideration being given to both the relative popularity of the food while also ensuring the inclusion of as wide a range of fortified foods as possible. The following sample plan was agreed in consultation between the NZFSA and ESR (Table 1). Further details of the foods listed in the MFD (Nutrition Services, 2005) as being fortified with vitamin C, zinc or selenium are shown in Appendix 2. The description of most foods is self explanatory with the exception of food drinks, a term used in the MFD for products including manufactured beverages (eg. Bournvita, drinking chocolate, Milo and sports drinks) and liquid meal replacements (eg. So Good, Up & Go, Alfalite, Naturally Slim, Vitaplan, Complan and liquid breakfasts).

Table 1: Selection and number of food products fortified with vitamin C or zinc, and infant formulae fortified with selenium, for analysis and comparison with label claims

Food Type	Vitamin C	Zinc	Selenium
Baby foods	5 (x5)	2 (x5)	0
Breakfast cereals	4 (x5)	7 (x5)	0
Dairy foods	0	1 (x5)	0
Food drinks	4 (x5)	4 (x5)	0
Fruit drink and cordial	5 (x5)	0	0
Fruit juice	4 (x5)	0	0
Miscellaneous	3 (x5)	6 (x5)	0
Standard IF	0	0	7 (x5)
Specialised IF	0	0	5 (x5)
Follow-on IF	0	0	6 (x5)
Specialised follow-on IF	0	0	2 (x5)
Total	**125**	**100**	**100**

number of batches per food product in parenthesis

2.2 Sampling and sample preparation

Samples were only analysed for a selected fortificant if the fortificant was declared on the product label, with the exception of one sample of infant formula that did not state a claim for selenium content. Infant formulae are required by legislation to contain a minimum of 0.25μg selenium per 100kJ (FSANZ, 2002, Standard 2.9.1).

Foods were purchased between November 2006 and March 2007. Single packets from five batches of each selected food item were purchased largely from Christchurch retail outlets with a few purchases made in Wellington and Auckland to obtain the required number of batches. Because of the long shelf life of the infant formulae there were two products for which it was possible to purchase only four different batches, and one product for which only three batches were obtained.

Samples for vitamin C analysis were dispatched to the analytical laboratory unopened to avoid loss after opening. Samples were analysed as received and not prepared as for consumption.

Powdered food drinks and meal replacements for zinc analysis, and all infant formulae for selenium analysis, were prepared for consumption as per the manufacturers instructions. Sub-samples were frozen at -15°C until dispatch to the analytical laboratory by overnight courier.

For dry products not reconstituted, such as breakfast cereals and snack bars, the entire packet was ground in a domestic blender. For the analysis, approximately 50ml of the powdered material was frozen at -15°C until dispatch to the analytical laboratory by overnight courier.

2.3 Laboratory analytical methods

2.3.1 Vitamin C analysis

Vitamin C analyses were undertaken, on products as received, using published methodology (Dodson *et al*., 1992). In summary, samples were acid extracted with phosphoric acid-acetic acid, oxidised to dehydroascorbic acid and derivatised for analysis by high pressure liquid chromatography with fluorescence detection. These analyses were undertaken by AgriQuality Laboratory Services, Auckland who are accredited by International Accreditation New Zealand (IANZ) for vitamin C analyses by this method.

2.3.2 Zinc analysis

Accurately weighed sub-samples (0.5-2.5g) of the homogenized foods were acid digested with nitric and hydrochloric acid at 85°C for one hour and analysed by Inductively Coupled Plasma Mass Spectrometry (ICP-MS). Analyses were undertaken by Hill laboratories, Hamilton, who are accredited by International Accreditation New Zealand (IANZ) for this method.

2.3.3 Selenium analysis

Accurately measured sub-samples (0.5-2.5g) of the homogenized foods were acid digested with nitric and hydrochloric acid, converted to selenium hydrides by sodium borohydride reagent and analysed by atomic absorption, based on APHA, 3114C (1998). Analyses were undertaken by Hill laboratories, Hamilton, who are accredited by International Accreditation New Zealand (IANZ) for this methodology.

2.3.4 Moisture

The moisture content of samples submitted for zinc and selenium analyses were determined by drying for 16 hours at 103 ± 3°C at ambient pressure (AOAC Official Method 934.01, modified).

2.3.4 Quality control procedures

The following quality assurance procedures were undertaken to ensure robust results:

- The analytical repeatability, in terms of coefficient of variation (CV) was determined for vitamin C, zinc and selenium by undertaking five analyses of each of three samples representing different food matrices. A coefficient of variation (CV = standard deviation of results divided by mean x 100%) of less than 10% is considered good but higher values may be more realistic for some matrices, analyte and concentration combinations (Vannoort, personal communication, 2005). The repeatability for vitamin C ranged from 1 to 12%, 2 to 3% for zinc and 4 to 6% for selenium (Appendix 3.1 to 3.3).
- Recovery compares the amount of the analyte (eg. vitamin C, zinc or selenium), measured in a sample to which a known amount has been added and corrected for the amount of analyte in the unspiked sample, with the amount of analyte added in the spike. Acceptable recoveries for nutrient analyses would generally be 70-125% (Vannoort, personal communication, 2005). The recoveries of vitamin C, zinc and selenium from spiked samples were good, ranging from 83-112%, 88-110% and 87-102% respectively, confirming the accuracy of the analytical method (Appendix 3.4).
- Blind duplicates of different food types were submitted for analysis. The CVs for vitamin C and zinc were within 13% (Appendix 3.5.1 and 3.5.2). Greater variability (CV-21%) was observed for selenium in one of the infant formulae, possibly reflecting the lack of even distribution of selenium in the product.
- Certified reference materials were analysed as a measure of the accuracy of the determinations for each of the selected analytes. Measured values were 83% or better of certified values giving confidence in the accuracy of the determinations.

2.4 Derivation of ranges for overage or underage assessment

No analytical result is exact, but the result will always have an associated degree of uncertainty indicating the “±” range from the measured result within which the true result will lie. It is important to quantify the measurement uncertainty so that a range can be defined, for which there is a known probability that a measured result will occur, as a basis for comparing the measured concentration of a fortificant with an average label claim.

Uncertainty for the current samples is due to:

1. Intra-sample variability, or repeatability - a measure of the variation in results for multiple analyses of the same sample. This is a measure of variability resulting from the analytical method and sub-sampling procedures.
2. Inter-sample variability – a measure of the variability between different batches of the same product. This includes the variability of both the analytical method and the manufacturing technique. The homogeneity of a product depends on when and how the fortificant is added and may differ for different products. Lack of homogeneity is one source of both intra- and inter-sample variability.

A 95% uncertainty range of the mean was determined for each product sampled, using the standard deviation derived from the analysis of five different batches of each product and the formula (TELARC, 1987):

$$\text{Range (confidence limits)} = \text{mean} \pm \frac{t \times \text{standard deviation}}{\sqrt{n}}$$

where: "t" = a statistical factor found in statistical tables
n = number of sample replicates (5)

For a mean concentration falling within this range, there is a 95% probability that the true result lies within a range of the mean ± 1.2 (i.e. 2.78/√5) x standard deviation of the measured concentration. It follows then that for a product where the average label claim was outside this range, the level of confidence that the sample does not meet the label claim is 95% or more.

Samples were assessed as complying with the average label claim if the label claim was within the 95% uncertainty range and defined as non-complying if the label claim was outside this range.

The % overage or underage was calculated as : $\frac{\text{mean concentration-label claim}}{\text{label claim}} \times 100$

3 RESULTS

3.1 Concentration of vitamin C in fortified foods

The mean concentration of vitamin C in the selected food products as purchased ranged from 5 to 291 mg/100g (Table 2). A full set of results is included in Appendix 4.1. The "label" claims cited in Table 2 are those stated in, or derived from, the MFD (Nutrition Services, 2005).

Table 2: Mean concentrations of vitamin C (mg/100g or mg /100ml) in fortified foods compared with average label claim

Food product	Label Claim	Measured mean	Std dev	% CV	95% uncertainty Range[a]	% overage	
Baby food 1	50	26	6.8	26	18-34	-48	*
Baby food 2	25	47	9.1	19	36-58	89	*
Baby food 3	15	48	11.3	24	34-61	218	*
Baby food 4	30	189	17.2	9	168-209	529	*
Baby food 5	6.6	22	8.2	38	12-31	228	*
Breakfast cereal 1	33.3	44	12.6	29	29-59	32	
Breakfast cereal 2	20	27	8.8	32	16-38	35	
Breakfast cereal 3	33.3	33	8.6	26	23-44	0	
Breakfast cereal 4	33.3	37	8.0	22	27-46	10	
Food drink 1	43	67	18.6	28	44-89	55	*
Food drink 2	18.2	25	0.4	2	25-26	39	*
Food drink 3	90	110	12.1	11	95-124	22	*
Food drink 4	4.0	4.5	1.0	22	3-6	11	
Fruit cordial 1	240	191	19.2	10	168-214	-21	*
Fruit cordial 2	125	161	2.5	1	158-164	29	*
Fruit drinks 1	163	193	13.2	7	177-209	19	*
Fruit drinks 2	35	52	5.6	11	45-58	48	*
Fruit drinks 3	286	291	15.3	5	273-310	2	
Fruit juice 1	40	68	19.6	29	44-91	70	*
Fruit juice 2	25	55	14.9	27	37-73	124	*
Fruit juice 3	35	24	3.6	15	20-28	-32	*
Fruit juice 4	40	55	5.2	9	49-61	38	*
Miscellaneous 1	15	7	2.0	30	4-9	-57	*
Miscellaneous 2	47	51	2.8	6	47-54	8	
Miscellaneous 3	160	25	14.9	60	7-43	-84	*

CV = coefficient of variation, a= mean ± 1.2 standard deviations of the measured concentration
* = measured concentration greater than, or less, than the label claim at 95% level of confidence

A comparison of the results for different batches of the same product (Appendix 4.1, Table 1A) showed variability, measured as % CV, ranging from 2- 60%. Fifty two percent of products, (13/25), had CV values greater than 20% suggesting that vitamin C concentrations between batches of the same product are variable. The highest variability was observed for a baby fruit gel product.

The mean concentrations of vitamin C compared with average label claima, are shown graphically in Figure 1. Error bars for ± 1.2 standard deviation represent the variability across five batches of the same product. Where there is no error bar, multiple samples gave indistinguishable results.

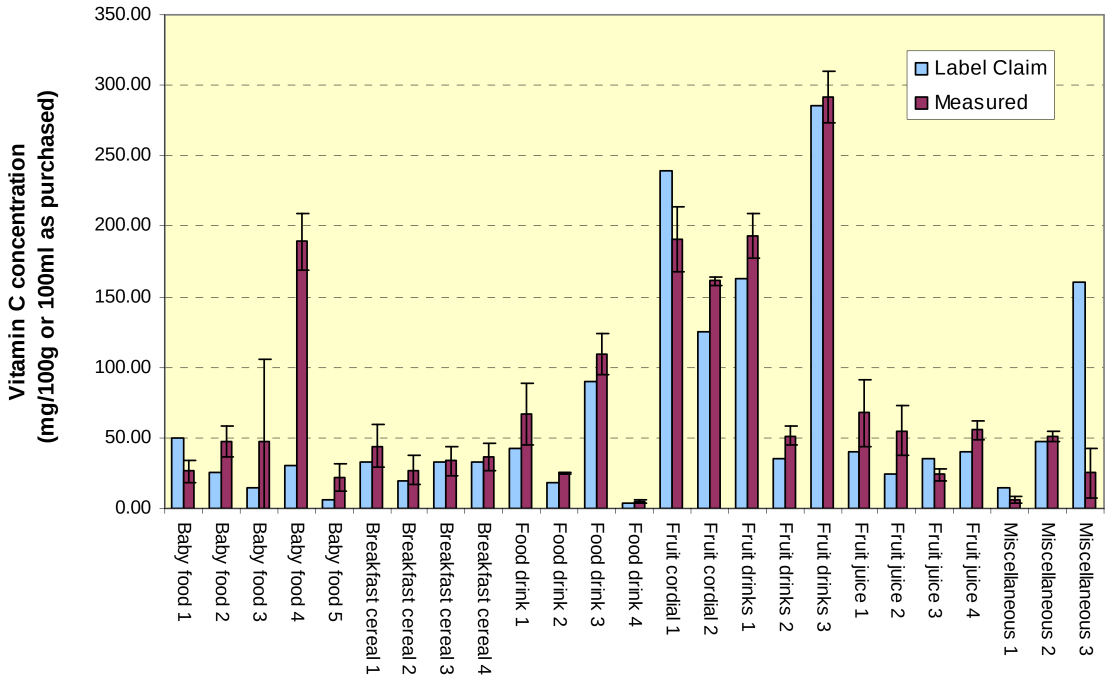

Figure 1: Measured concentrations of vitamin C compared with average label claim
Errors bars are ± 1.2 x standard deviation.

The mean concentration of twenty eight percent (7/25) of the selected foods met the average label claim for vitamin C content at the 95% level of confidence. Fifty two percent (13/25) of selected fortified foods contained more vitamin C than stated, with overages ranging from 19-529%. The highest overage of 529% was for one fruit based baby food product. Twenty percent (5/25) of selected foods contained less vitamin C than claimed, with one fruit salad product containing, on average, six times less than the level claimed on the label.

3.2 Dietary modelling of exposure to vitamin C

Because of inconclusive data there is no upper limit of vitamin C intake. However, 1000 mg/day is considered a prudent limit, with no distinction for different age groups (AG/MoH, 2006). The product with the highest % vitamin C overage, and one of the highest concentrations of vitamin C, was a canned baby food with a mean vitamin C content of 189 mg/100g. A single 120g serving of this product, with an overage of 529% would result in an intake of 227 mg of vitamin C contributing between seven to eight times the adequate intake of vitamin C for a 7-12 month infant and 23% of the prudent upper limit. A child consuming 530g (4-5 cans) per day of this product would reach the prudent upper limit of vitamin C intake.

3.3 Concentration of zinc in fortified foods

The mean concentration of zinc in the selected food products as consumed ranged from 0.4 to 8.6 mg/100g with higher levels consistently observed in cereal products (Table 3). A full set of results is included in Appendix 4, Table 4.2A. The “label” claims cited in Table 3 are those stated in, or derived from, the MFD (Nutrition Services, 2005).

A comparison of the results for different batches of the same product (Appendix 4, Table 4.2A) shows that variability between batches (as measured by CV) ranged from 3-42 % and was more variable than intra-sample variability. In general, more variability was observed for the cereal products than for other foods with the highest variability served for a breakfast cereal where the measured concentration of zinc varied by a factor of 2.7 across five batches.

Table 3: Mean concentrations of zinc (mg/100g or mg/100ml) in fortified foods compared with average label claim

Product	Label claim	Measured mean	Std dev	% CV	95% uncertainty range[a]	% overage	
Baby food 1	0.50	0.6	0.09	15.0	0.5-0.7	16	
Baby food 2	0.50	0.4	0.03	6.2	0.4-0.5	-12	
Breakfast Cereal 1	5.10	6.3	0.2	2.9	6.1-6.6	24	*
Breakfast Cereal 2	6.00	6.4	1.4	21.1	4.8-8.1	7	
Breakfast Cereal 3	6.00	7.1	0.5	7.5	6.4-7.7	18	*
Breakfast Cereal 4	6.00	8.6	0.5	6.3	7.9-9.2	43	*
Breakfast Cereal 5	6.00	7.5	1.8	24.0	5.3-9.6	25	
Breakfast Cereal 6	5.14	4.6	1.9	41.9	2.3-7.0	-10	
Breakfast Cereal 7	4.00	7.3	0.2	2.6	7.1-7.5	83	*
Dairy food 1	2.0	1.6	0.1	3.3	1.6-1.7	-18	*
Food Drinks 1	1.20	1.3	0.1	6.8	1.2-1.4	6	
Food Drinks 2	3.53	1.5	0.1	3.6	1.5-1.6	-56	*
Food Drinks 3	1.47	1.4	0.1	8.8	1.3-1.6	-2	
Food Drinks 4	1.4	0.9	0.1	6.5	0.9-1.0	-35	*
Miscellaneous 1	3.6	4.9	0.3	5.7	4.5-5.2	36	*
Miscellaneous 2	1.3	1.2	0.1	5.9	1.1-1.3	-7	
Miscellaneous 3	3.10	5.1	0.6	12.4	4.3-5.8	64	*
Miscellaneous 4	0.72	0.7	0.1	14.0	0.6-0.8	-3	
Miscellaneous 5	6.20	5.4	0.2	3.9	5.1-5.6	-14	*
Miscellaneous 6	No claim	3.4	0.2	4.9	3.2-3.6	NR	*

a= ± 1.2 standard deviations of the mean of the measured concentration
* = measured concentration greater than, or less, than label claim at 95% level of confidence

The mean concentrations of zinc compared with average label claims, are shown graphically in Figure 2. Error bars for ± 1.2 standard deviation represent the variability across five batches of the same product. Where there is no error bar, multiple batches gave indistinguishable results.

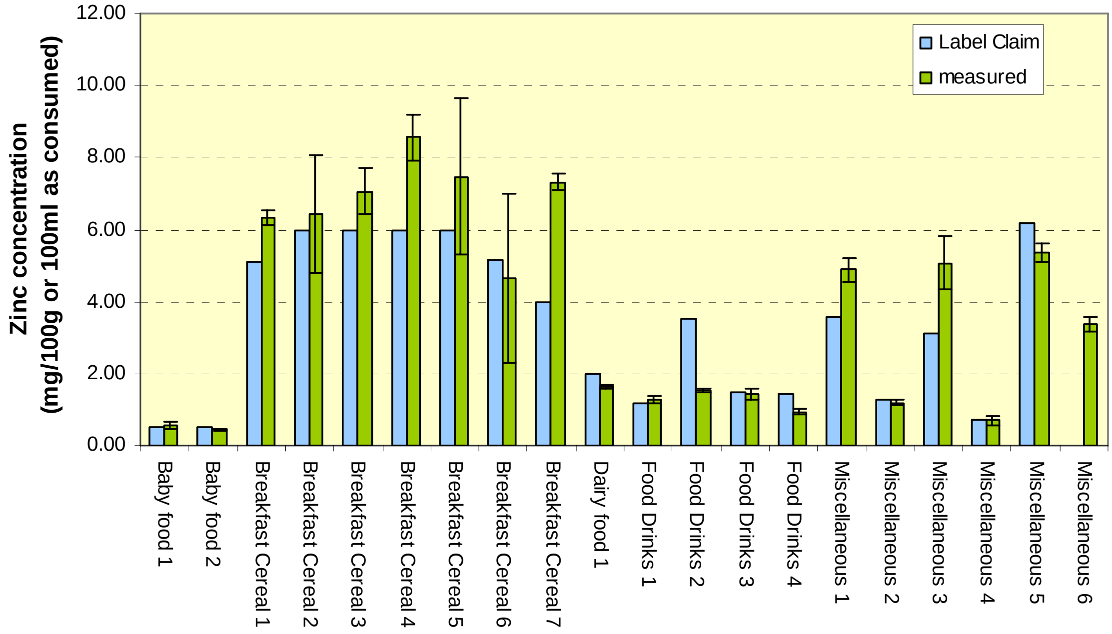

Figure 2: Measured concentrations of zinc compared with average label claim. Mean of five batches Errors bars are ± 1.2 x standard deviation.

The mean concentration of forty five percent (9/20) of the selected fortified foods met the average label claim for zinc content at the 95% level of confidence. Thirty percent (6/20) contained more zinc than stated with the highest overage of 83% for one breakfast cereal product. Twenty percent (4/20) of the selected foods contained 14-56% less zinc than claimed.

3.4 Dietary modelling of exposure to zinc

The maximum zinc overage was found in a breakfast cereal with an overage of 83%. Consumption of a single 45g serving of this product would result in an intake of 3.3 mg of zinc, equating to 24-55% of the RDI depending on the age of the consumer or 8-13% of the upper daily limit of zinc intake. Interrogation of the NNS (Russell *et al.*, 1999) shows that a high adult consumer may consume 125 g of this product in which case intake of zinc would be 9.1 mg per day, well within the UL of 35-40 mg/day for an adult consumer (AG/MoH, 2006).

3.5 Concentration of selenium in infant formulae

The mean concentration of selenium in the infant formuale ranged from 0.3 to 2.6 µg/100ml (Table 4). A full set of results is included in Appendix 4.3.

The selenium concentrations of prepared infant formula showed that inter-sample variability, as measured by CV, ranged from 0-63% for different batches of the same product (Appendix 4, Table 4.3A).

Table 4: Mean concentrations of selenium in infant formulae (µg/100 mg/100ml), prepared as for consumption, compared with average label claim

Food	Label claim	Measured mean	Std dev	% CV	95% uncertainty range[a]	% overage	
Standard 1	NR	0.3	0.1	16.8	0.3-0.4	NR	
Standard 2	2.0	2.3	0.3	15.2	1.8-2.7	13	
Standard 3	1.7	2.4	0.4	16.8	1.9-2.9	40	*
Standard 4	1.6	2.2	0.2	9.1	2.0-2.4	38	*
Standard 5	1.4	1.6	0.1	4.4	1.5-1.7	14	*
Standard 6	1.4	1.4	0.3	18.1	1.1-1.8	3	
Standard 7	1.4	1.5	0.0	0.0	1.5-1.5	7	*
Specialised 1	1.4	1.6	0.5	29.5	1.0-2.2	15	
Specialised 2	2.1	1.7	0.4	22.8	1.2-2.1	-21	
Specialised 3	1.4	0.9	0.4	42.5	0.4-1.4	-35	
Specialised 4	2.6	2.5	0.2	7.2	2.3-2.7	-5	
Specialised 5	2.4	1.8	1.2	63.0	0.4-3.2	-23	
Follow-on 1	2.1	2.4	0.3	10.7	2.1-2.7	15	
Follow-on 2	2.1	2.5	0.6	23.4	1.8-3.2	18	
Follow-on 3	1.6	2.4	0.0	1.9	2.3-2.4	49	*
Follow-on 4	1.6	2.4	0.1	5.5	2.2-2.5	49	*
Follow-on 5	1.4	1.6	0.1	7.3	1.4-1.7	11	
Follow-on 6	1.4	1.8	0.1	4.9	1.7-1.9	31	*
Special follow-on 1	1.4	1.4	0.1	7.9	1.2-1.5	-2	
Special follow-on 2	2.6	2.6	0.1	3.8	2.5-2.7	0	

a= ± 1.2 standard deviations of the mean of the measured concentration
* = measured concentration greater than, or less, than label claim at 95% level of confidence

The mean concentration of sixty percent (12/20) of the selected infant formulae met the average label claim for selenium content at the 95% level of confidence. Thirty five percent (7/20) contained more selenium than stated with overages of 7 to 49% with the highest overages found in two standard follow-on formulations. One product made no claim for selenium content and a low concentration (0.3µg/100ml) was measured in this product.

The mean concentration of selenium compared with average label claim, is shown graphically in Figure 3. Error bars for ± 1.2 standard deviation represent the variability between the five samples of each product tested.

Each of the infant formulae with a selenium label claim, complied with the maximum and minimum permissible amounts of selenium (3.3 and 0.7µg/100ml of prepared formula respectively).

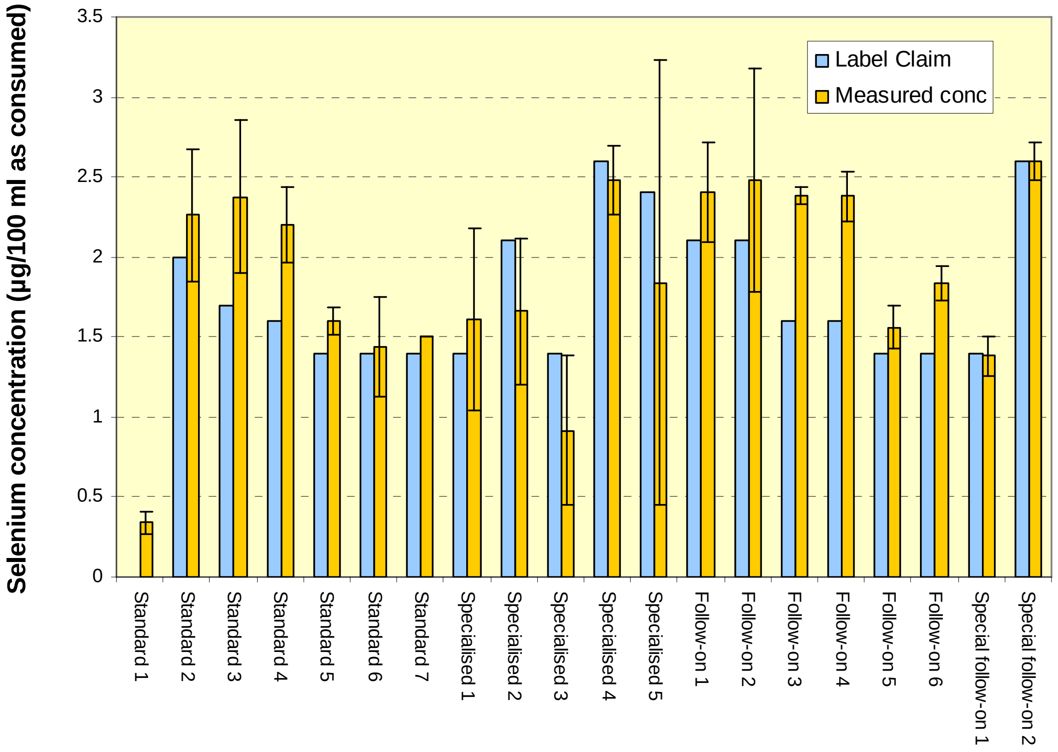

Figure 3: Measured concentrations of selenium in infant formulae compared with average label claim Errors bars are ± 1.2 x standard deviation.

3.6 Dietary modelling of exposure to selenium from fortified foods

The highest % selenium overage was found for two follow-on products with overages of 49%. Consumption of the recommended 3-4 feeds per day, where one feed is 4 scoops of formula plus 200ml of water, would result in an intake of 19.2µg of selenium per day, compared with an adequate intake of 15 µg/day for a 7-12 month infant (AG/MoH, 2006), equating to an intake of 128% of the AI. A 7-12 month infant would need to consume 12 feeds per day to reach the upper intake limit of selenium (60 µg/day), from the consumption of infant formulae alone.

4 DISCUSSION AND CONCLUSIONS

Vitamin C and zinc

All analytical measurements have associated uncertainty arising from sampling, the analytical method and the manufacturing technique. From this study, it is seen that most (i.e. 95%) of foods fortified with zinc had CV values of less than 25% and therefore this degree of tolerance around an average label claim may be considered appropriate. For the vitamin C foods selected, greater variability was observed with only sixty percent of the foods with CV values less than 25% and 88% of foods with CV values of less than or equal to 30%. For vitamin C, a tolerance of ± 30% CV of the average label claim may be considered appropriate for this vitamin. Since measured concentrations in fortified foods are close to label values, the uncertainty in measured concentrations is important when assessing compliance with label claims.
Consideration may be given in standard setting to defining a tolerance around the average label claim that incorporates these uncertainties. For example, compliance might be the label claim ± 1 standard deviation. Alternatively, a flat tolerance of ± 50% of the label claim might be considered as adopted by the Canadian Food Inspection Agency (CFIA, 2003). The degree of tolerance may vary for different fortificants depending on the health significance of overages for each fortificant.

Estimating a concentration range that includes the uncertainty for each product provides a transparent, science-based systematic approach to assessing whether the concentration measured in a sample meets its average label claim.

The magnitude of the tolerance, and hence uncertainty range, will depend on the level of confidence that is required. The % level of confidence is a measure of how likely the stated outcome is true or correct. In other words, what is the likelihood that some samples that have been found to meet the average label claim in fact do not and, what is the likelihood that some samples found to comply, in fact do not.

For a mean of five analyses, as in this study, the level of confidence that the true result lies within a range of the mean ± 1.2 times the CV is 95%. This means that if the concentration of a product is found to be just outside this range, there is a 5% chance that a product does in fact meet its average label claim and a 95% chance that it does not.

If product compliance is based on the standard deviation, a highly variable product will have a wider tolerance range and therefore will more easily comply than a consistent product with a tighter tolerance range. Thus more variability favours the manufacturer and this may not be desirable nor equitable.

For foods voluntarily fortified with vitamin C or zinc, the mean concentration of 20% (9/45) of the foods sampled was less than claimed, based on the criteria applied in this assessment. Consumers of these products are ingesting less of the added nutrients than they would believe, based on average label claims.

A total of 44% (20/45) of the foods sampled contained more vitamin C or zinc than claimed. None of these selected fortified foods appear to present a realistic hazard of a consumer exceeding the UL for either vitamin C or zinc.

Selenium

Although selenium is mandatory in infant formulae, issues around measurement uncertainty and therefore tolerance around an average value, are the same as for a product that is voluntarily fortified.

Most (i.e. 85%) of the infant formulae analysed for selenium had CV values of less than 25%, demonstrating consistent analytical results. The high variability in selenium concentration across four batches of one infant formulae (CV=63%) is noteable since this was not consistently seen with other infant formulae suggesting something different about this particular product. The observed variability between different batches of the same product may reflect either a lack of homogeneity of the distribution of selenium within the sample or real variability in selenium content between batches. Repeatability tests were undertaken on different sub-samples of the same prepared solution and not on different solutions prepared from the same sample of infant formula and so do not clarify the situation. CV values up to 21% between some of the blind duplicates suggests that the variability is in fact a combination of both the distribution of the selenium within the infant formula and variability between batches.

One standard infant formula did not comply with the Food Code by having no claim, and a low measured level of selenium.

None of the selected infant formuale appear to present a realistic hazard of the intended consumer exceeding the UL of selenium.

5 REFERENCES

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Appendix 1: New Zealand and Australia RDIs and ULs for vitamin C, zinc and selenium (AG/MoH, 2006)

Age/gender group		Vitamin C (mg/day)[a]		Zinc (mg/day)		Selenium (µg/day)	
		RDI	UL	RDI	UL	RDI	UL
Infants	0-6 mo.	AI = 25	BM	AI=2.05	4	AI=12	45
	7-12 mo.	AI = 30	B/F	3.0	5	AI=15	60
Children	1-3 yrs	35	NP	3	7	25	90
	4-8 yrs	35	NP	4	12	30	150
Boys	9-13 yrs	40	NP	6	25	50	280
	14-18 yrs	40	NP	13	35	70	400
Girls	9-13 yrs	40	NP	6	25	50	280
	14-18 yrs	40	NP	7	35	60	400
Men	19-30 yrs	45	NP	14	40	70	400
	31-50 yrs	45	NP	14	40	70	400
	51-70 yrs	45	NP	14	40	70	400
	>70 yrs	45	NP	14	40	70	400
Women	19-30 yrs	45	NP	8	40	60	400
	31-50 yrs	45	NP	8	40	60	400
	51-70 yrs	45	NP	8	40	60	400
	>70 yrs	45	NP	8	40	60	400
Pregnant	14-18 yrs	55	NP	10	35	65	400
	19-30 yrs	60	NP	11	40	65	400
	31-50 yrs	60	NP	11	40	65	400
Lactating	14-18 yrs	80	NP	11	35	75	400
	19-30 yrs	85	NP	12	40	75	400
	31-50 yrs	85	NP	12	40	75	400

AI = Adequate intake, BM = amount normally received from breast milk of healthy women; B/F = amount in breast milk and food, NP = not possible to set-may be insufficient evidence or no clear level for adverse effects.

APPENDIX 2: Foods fortified with vitamin C and/or zinc and infant formulae fortified with selenium (Nutrition Services, 2005)

Food manufacturers have identified the following numbers of infant formulae foods as being fortified with selenium and foods fortified with vitamin C and/or zinc. The numbers include different flavours of the same product where these occur. This may not be a complete list but includes those companies who submitted data to the Manufactured Food Database and will reflect the situation as at December 2004 (Nutrition Services, 2005).

	Vitamin C	Zinc	Selenium
Standard infant formulae	-	-	10
Soy-based infant formulae	-	-	2
Specially modified infant formulae	-	-	3
Follow-on formulae	-	-	9
Soy-based follow-on formula	-	-	1
Specially modified follow-on formula	-	-	1
Baby Food	36	10	-
Breakfast cereals	15	10	-
Food drinks	28	5	-
Fruit cordial	9	-	-
Fruit drinks and fruit nectar	83	-	-
Fruit juice	71	-	-
Pasta	-	2	-
Miscellaneous	77	14	-
Total	**286**	**50**	**26**

Appendix 3: Quality assurance data

3.1 Repeatability for vitamin C

Food type	label claim	Analysis (mg/100g) 1	2	3	4	5	mean	Std dev	CV
Baby puree fruit	30.0	206	206	205	205	201	205	2.1	1.0
Breakfast cereal	20.0	34.5	32.7	35.7	30.8	35.7	33.9	2.1	6.3
Orange juice	40.0	43.7	52.6	57.2	55.5	44.9	50.8	6.2	12.1

3.2 Repeatability for zinc

Food type	label claim	Analysis (mg/100g) 1	2	3	4	5	mean	Std dev	CV
Baby food	0.50	0.427	0.442	0.424	0.429	0.421	0.429	0.01	1.9
Breakfast cereal	4.67	8.46	8.26	8.42	8.21	8.54	8.38	0.14	1.7
Food drink	5.22	1.20	1.23	1.19	1.15	1.16	1.19	0.03	2.7

3.3 Repeatability for selenium

Food type	label claim	Analysis (µg/100ml) 1	2	3	4	5	mean	Std dev	CV
Standard infant formula	1.7	3.04	3.26	2.83	2.88	2.87	2.98	0.18	6.0
Specialised infant formula	1.4	2.13	2.16	2.29	2.33	2.32	2.25	0.09	4.2
Follow-on formula	2.1	2.84	2.87	3.01	2.66	2.76	2.83	0.13	4.6

std dev = standard deviation. CV= standard deviation relative to the mean ((std dev/mean)x100)

3.4 Spike recoveries for vitamin C, zinc and selenium

Vitamin C		Zinc		Selenium	
Food type	**% Recovery**	**Food type**	**% Recovery**	**Food type**	**% Recovery**
Baby food	87 ,89, 110, 83 89	Baby food 1	94	Std IF 2	99
		Baby food 3	98. 103	Std IF 6	97
Cereal	86, 87, 97, 100	Baby food 4	103, 100	Sp IF 1	89
Food drink	112, 106, 80, 109, 104	Baby food 5	100	Sp IF 4	87
		Cereal 4	108	FoF 1	102
Fruit cordial	109, 106	Food drink 1	110	FoF 3	99
Fruit drink	99, 80, 78	Food drink 4	98	FoF 4	91
Fruit juice	95, 90, 79	Miscellaneous	81, 77	FoF 6	101, 99
Miscellaneous	103, 96, 102	Miscellaneous	88	Sp Fof 1	90
				Sp FoF 2	92

3.5.1 Blind duplicates for vitamin C (mg/100ml or 100g), as purchased.

Food sample	Result 1	Result 2	mean	Std dev	%CV
Baby food 1	19.7	19.8	19.8	0.1	0
Baby food 4	169	151	160.0	12.7	8
Cereal 4	32	33	32.5	0.7	2
Food drink 2	25	26	25.5	0.7	3
Food drink 4	4	5	4.7	0.4	9
Fruit drink & fruit nectar 2	46	46	46.0	0.0	0
Fruit juice 3	21.7	23	22.4	0.9	4
Miscellaneous 3	18.1	17.8	18.0	0.2	1

3.5.2 Blind duplicates for zinc (mg/100ml or 100g), as consumed.

Food sample	Result 1	Result 2	mean	Std dev	CV
Baby Food 3	3.2	3.3	3.3	0.1	2
Baby Food 4	1.6	1.4	1.5	0.1	9
Breakfast Cereal 5	4.3	4.6	4.5	0.2	5
Breakfast Cereal 7	7.6	7.0	7.3	0.4	6
Food Drink 3	14.7	14.4	14.6	0.2	1
Food Drink 4	0.97	0.9	0.9	0.0	5
Miscellaneous 3	4.5	5.4	5.0	0.6	13
Miscellaneous 5	5.4	4.6	5.0	0.6	11

3.5.3 Blind duplicates for selenium (µg/100ml) as for consumption

Food sample	Result 1	Result 2	mean	Std dev	CV
Standard Infant Formulae 3	1.7	2.3	2.0	0.4	21
Standard Infant Formulae 5	1.4	1.6	1.5	0.1	9
Standard Infant Formulae 7	1.7	1.5	1.6	0.2	10
Specialised Infant Formulae 2	1.3	1.4	1.3	0.1	7
Specialised Infant Formulae 3	0.6	0.5	0.6	0.1	13
Specialised Infant Formulae 4	2.7	2.5	2.6	0.1	5
Follow-on Formulae 6	1.5	1.7	1.6	0.1	9
Specialised Follow-on formulae 2	2.5	2.5	2.5	0.0	0

3.6 Analysis of certified reference materials showing certified and measured concentrations of Vitamin C, zinc and selenium

Reference material	Vitamin C		Zinc		Selenium	
	Certified mg/100g	Measured mg/100g	Certified mg/kg	Measured mg/kg	Certified µg/100g	Measured µg/100g
NIST 1549 nonfat milk powder	-	-	46.1	44.8 ± 0.8 n=4	11 ± 1	10.8 ± 0.6 n=6
NIST 8435 Whole milk powder	-	-	28 ± 3.1	23.3 ± 0.2 n=3	13.1 ± 1.4	12.1 ± 1.2 n=6
NIST 1568a Rice flour	-	-	19.5 ± 0.5	19.4 ± 2.3 n=4	-	-
NIST 1846 Infant formula	115	118 ± 17 n=9	-	-	-	-

Appendix 4: Results for individual foods

Table 4.1A: Vitamin C concentration (mg/100g or 100ml) as purchased

Food	Label claim	Measured mean	Std dev.	%CV	95% uncertainty range[a]	% overage or underage
Baby food 1	50	24				
		23				
		21				
		38				
		26				
		26	**6.8**	**26.1**	**18-34**	**-48**
Baby food 2	25	46				
		46				
		62				
		37				
		45				
		47	**9.1**	**19.3**	**36-58**	**89**
Baby food 3	15	39				
		48				
		36				
		52				
		64				
		48	**11.3**	**23.8**	**34-61**	**218**
Baby food 4	30	205				
		168				
		205				
		175				
		193				
		189	**17.2**	**9.1**	**168-209**	**529**
Baby food 5	6.6	32				
		13				
		18				
		25				
		22	**8.2**	**37.8**	**12-31**	**228**
Breakfast cereal 1	33.3	57				
		31				
		45				
		32				
		57				
		44	**12.6**	**28.7**	**29-59**	**32**
Breakfast cereal 2	20	41				
		30				
		19				
		25				
		21				
		27	**8.8**	**32.5**	**16-38**	**35**
Breakfast cereal 3	33.3	25				
		27				
		42				
		31				
		43				
		33	**8.6**	**25.7**	**23-44**	**0**
Breakfast cereal 4	33.3	48				
		37				

Food	Label claim	Measured mean	Std dev.	%CV	95% uncertainty range[a]	% overage or underage
		27				
		40				
		32				
		37	**8.0**	**21.9**	**27-46**	**10**
Food drink 1	43	59				
		61				
		58				
		100				
		57				
		67	**18.6**	**27.8**	**44-89**	**55**
Food drink 2	18.2	26				
		26				
		25				
		26				
		26				
		25	**0.4**	**1.8**	**25-26**	**39**
Food drink 3	90	123				
		118				
		105				
		92				
		113				
		110	**12.1**	**11.0**	**95-124**	**22**
Food drink 4	4.0	4.5				
		5.3				
		5.6				
		3.9				
		3.1				
		4.5	**1.0**	**22.4**	**3-6**	**11**
Fruit cordial 1	240	210				
		163				
		193				
		205				
		181				
		191	**19.2**	**10.1**	**168-214**	**-21**
Fruit cordial 2	125	163				
		160				
		161				
		157				
		163				
		161	**2.5**	**1.5**	**158-164**	**29**
Fruit drinks & fruit nectar 1	163	211				
		186				
		181				
		203				
		186				
		193	**13.2**	**6.8**	**177-209**	**19**
Fruit drinks & fruit nectar 2	35	57				
		<1				
		51				
		54				
		44				
		52	**5.6**	**10.8**	**45-58**	**48**
Fruit drinks & fruit nectar 3	286	310				
		299				
		291				
		268				

Food	Label claim	Measured mean	Std dev.	%CV	95% uncertainty range[a]	% overage or underage
		290				
		291	**15.3**	**5.3**	**273-310**	**2**
Fruit juice 1	40	51 61 102 64 61				
		68	**19.6**	**29.0**	**44-91**	**70**
Fruit juice 2	24.5	60.0 31.0 71.0 60.0 53.0				
		55	**14.9**	**27.1**	**37-73**	**124**
Fruit juice 3	35	24 22 22 22 30				
		24	**3.6**	**14.9**	**20-28**	**-32**
Fruit juice 4	40	53 49 58 61 NR				
		55	**5.2**	**9.3**	**49-61**	**38**
Miscellaneous 1	15	7.3 7.6 7.7 6.9 3.0				
		6.5	**2.0**	**30.4**	**4-9**	**-57**
Miscellaneous 2	47	51 53 46 51 52				
		51	**2.8**	**5.6**	**47-54**	**8**
Miscellaneous 3	160	19 27 7 25 47				
		25	**14.9**	**59.7**	**7-43**	**-84**

a= mean ± 1.2 standard deviations of the measured concentration

Table 4.2A: Zinc concentration (mg/100g or 100ml) as consumed

Food	Moisture g/100g	Label Claim	Measured mg/100g	Std dev	% CV	95% uncertainty Range[a]	% over/under
Baby food 1	85	0.5	0.7				
	86		0.5				
	86		0.6				
	86		0.5				
	86		0.5				
		mean	**0.6**	**0.09**	**15.0**	**0.5-0.7**	**16**
Baby food 2	89	0.5	0.4				
	87		0.5				
	88		0.4				
	87		0.5				
	89		0.4				
		mean	**0.4**	**0.03**	**6.2**	**0.4-0.5**	**-12**
Breakfast Cereal 1	3	5.1	6.4				
	3.5		6.6				
	3		6.1				
	3.6		6.3				
	3.5		6.3				
		mean	**6.3**	**0.18**	**2.9**	**6.1-6.6**	**24**
Breakfast Cereal 2	4.1	6.0	6.9				
	3.4		5.8				
	4		7.3				
	3.9		4.4				
	3.6		7.8				
		mean	**6.4**	**1.36**	**21.1**	**4.8-8.1**	**7**
Breakfast Cereal 3	4.1	6.0	7.3				
	4.3		7.5				
	4.4		6.2				
	4.1		6.9				
	4.7		7.4				
		mean	**7.1**	**0.53**	**7.5**	**6.4-7.7**	**18**
Breakfast Cereal 4	3.5	6.0	8.6				
	3.2		8.8				
	2.9		7.9				
	3.8		9.3				
	3.3		8.2				
		mean	**8.6**	**0.54**	**6.3**	**7.9-9.2**	**43**
Breakfast Cereal 5	5	6.0	8.3				
	4.3		8.5				
	4.7		7.9				
	4.6		4.3				
	4.4		8.4				
		mean	**7.5**	**1.79**	**24.0**	**5.3-9.6**	**25**
Breakfast Cereal 6	5.6	5.1	5.5				
	6.1		2.7				
	5.9		6.5				
	5.7		6.1				
	6.1		2.4				
		mean	**4.6**	**1.94**	**41.9**	**2.3-7.0**	**-10**
Breakfast Cereal 7	5.4	4.0	7.4				
	5.4		7.6				
	5.3		7.6				

Food	Moisture g/100g	Label Claim	Measured mg/100g	Std dev	% CV	95% uncertainty Range[a]	% over/under
	5.5		7.2				
	5.4		6.8				
		mean	**7.3**	**0.19**	**2.6**	**7.1-7.5**	**83**
Dairy food 1	76	2.0	1.6				
	76		1.6				
	80		1.7				
	78		1.7				
	77		1.6				
		mean	**1.6**	**0.05**	**3.3**	**1.6-1.7**	**-18**
Food Drinks 1		1.2	1.2				
	90		1.3				
	90		1.4				
	90		1.3				
	90		1.2				
		mean	**1.3**	**0.09**	**6.8**	**1.2-1.4**	**6**
Food Drinks 2	78	3.5	1.6				
	79		1.5				
	78		1.5				
	78		1.6				
	79		1.5				
		mean	**1.5**	**0.05**	**3.6**	**1.5-1.6**	**-56**
Food Drinks 3	91	1.5	1.6				
	91		1.4				
	91		1.3				
	91		1.4				
	90		1.5				
		mean	**1.4**	**0.13**	**8.8**	**1.3-1.6**	**-2**
Food Drinks 4	84	1.4	0.9				
	84		0.8				
	80		1.0				
	80		1.0				
	80		1.0				
		mean	**0.9**	**0.06**	**6.5**	**0.9-1.0**	**-35**
Miscellaneous 1	19	3.6	5.0				
	20		4.7				
	20		5.0				
	25		5.2				
	23		4.5				
		mean	**4.9**	**0.28**	**5.7**	**4.5-5.2**	**36**
Miscellaneous 2	90	1.3	1.3				
	91		1.2				
	91		1.2				
	91		1.2				
	91		1.1				
		mean	**1.2**	**0.07**	**5.9**	**1.1-1.3**	**-7**
Miscellaneous 3	9.9	3.1	5.8				
	11		4.4				
	11		5.6				
	8.8		5.1				
	10		4.5				
		mean	**5.1**	**0.63**	**12.4**	**4.3-5.8**	**64**
Miscellaneous 4	91	0.7	0.7				
	91		0.7				

Food	Moisture g/100g	Label Claim	Measured mg/100g	Std dev	% CV	95% uncertainty Range[a]	% over/under
	91		0.6				
	91		0.6				
	92		0.9				
		mean	**0.7**	**0.10**	**14.0**	**0.6-0.8**	**-3**
Miscellaneous 5	15	6.2	5.6				
	15		5.1				
	13		5.5				
	15		5.2				
	13		5.4				
		mean	**5.4**	**0.21**	**3.9**	**5.1-5.6**	**-14**
Miscellaneous 6	88	no claim	3.5				
	88		3.5				
	88		3.2				
	88		3.5				
	88		3.2				
		mean	**3.4**	**0.16**	**4.9**	**3.2-3.6**	**NR**

a= mean ± 1.2 standard deviations of the measured concentration
NR = no result

Table 4.3A: Selenium concentration in infant formulae as consumed (µg/100ml)

Food	Moisture g/100g	Label claim	Measured	Std dev	%CV	95 % uncertainty range [a]	% over or under
Standard Infant Formulae1	88	No claim	0.3				
	88		0.3				
	87		0.4				
	88		0.3				
	88		0.3				
		mean	**0.3**	**0.06**	**16.8**	**0.3-0.4**	**NR**
Standard Infant Formulae 2	87	2.0	2.1				
	87		2.0				
	88		2.4				
	88		2.0				
	87		2.8				
		mean	**2.3**	**0.34**	**15.2**	**1.8-2.7**	**13**
Standard Infant Formulae 3	NR	1.7	3.0				
	88		2.3				
	88		1.9				
	89		2.2				
	88		2.5				
		mean	**2.4**	**0.40**	**16.8**	**1.9-2.9**	**40**
Standard Infant Formulae 4	87	1.6	2.2				
	87		2.4				
	87		2.0				
		mean	**2.2**	**0.20**	**9.1**	**2.0-2.4**	**38**
Standard Infant Formulae 5	87	1.4	1.6				
	88		1.6				
	88		1.6				
	87		1.7				
	88		1.5				
		mean	**1.6**	**0.07**	**4.4**	**1.5-1.7**	**14**
Standard Infant Formulae 6	88	1.4	1.9				
	88		1.3				
	88		1.4				
	89		1.3				
	88		1.3				
		mean	**1.4**	**0.26**	**18.1**	**1.1-1.8**	**3**
Standard Infant Formulae 7	88	1.4	1.5				
	88		1.5				
	88		1.5				
	88		1.5				
	88		1.5				
		mean	**1.5**	**0.00**	**0.0**	**1.5-1.5**	**7**
Specialised Infant Formulae 1	NR	1.4	2.2				
	89		1.3				
	89		1.2				
	89		1.7				
	NR						
		mean	**1.6**	**0.47**	**29.5**	**1.0-2.2**	**15**

Food	Moisture g/100g	Label claim	Measured	Std dev	%CV	95 % uncertainty range [a]	% over or under
Specialised Infant	88	2.1	.3				
Formulae 2	89		1.4				
	89		1.4				
	88		1.5				
	88		1.7				
		mean	**1.7**	**0.38**	**22.8**	**1.2-2.1**	**-21**
Specialised Infant	88	1.4	0.5				
Formulae 3	88		1.2				
	88		1.2				
	88		1.2				
	88		0.5				
		mean	**0.9**	**0.39**	**42.5**	**0.4-1.4**	**-35**
Specialised Infant	87	2.6	2.5				
Formulae 4	87		2.5				
	88		2.2				
	87		2.7				
	87		2.5				
		mean	**2.5**	**0.18**	**7.2**	**2.3-2.7**	**-5**
Specialised Infant	86	2.4	3.5				
Formulae 5	87		0.9				
	87		1.3				
	87		1.7				
		mean	**1.8**	**1.16**	**63.0**	**0.4-3.2**	**-23**
Follow-on Formulae 1		2.1	2.8				
	87		2.2				
	87		2.4				
	90		2.2				
	88		2.4				
		mean	**2.4**	**0.26**	**10.7**	**2.1-2.7**	**15**
Follow-on Formulae 2	88	2.1	2.2				
	88		2.4				
	88		2.2				
	88		2.1				
	88		3.5				
		mean	**2.5**	**0.58**	**23.4**	**1.8-3.2**	**18**
Follow-on Formulae 3	87	1.6	2.4				
	87		2.4				
	87		2.4				
	87		2.3				
	87		2.4				
		mean	**2.4**	**0.04**	**1.9**	**2.3-2.4**	**49**
Follow-on Formulae 4	87	1.6	2.3				
	87		2.6				
	87		2.4				
	86		2.3				
	86		2.3				
		mean	**2.4**	**0.13**	**5.5**	**2.2-2.5**	**49**
Follow-on Formulae 5	87	1.4	1.6				
	87		1.5				
	87		1.6				
	88		1.7				

Food	Moisture g/100g	Label claim	Measured	Std dev	%CV	95 % uncertainty range [a]	% over or under
	89		1.4				
		mean	**1.6**	**0.11**	**7.3**	**1.4-1.7**	**11**
Follow-on Formulae 6	87	1.4	1.8				
	88		1.9				
	88		1.9				
	88		1.7				
	88		1.9				
		mean	**1.8**	**0.09**	**4.9**	**1.7-1.9**	**31**
Specialised Follow-on formulae 1	87	1.4	1.4				
	88		1.4				
	88		5.1				
	88		1.2				
	88		1.5				
		mean	**1.4**	**0.1**	**7.9**	**1.2-1.5**	**-2**
Specialised Follow-on formulae 2	86	2.6	2.7				
	87		2.7				
	86		2.6				
	87		2.5				
	86		2.5				
		mean	**2.6**	**0.10**	**3.8**	**2.5-2.7**	**0**

a= mean ± 1.2 standard deviations of the measured concentration

NR = no result