FORTIFICATION OVERAGES
OF THE FOOD SUPPLY

FOLATE AND IRON

Prepared as part of a New Zealand Food Safety Authority
contract for scientific services

by

Dr Barbara Thomson

September 2005

Client Report
FW0536

FORTIFICATION OVERAGES OF THE FOOD SUPPLY

FOLATE AND IRON

Kevin Taylor
Food Safety Programme Manager

Dr Barbara Thomson
Project Leader

Dr John Love
Peer Reviewer

DISCLAIMER

This report or document ("the Report") is given by the Institute of Environmental Science and Research Limited ("ESR") solely for the benefit of the New Zealand Food Safety Authority ("NZFSA"), Public Health Services Providers and other Third Party Beneficiaries as defined in the Contract between ESR and the NZFSA, and is strictly subject to the conditions laid out in that Contract.

Neither ESR nor any of its employees makes any warranty, express or implied, or assumes any legal liability or responsibility for use of the Report or its contents by any other person or organisation.

ACKNOWLEDGEMENTS

The contribution of Lyn Gillanders and Alannah Steeper, representatives from the Manufactured Food Database (The Auckland District Health Board), to the planning and selection of foods for this project is most gratefully acknowledged.

The iron analyses were ably carried out by RJHill Laboratories Ltd, Lower Hutt and the folate analyses by The Royal Perth Hospital, Adelaide, Australia.

Thanks to Peter Cressey, ESR, for the interrogation of the 1997 National Nutrition Survey.

CONTENTS

LIST OF TABLES

LIST OF FIGURES

SUMMARY

The aim of the current project was to assess the levels of iron and folate in fortified foods and to compare levels to those claimed on product labels.

Approximately 260 samples from nine different food and supplement groups were analysed for added iron or folate. Samples were purchased in September or November 2004 from Christchurch retail outlets with the exception of the bread samples, which were purchased in March 2005 from Auckland, Wellington and Christchurch according to the manufacturing locations of the selected breads.

The stability of the folate fortificant was assessed by measuring concentrations in selected foods over a six month period of storage.

Iron content was determined using a high pressure microwave nitric/hydrochloric acid digestion and analysis by Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES). Inter-sample variability for iron was generally ± 20% CV. Total folate was extracted by a tri-enzyme technique and assayed by a microbiological method using *Lactobacillus casei* as the test organism. Inter-sample variability for folate was generally ± 30% CV.

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.

<u>Iron</u> concentration in fortified foods met or exceeded the label claim for iron. Fifty seven percent of selected products (21/37) had iron overages ranging from 16-166%. High consumption of the product with the maximum iron overage would result in an iron intake of 35% of the proposed Upper Intake Limit (UIL) for adults.

<u>Folate</u> concentration was 15-33% below the label claim in 24% of the products tested (9/38) and exceeded the label claim for folate in 34% (13/38) of products with overages of 41-296%. High consumption of the product with the maximum folate overage would result in a folate intake above the proposed UIL for adults.

There was no measurable degradation of folate in fortified products after storage for a six month period.

For standard setting, consideration may be given to defining an acceptable range around the label claim that takes measurement uncertainty into account. The size of this range will depend on the level of confidence required. A higher level of confidence will require a wider acceptable range than a lower level of confidence. The level of confidence may be increased by increasing the number of samples on which the uncertainty is based.

1 INTRODUCTION

Work is currently being conducted on the development of food standards relating to nutrient fortification. The establishment of safe upper limits for nutrients added to foods relies on robust data on current intake, based on consumption data and concentration information for the foods of interest.

While there is sufficient data on the composition of unfortified foods, there is no independent data on the actual levels of fortificants in fortified foods in New Zealand although the Manufactured Foods Database (MFD) does have producer supplied composition data that may be based on analytical or calculated amounts. International evidence suggests that actual levels can vary significantly, by up to 320% of the claimed label value (Whittaker *et al*., 2001).

There is also a potential public health and safety issue associated with over-consumption of some nutrients and interactions between nutrients if levels are too high. For this reason, Recommended Dietary Intakes (RDI)s and Upper Intake Limits (UIL)s have been estimated for New Zealand and Australia, for a range of nutrients including folate and iron, although these are currently in draft form (NHMRC, 2004a). Details for iron and folate RDIs and UILs are provided in Appendix 1.

The severity of iron toxicity can range from gastrointestinal irritation to systemic toxicity. For adults, pregnant and lactating women an UIL of 45 mg/day has been estimated, based on gastrointestinal symptoms. A lower UIL for children (20 mg/day for 0-3 years, and 40 mg/day for 4-13 years) takes into account potential adverse growth effects (NHMRC, 2004b).

High supplemental intakes of folate have been associated with adverse neurological effects in people with vitamin B12 deficiency, general toxicity, increased risk of developing some cancers and adverse reproductive and developmental effects (NHMRC, 2004b). An adult UIL of 1000 µg/day for folate has been estimated on the basis of neurological effects observed with vitamin B12 deficiency since this condition is relatively common in the population, and as the associated data has some dose response characteristics. The adult UIL for folate has been extrapolated to other population groups with an adjustment for body weight.

There are an increasing number of fortified foods available on the New Zealand market. An analysis of actual levels of nutrients being added to these fortified foods is essential for undertaking a robust risk assessment of the consequences of nutrient additions to foods, both mandatory and voluntary, and will feed directly into the food standard setting process.

The goal of the current project was to measure the actual levels of the fortificants iron and folate added to fortified foods and to compare actual levels with levels claimed on product labels.

2 MATERIALS AND METHODS

2.1 Selection of foods for inclusion in the study

Foods that are fortified with iron or folate 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 with representatives from the MFD (Auckland District Health Board), the New Zealand Food Safety Authority and ESR (Table 1). A complete list of foods that were listed in the MFD as being fortified with iron or folate is shown in Appendix 2 (Nutrition Services, 2003).

The following shelf lives were ascertained from package labelling as a basis for selecting foods for studies on the stability of the fortificants over time. Approximate shelf lives: baby foods 7-10 months; bread 3 days; breakfast cereals 9-11 months; extract of meat 21 months; food drinks 20 months.

Table 1: Selection of foods fortified with iron or folate for analysis and comparison with label claim and stability

Food Type	**Iron**		**Folate**		
	Time 1	**Time 2**	**Time 1**	**Time 2**	**Time 3**
Baby foods	1 (x3)	1	1 (x3)	0	1
Breads	7 (x3)	0	6 (x3)	0	0
Breakfast cereals/snack bars	21 (x3)	21	21 (x2)	8	8
Extracts of meat	1 (x3)	0	1 (x3)	0	1
Food drinks	3 (x3)	3	3 (x3)	0	3
Fruit juice	0	0	1 (x3)	0	1
Protein products	1 (x3)	1	1 (x3)	0	1
Dietary supplements	3 (x3)	3	3 (x3)	0	3
Pharmacy medicine	0	0	1 (x3)	0	1
Total	**111**	**29**	**93**	**8**	**19**

number of batches in parenthesis

2.2 Sampling and sample preparation

2.2.1 Samples for iron analysis

All foods were purchased in September 2004 with the exception of the breads, which were purchased in March 2005. Single packets from three batches of each selected food item were purchased from Christchurch retail outlets except for the bread samples, which were purchased in Auckland, Wellington and Christchurch according to the manufacturing locations of the selected products.

A second packet of one batch of each food item was purchased at the same time, to be analysed at a second time interval to confirm the repeatability of iron analysis over two time intervals six months apart. Bread samples were not included in the repeatability study because of the short shelf life of this product.

For testing, the entire packet of each sample 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.

2.2.2 Samples for folate analysis

Single packets of three batches of selected food items were purchased, except for cereals where two batches were purchased, for analysis as "Time 1" samples and to provide information on batch variability of folate concentration. All foods were purchased from Christchurch retail outlets in September 2004 with the exception of the bread samples, which were purchased from both Christchurch and Auckland outlets in November 2004.

Two further packets of one of the original batches of each cereal product were purchased at the same time as the original samples and were analysed as "Time 2" (November 2004) and "Time 3" (March 2005) samples to give information on the stability of folate. Cereals were targeted as they are the largest food group fortified with folate. The batches were selected to ensure they remained within their labelled "use by" dates for the duration of the project.

For testing, the entire packet of each sample was ground in a domestic blender. For the analysis, approximately 200ml of the powdered material was frozen at -15°C until dispatch by air freight in insulated boxes with iced packaging, to the laboratory in Perth. This involved samples being cleared through customs in Melbourne, and freezer or cold storage before forwarding to Perth. Samples arrived at the laboratory in cold condition five days after dispatch from Christchurch.

2.3 Laboratory analytical methods

2.3.1 Iron analysis

Samples were measured for iron content using a high pressure microwave nitric/hydrochloric acid digestion and analysis by Inductively Coupled Plasma-Optical Emission Spectroscopy (ICP-OES) by Hill Laboratories Ltd. Hill laboratories is accredited by IANZ (International Accreditation New Zealand) to the standard NZS/ISO/IEC/17025, The general requirements for the competence of testing and calibration laboratories.

2.3.2 Quality control procedures for iron analyses

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

- Fourteen samples, representing different food types were analysed in duplicate within the two batches of analyses to ascertain repeatability and intra-sample variability. 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 acceptable for some matrices, analyte and concentration combinations (Vannoort, personal communication, 2005). Data for duplicate and replicate analyses for iron are provided in Appendix 3. The analytical precision and intra-sample variability, based on repeat analyses (n=4) of two cereals and duplicate analyses of an additional 12 samples was good with all CVs less than 10%.

- Six samples were spiked with iron to correspond to a spike level of 10 mg iron/100g. Recovery compares the amount of iron measured in the spiked sample corrected for the amount of iron in the unspiked sample, with the amount of iron added in the spike. Acceptable recoveries for iron analyses would generally be 70-125%. The recovery of iron from spiked samples was acceptable, ranging from 84-122%, confirming the accuracy of the analytical method (Appendix 3).
- Two samples of a rice flour Matrix Certified Reference Material (CRM) (CRM number NIST1568a) were analysed with each batch to ascertain the accuracy of the method. CRMs are stable and homogenous materials with the level of analyte present and its uncertainty being certified by the supplier normally a national metrology institute such as NIST in the United States or IRMM in the European Union. The analysis of iron in the CRM was acceptable, also confirming the accuracy of the analytical method (Appendix 3).
- Ten blind duplicates from each of the food types, were submitted for analysis. The CVs reflecting sampling and analytical variability of duplicates ranged from 1-20% (Appendix 3).

2.3.3 Folate analysis

Folate is difficult to measure in foods because it is present in different forms. Folate, a B-vitamin, is the commonly used group name for a number of chemical forms which are structurally related and which have similar biological activity to folic acid. Synthetic folic acid is used in supplements and for food fortification as it is more stable than naturally occurring folate (NHMRC, 2004b). The label claim for folate includes both naturally occurring folate and added folic acid.

Commercial analyses of both free folic acid by HPLC, or total folate using a tri-enzyme extraction and microbiological detection, are available. For this study, total folate, including naturally occurring and added folic acid, was determined using the tri-enzyme extraction and microbiological detection using *Lactobacillus casei* as the test organism to achieve the detection limits necessary to quantify folate in the range of foods selected. Folate analysis was undertaken by the Royal Perth Hospital in accordance with their NATA accreditation to ISO/IEC 17025, for the microbiological assay of vitamins in food.

The Royal Perth Hospital is the only known laboratory in Australasia that is accredited for folate analysis to the detection limits required for this study. All folate samples were run in duplicate with each batch also including a known food control, a yeast and an enzyme control. Duplicate results were accepted within a CV of 10%.

2.3.4 Quality control procedures for folate analyses

In addition to the controls used by the laboratory as described in section 2.3.3, ten blind duplicates from each of the food types, were submitted for analysis.

The intra-sample variability, expressed as the CV for one composite cereal and one wheat based cereal, each analysed four times, was 17% and 20% respectively (Appendix 3). The inter-sample variability, also expressed as the CV, ranged from 0 to 67%, although most samples (87%) had a variability of less than 30%.

2.4 Derivation of ranges for overage or underage assessment

The uncertainties derived from measured results in this study were used to derive acceptable ranges for overage or underage assessment.

No analytical result is exact but 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 before comparing the measured concentration of a fortificant with a label claim so as to know if differences are significant.

For most nutritionally important tests, the analytical uncertainty ranges from less than 5% of the measured value for some proximate analyses to approximately 10% of the measured value for many trace elements and vitamins (Love, personal communication, 2005). For example if the measured concentration of iron is 20 mg/100g and the uncertainty is ± 10%, then there is a high degree of certainty that the true result will be between 18 and 22 mg/100g.

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 when and how the fortificant is added and may differ for different products. Lack of homogeneity is one source of between sample variability.

The laboratories that carried out the tests estimate that for the methods they use, their uncertainty for iron analysis of foods is ± 20% and for folate analysis is ± 15%. Uncertainty resulting from the manufacturing technique, for example lack of homogeneity and stratification in the bulk products are additional to the uncertainty associated with the analytical method and contribute to the differences in measured concentrations for different batches of the same product.

Most measurements are used to assess compliance with regulatory or specification requirements and uncertainty is unimportant if the measured amount is well removed from the target limit. However uncertainty is important if the measured result is close to the limit, as in the case of assessing concentrations relative to label claims.

An acceptable range of ± two standard deviations of the mean of the measured concentration was determined for each product sampled, using the standard deviation derived from triplicate (or duplicate) samples of each product. The label claim was assessed relative to this range as this more closely indicates the composition of a typical sample of that product than individual samples of the same product. For a product where the label claim was outside this range, the level of confidence that the sample does not meet the label claim is approximately 80% (Levine *et al*., 2001).

3 RESULTS

3.1 Concentration of iron in fortified foods

A summary of the mean concentration of iron in the selected food products is shown in Tables 2 and 3 with a full set of results included in Appendix 4. For the bread samples it is noted that one product is manufactured at three sites with the other two being manufactured at two sites only. Breakfast cereals and breads have been sorted by product number.

A comparison of the results for different batches of the same product (Appendix 4, Table 1A) shows that overall inter-sample variability is somewhat higher than intra-sample variability with CVs ranging from 1-17%. However, an exception to this were two breads and one cereal that were highly variable (CV=73, 49 and 29% respectively). Further detail of the bread analyses is provided in Figure 1.

No sample contained less iron than indicated on the label.

Products are identified by an asterisk (Tables 2 and 3) where the label claim was outside the acceptable range (see Section 2.4). For all samples, the % overage was calculated as the difference between the mean concentration and the label claim as a percentage of the label claim. For those results that do not have an asterisk, there is a possibility that these products are non-complying but there is less certainty than where an asterisk is shown.

Table 2: Mean concentrations of iron (mg/100g) in fortified foods compared with label claim

Food	Label claim (mg/100g)	Product	Measured (mg/100g)	CV	Acceptable range[1]	% overage
Baby foods	4.3	Bread sticks	7.1	13.1	5.2-8.9	64*
Breads	6	Product 1, Ch	7.6	4.2	7.0-8.3	27*
	6	Product 1, Ak	6.4	72.7	0.0-15.7	6
	6	Product 1, Wn	9.2	49.4	0.1-18.2	53
	4.5	Product 2, Ch	4.6	5.8	4.1-5.1	2
	4.5	Product 2, Ak	4.7	6.7	4.0-5.3	3
	4.5	Product 3, Ch	4.9	7.8	4.1-5.6	8
	4.5	Product 3, Ak	5.2	1.1	5.1-5.3	16*
Breakfast	6.7	Product 1	14.7	6.2	12.9-16.5	119*
cereals and	6.7	Product 2	6.5	3.6	6.0-6.9	-3
snack bar	10	Product 3	12.7	14.9	8.9-16.5	27
	6.7	Product 4	13.8	3.4	12.8-14.7	105*
	6.7	Product 6	10.4	10.7	8.23-12.7	56*
	6	Product 7	7.8	10.5	6.2-9.4	30*
	6.7	Product 9	8.0	4.5	7.3-8.7	19*
	10	Product 10	13.7	17.1	9.0-18.4	37
	10	Product 11	13.0	5.1	11.7-14.4	30*
	6.7	Product 12	11.5	2.2	11.0-12.0	72*
	6.7	Product 13	17.8	3.5	16.6-19.0	166*
	10	Product 15	16.7	14.1	12.0-21.4	67*
	7.5	Product 16	12.0	3.6	11.1-12.9	60*
	6.7	Product 17	16.9	9.8	13.6-20.2	152*
	10	Product 18	15.2	2.1	14.5-15.8	52*
	6.7	Product 19	12.8	14.3	9.2-16.4	91*
	10	Product 20	10.6	8.1	8.9-12.3	6
	10	Product 21	15.7	6.2	13.7-17.6	57*
	6.7	Product 22	11.0	11.0	8.6-13.4	64*
	No claim	Product 23	4.8	2.1	4.6-5.0	NA
	12	Product 24	8.0	28.9	3.4-12.6	-34
Meat extract	36	Meat extract	46.3	2.9	43.6-48.9	29*
Food drinks	5.5	Food drink 1	5.5	1.0	5.4-5.6	1
	0.9	Food drink 2	1.2	5.0	1.1-1.3	30*
	27	Food drink 3	31.3	7.7	26.5-36.1	16
Protein product	0.96	Protein product	1.1	17.1	0.7-1.5	18

CV = coefficient of variation   1= ± 2 standard deviations of the mean of the measured concentration
* = sample concentration greater than label claim at 80% level of confidence

The iron content of dietary supplements is shown as mg per tablet to facilitate a comparison with label claim (Table 3).

Table 3: Mean concentrations of iron (mg/tablet) in dietary supplements compared with label claim

Dietary Supplement	Label claim (mg per tablet)	Measured (mg per tablet)	CV	Acceptable range[1]	% overage
1	4	3.8	3.6	3.5-4.0	-6
2	12	11.7	0.7	11.5-11.9	-3
3	1	2.6	4.9	2.3-2.8	156*

1= ± 2 standard deviations of the mean of the measured concentration
***** = sample concentration greater than label claim at 80% confidence

Twenty foods and one dietary supplement from a total of 37 products (57%) exceeded the label claim for iron based on the mean concentration for three batches. Overages ranged from 16- 166% with five products having iron concentrations 100% above their label claim. One product, identified from the MFD, contained elemental iron but in fact had no label claim.

The mean concentration of iron compared with label claim, is shown graphically in Figures 1-3. Error bars for ± 1 standard deviation represent the variability of triplicate samples. Where there is no error bar, multiple samples gave indistinguishable results.

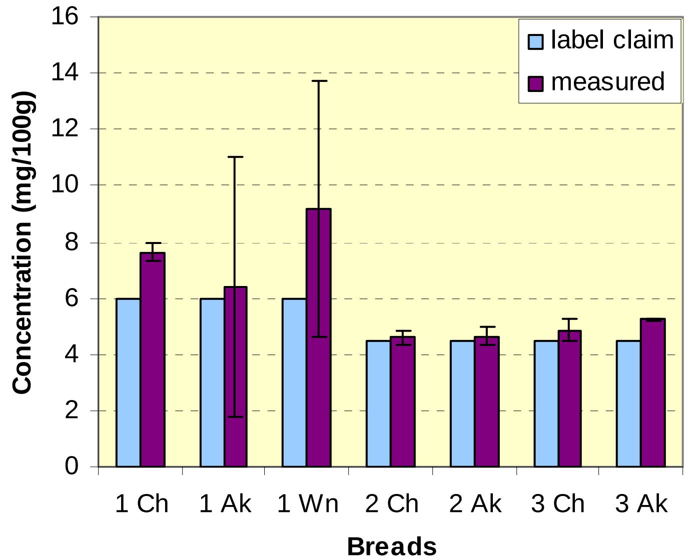

Figure 1: Measured concentrations of iron compared with label claim for three bread products (1-3) purchased from two or three different regions, Christchurch (Ch), Auckland (Ak), Wellington (Wn)

Errors bars are ± 1 standard deviation.

Figure 1 shows that sample variability for the bread samples was low (CV less than 8%) except for two samples. These samples (1Ak and 1Wn) were both of the same product but were baked at and purchased from different locations. For sample “1Ak”, iron concentrations were 9.5, 8.6, and 1.1 mg/kg for three different batches of the same product and the low result was confirmed by duplicate analysis. For sample “1Wn”, iron concentrations were 6.6, 6.5 and 14.4 mg/kg, with the high result confirmed by a duplicate analysis.

The variability of iron levels suggests there could be a quality control issue with the fortification of this product and that this is occurring at both these sites. The same product from the Christchurch site was less variable although three samples are insufficient to be sure that quality control is better in the Christchurch plant.

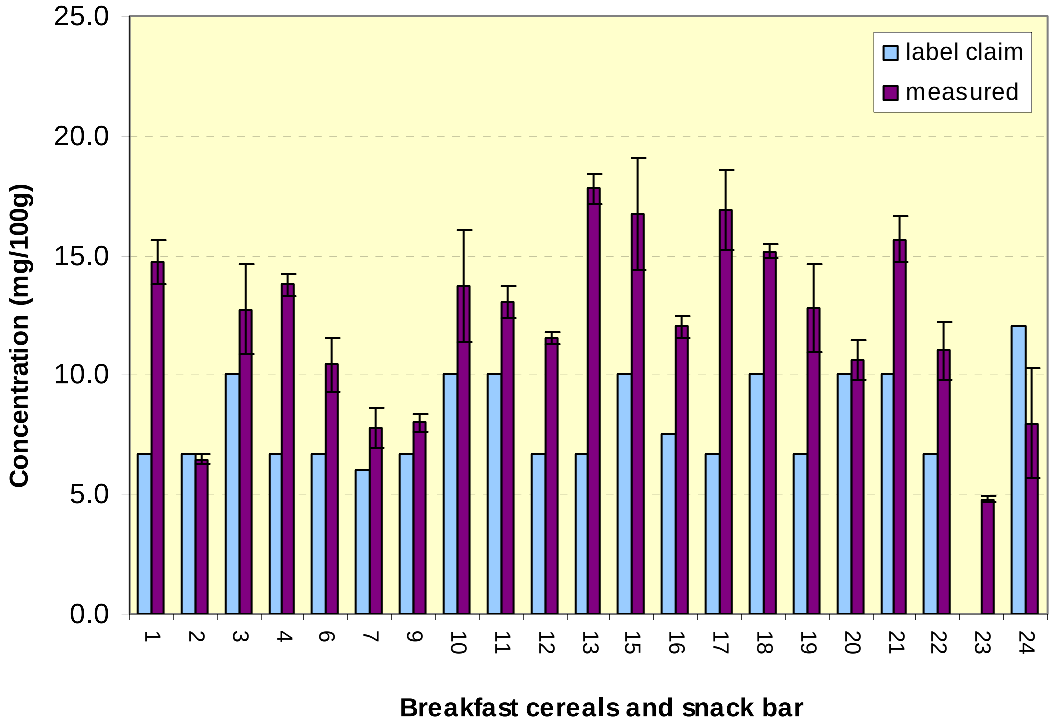

Figure 2: Measured concentrations of iron compared with label claim for 23 breakfast cereals and a cereal snack bar

The variability and degree of overage was not associated with any particular cereal brand nor any particular grain type (i.e. corn, rice, wheat or composite) (Figure 2).

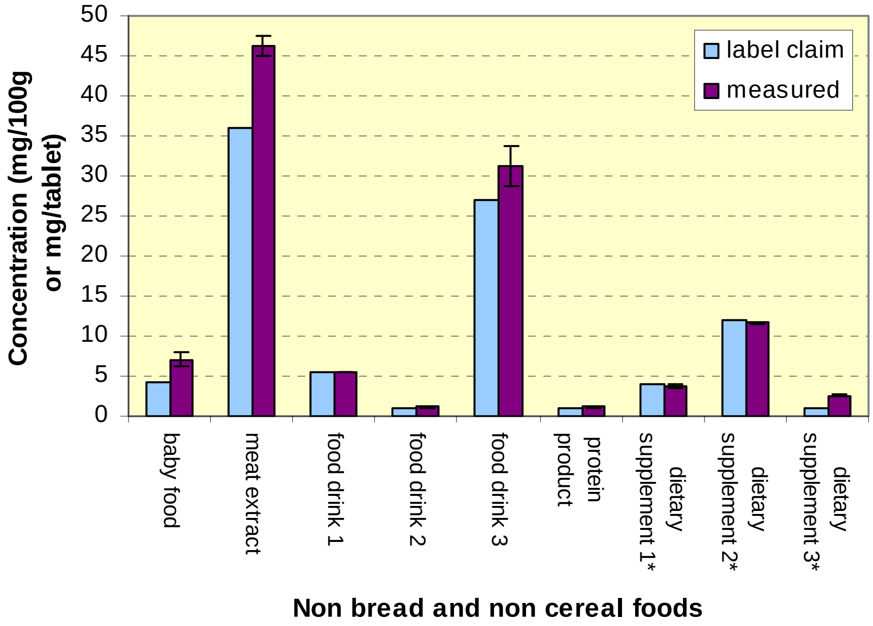

Figure 3: Measured concentrations of iron compared with label claim for selected foods

* Concentration measured in mg/100g for foods and mg/tablet for supplements

3.2 Repeatability of iron fortification with time

The concentration of iron in food samples and dietary supplements that were analysed at a second time interval six months apart are shown in Tables 4 and 5 and graphically in Figure 4.

Table 4: Concentration of iron in fortified foods measured at two time intervals, six months apart (mg/100g)

	Iron concentration (mg/100g)		
Food type	**Label claim**	**Time 1**	**Time 2**
Baby foods	4.3	6.3	5.1
Cereal, Product 1	6.7	13.7	11.6
Cereal, Product 2	6.7	6.6	6.4
Cereal, Product 3	10	10.9	12.3
Cereal, Product 4	6.7	13.5	13.1
Cereal, Product 6	6.7	10	12.1
Cereal, Product 7	6	8.5	7.8
Cereal, Product 9	6.7	8.3	7.5
Cereal, Product 10	10	16.4	15.8
Cereal, Product 11	10	12.3	11.9
Cereal, Product 12	6.7	11.3	12.4
Cereal, Product 13	6.7	17.3	8.8
Cereal, Product 15	10	19.3	17.4
Cereal, Product 16	7.5	11.8	7.05
Cereal, Product 17	6.7	17.7	13.1
Cereal, Product 18	10	15.3	15.6
Cereal, Product 19	6.7	11.9	13.4
Cereal, Product 20	10	10.7	11.1
Cereal, Product 21	10	14.6	14.5
Cereal, Product 22	6.7	9.7	5.85
Cereal, Product 24	12	10.5	8.1
Food drink 1	5.5	5.6	4.8
Food drink 2	0.9	1.2	0.9
Food drink 3	27	28.8	33.1
Protein product	0.96	1.34	1.1

Table 5: Concentration of iron in dietary supplements measured at two time intervals, six months apart (mg/tablet)

	Iron concentration (mg/tablet)		
Dietary supplement	**Label claim**	**Time 1**	**Time 2**
1	4	3.9	3.9
2	12	11.7	11.4
3	1	2.4	2.5

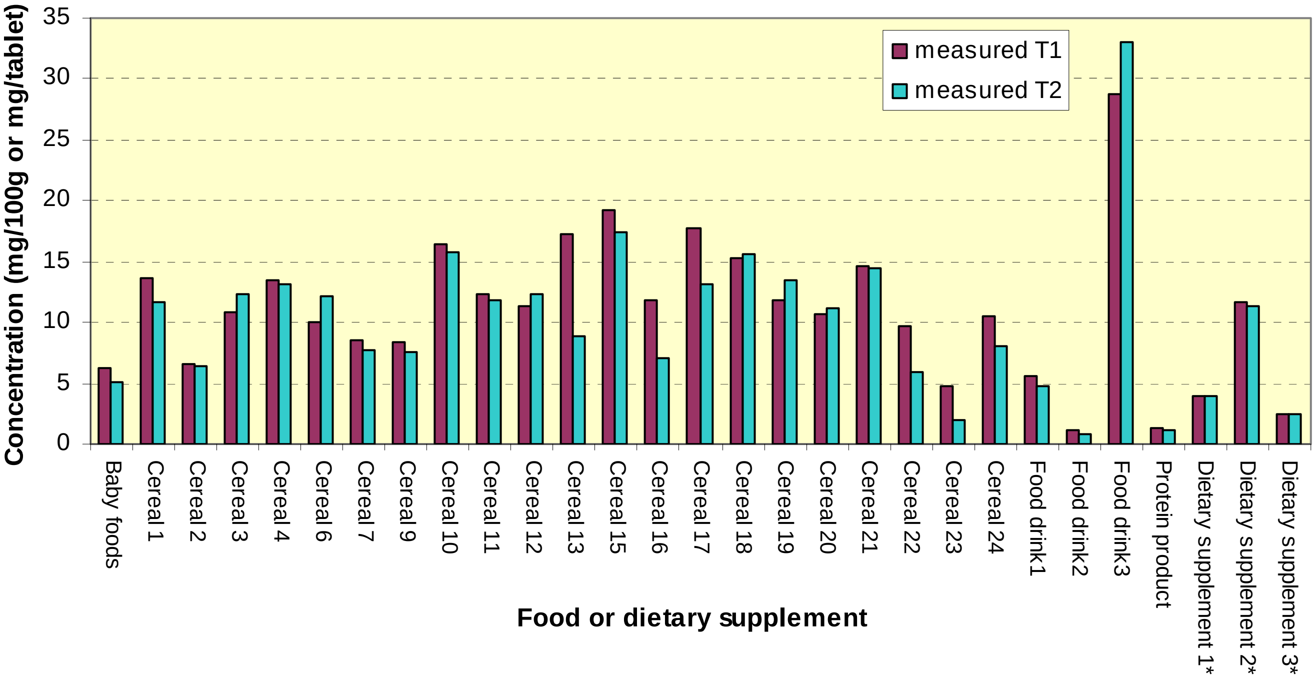

Figure 4: Iron concentrations for the same product analysed at two time intervals, six months apart

* Concentration measured in mg/100g for foods and mg/tablet for supplements

The iron concentration measured in time 2 samples was lower than the value for time 1 for 20 samples, was equal for one sample, and higher for eight samples. A loss of iron is not expected since iron is a non-volatile element and cannot disappear, and the differences observed between time 1 and time 2 reflect sampling and analytical variability.

3.3 Concentration of folate in fortified foods

Data for duplicate and replicate samples are provided in Appendix 3.

A summary of the mean concentration of folate in the selected foods is shown in Tables 6 and 7 with a full set of results included in Appendix 4. The selected breads are manufactured in Auckland and Christchurch, hence the two purchase locations for each product.

For food products that were outside the acceptable range, the % overage or % underage was calculated as the difference between the mean concentration and the label claim as a percentage of the label claim. Products are identified by an asterisk (Tables 6 and 7) where the label claim was outside the acceptable range. For those results that do not have an asterisk, there is a possibility that these products are non-complying but there is less certainty.

Table 6: Mean concentrations of folate (µg/100g) in fortified foods compared with label claim

Food	Label claim (µg/100g)	Product	Measured (µg/100g)	CV	Acceptable range[1]	% overage
Baby food	140	Baby food	97	67	0-225	-31
Bread	200	Product 2, Ak	137	11	106-167	-32*
	200	Product 2, Ch	133	11	103-164	-33*
	200	Product 3, Ak	170	0	170-170	-15*
	200	Product 3, Ch	177	12	135-218	-12
	200	Product 4, Ak	140	7	120-160	-30*
	200	Product 4, Ch	147	8	124-170	-27*
Breakfast cereals	333	Product 1	335	23	179-491	1
	333	Product 2	240	0	240-240	-28*
	333	Product 3	445	30	176-714	34
	333	Product 4	380	33	125-635	14
	333	Product 5	260	11	203-317	-22*
	333	Product 6	370	0	370-370	11
	200	Product 7	290	15	205-375	45*
	333	Product 8	350	8	293-407	5
	333	Product 9	240	6	212-268	-28*
	167	Product 10	220	19	135-305	32
	167	Product 11	460	15	319-601	175*
	222	Product 12	880	0	880-880	296*
	222	Product 13	445	11	346-544	100*
	333	Product 14	470	6	413-527	41*
	333	Product 15	360	35	105-615	8
	333	Product 17	230	25	117-343	-31
	333	Product 18	530	11	417-643	59*
	222	Product 19	700	61	0-1550	215
	167	Product 20	230	25	117-343	38
	167	Product 21	355	6	313-397	113*
	333	Product 23	483	31	183-784	45
Food drinks/ juice	90.9	Drink 1	133	4	122-145	47*
	35	Drink 2	41	18	26-56	16
	40	Drink 3	43	20	26-60	8
	40	Drink 4	63	12	48-77	57*
Protein product	32	Protein product	89	26	43-135	178*
Meat extract	2000	Meat extract	3337	15	2340-4340	67*

1= ± 2 standard deviations of the mean of the measured concentration
* = sample concentration greater than or less than label claim at 80% level of confidence

The mean folate concentrations for eight of the 34 foods were 15-33% below the label claim. These eight foods comprised five breads and three cereals. Eleven foods including cereals, food and fruit drinks and the meat extract had folate contents above the label claim with the overages being between 41 and 296%. Five of these products (13%) had folate overages that were at least double the label claims.

The folate concentration of the dietary supplements and pharmacy medicine is shown as µg/tablet to facilitate a comparison with label claims (Table 7).

Table 7: Mean concentrations of folate (µg/tablet) in the dietary supplements and pharmacy medicine compared with label claim

Supplement or pharmacy medicine	Label claim (µg per tablet)	Measured (µg per tablet)	CV	Acceptable range[1]	% overage
1	200	332	11	257-407	66*
2	300	423	11	325-520	41*
3	300	359	11	277-442	20
4	800	606	2	585-627	-24*

1= ± 2 standard deviations of the mean of the measured concentration
* = sample concentration greater than or less than label claim at 80% level of confidence

Two dietary supplements were above the label claim by 66 and 41% and the pharmacy medicine contained 24% less folate than claimed on the label.

A total of 9/38 products (24%) contained less than the claimed level of folate and 13/38 (34%) contained more folate than claimed.

The mean concentration of folate compared with label claim, is shown graphically in Figures 5-7. Error bars for ± 1 standard deviation represent the variability between the triplicate samples of each product tested. Where there is no error bar, multiple samples gave indistinguishable results.

All bread samples contained less folate than the label claim, with Auckland and Christchurch samples of products 2 and 4 containing approximately 70% of the folate claimed on the label.

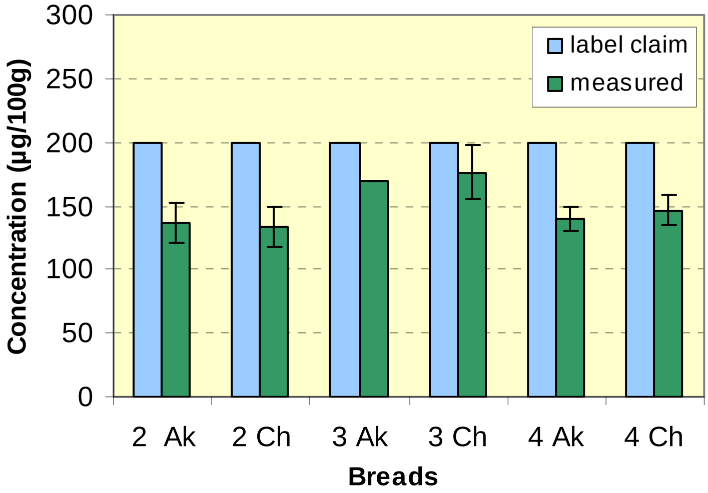

Figure 5: Measured concentrations of folate compared with label claim for three bread products purchased from Auckland (Ak) and Christchurch (Ch)

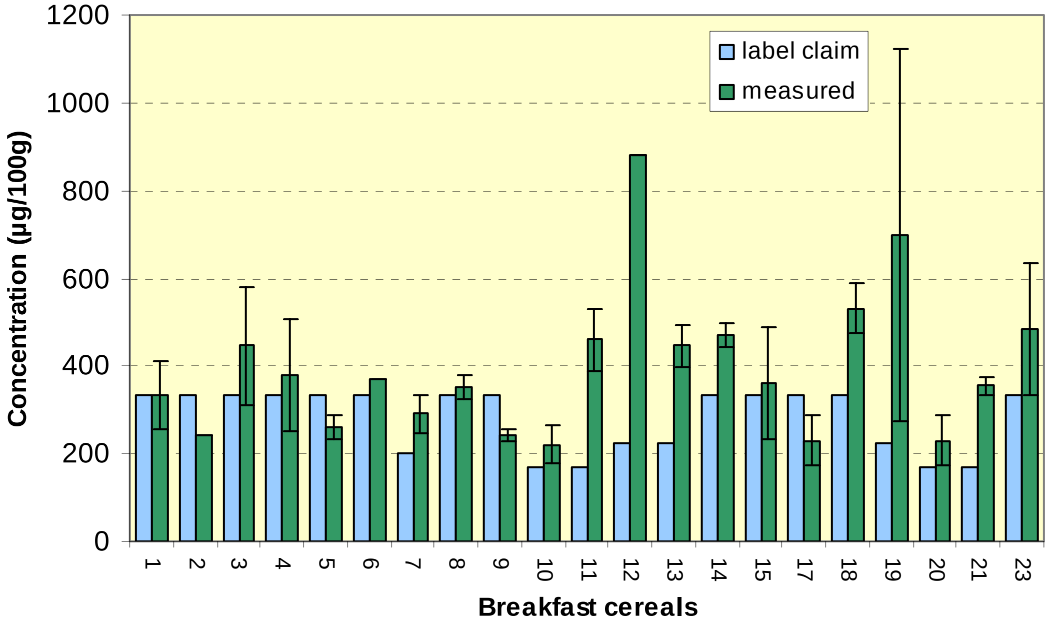

Figure 6: Measured concentrations of folate compared with label claim for breakfast cereals

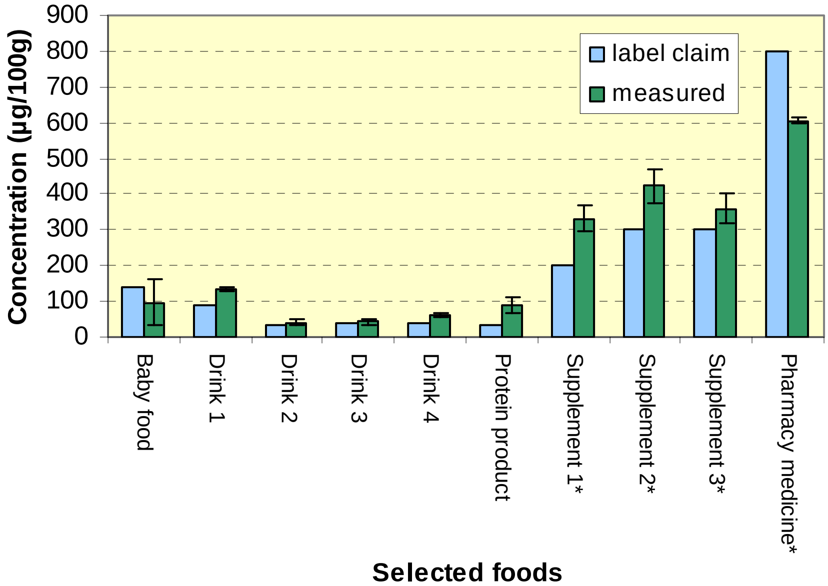

Figure 7: Measured concentrations of folate compared with label claim for selected foods, dietary supplements and pharmacy medicine

* Concentration measured in µg/100g for foods and µg/tablet for supplements and pharmacy medicines

3.4 Stability of folate fortification with time

Folate is likely to be lost from foods during storage although the rate will depend on many factors including the type of food, moisture content and exposure to light (Hawkes and Villota, 1989). An attempt was made at assessing the stability of folate in a selection of the sampled products but the reproducibility of the microbiological method of analysis was found to be insufficient to show small losses of folate over time. The data obtained are shown in Tables 8-10.

Table 8: Concentration of folate in fortified foods measured at two time intervals, six months apart (µg/100g)

	Folate concentration (µg/100g)		
Food	**Label claim**	**Time 1 September 2004**	**Time 2 March 2005**
Baby food	140	50	57
Meat extract	2000	3790	2490
Drink 1	90.9	140	190
Drink 2	35	48	67
Drink 3	40	44	65
Drink 4	40	70	90
Protein product	32	79	120

Table 9: Concentration of folate in the dietary supplements and pharmacy medicine measured at two time intervals, six months apart (µg/tablet)

	Folate concentration (µg/tablet)		
Supplement or pharmacy medicine	**Label claim**	**Time 1 September 2004**	**Time 2 March 2005**
1	200	307	177
2	200	388	364
3	300	384	186
4	800	599	1001

It cannot be concluded from this data that folate was lost from any of the products over the six months although there are indications that it could have been lost from the meat extract and two of the dietary supplements. However a number of replicates would need to be tested over the time interval to confirm this observation as real.

Table 10: Concentration of folate in fortified cereals measured at three time intervals over a six month period (μg/100g)

Cereal ID	Label claim (μg/100g)	Time 1 Sept 2004	Time 2[1] Nov 2004	Time 3[2] March 2005
Product 5	333	240	190	186
Product 8	333	370	220	286
Product 11	167	410	259	450
Product 14	333	450	330	448
Product 15	333	450	460	662
Product 18	167	190	200	201
Product 19	222	400	330	429
Product 23	333	330	NR	416

NR = no result, 1 = T2 < T1 (p =0.014), 2 = T2 > T3 (p=0.011)

Table 10 shows a significant difference in folate concentration from time 1 to time 2 ($p=0.014$) for eight cereals but this difference was in fact reversed for time 2 compared with time 3 ($p=0.011$), and there is no significant difference between time 1 and time 3 using a one sided, paired, student t-test at the 95th percent probability. Almost certainly, these observed differences arise from batch to batch variation in the analytical procedure and there is no evidence of measurable degradation of folate in fortified cereals over a six month period.

4 DISCUSSION AND CONCLUSIONS

4.1 Quantifying uncertainty for assessing label claims

The analyses for iron and folate in this study are as robust as current methodologies allow for the limits of detection necessary to measure the levels at which these fortificants are added to foods. For folate, the methodology is accredited for foods but is not ideal for supplement and pharmacy medicines because the high concentrations of folate require significant dilutions that are a source of error in the determination of these samples.

No analytical measurement is absolute. All analytical measurements have associated uncertainty arising from sampling, the analytical method and the manufacturing technique. From this study, it is seen that realistic uncertainties for different batches of foods fortified with iron are ± 20% CV and for samples fortified with folate are ± 30% CV. Since measured concentrations in fortified foods are close to label values, the uncertainty in measured concentrations is important when assessing compliance with label claim.

Therefore, consideration may be given in standard setting to defining a tolerance around the label claim that incorporates these uncertainties. For example, the acceptable range 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).

Estimating an acceptable 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 label claim.

The magnitude of the tolerance, and hence acceptable 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 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 triplicates, as in this study, the level of confidence that the true result lies within an acceptable range of the mean ± two times the CV is about 80%. This means that if the concentration of a product is found to be just outside this range, there is an 80% chance that a product does in fact meet its label claim and a 20% chance that it does not.

Generally, a 95% level of confidence is acceptable (TELARC, 1987) in which case the acceptable range would be wider (± 2.5 standard deviations) for uncertainties based on three results. Alternatively, a greater level of confidence, and narrower acceptable range could be obtained by analysing more samples of the same product. For example, a 95% level of confidence and acceptable range of ± 20% for iron or ± 30% for folate, would be achieved if the uncertainty was based on five samples.

4.2 Dietary modelling of exposure to iron and folate from fortified foods

The product with the highest % iron overage was a wheat-based cereal with a suggested serving size of 45 g. A single serving of this product, with an overage of 166% would result in an intake of 8.0 mg of iron contributing between 30 and 100% of the RDI for iron, depending on the population group (NHMRC, 2004a). The maximum permitted contribution of iron per serving is 3 mg or 50% of the RDI (FSANZ, 2002). Interrogation of the 1997 National Nutrition Survey (NNS) shows that a high consumer may consume 90 g of this product (Russell *et al*., 1999). Consumption of 90 g with an overage of 166% would result in an iron intake of 35% of the UIL for adults. To exceed the UIL of iron would require the consumption of 112 g or three servings per day by an infant or young child (1-3 years) or 250 g or six servings by an adolescent or adult.

The maximum folate overage was found in a wheat-based cereal with an overage of 296%. The suggested serving size for this product is 45 g and a single serving of this product would result in an intake of 396 µg of folate, equivalent to the draft RDI of folate for adults and adolescents over 14 years of age (400 µg/day), and in excess of the RDI for males and females younger than 14 years of age (300 µg/day) (Appendix 1). The maximum permitted contribution of folate per serving is 100 µg or 50% of the RDI (FSANZ, 2002). Interrogation of the NNS shows that a high consumer may consume 128 g of this product (Russell *et al*., 1999) in which case intake of folate would be 1126 µg per serving, in excess of the proposed UIL of 1000 µg/day for adults (NHMRC, 2004a).

Since a high consumer may exceed the UIL for folate as a result of consuming fortified foods and with the level of overage found in this study, a maximum acceptable level of fortification may be considered in the standards setting process, as there is for vitamin A for example (FSANZ, 2002). Such a limit could be derived from the UIL and New Zealand consumption information for the product and fortificant under consideration.

5 REFERENCES

CFIA (Canadian Food Inspection Agency). (2003). Nutrition labelling compliance test. Available at http://www.inspection.gc.ca/english/fssa/labeti/nutricon/nutricone.shtml

FSANZ (Food Standards Australia and New Zealand). (2002) Australia and New Zealand Food Standards Code 2002. Available at www.foodstandards.gov.au

Hawkes JG and Villota R. (1989). Folates in foods: reactivity, stability during processing, and nutritional implications. Critical Reviews of Food Science and Nutrition; 28 (6):439-538.

Levine DM, Ramsey PP, Smidt RK. (2001). Applied Statistics for engineers and scientists. New Jersey: Prentice Hall.

NHMRC (National Health Medical Research Council). (2004a). Executive summary of nutrient reference values for Australia and New Zealand including Recommended Dietary Intakes. Draft. Canberra: Commonwealth of Australia and New Zealand Government. Available at www.nhmrc.gov.au/advice/pdf/nrvs.pdf

NHMRC (National Health Medical Research Council). (2004b). Nutrient reference values for Australia and New Zealand including Recommended Dietary Intakes. Draft. Canberra: Commonwealth of Australia and New Zealand Government. Available at www.nhmrc.gov.au/advice/pdf/nrvs.pdf pp101-110, 199-204.

Nutrition Services. (2003). Fortified foods available in New Zealand. December 2003. Wellington: Ministry of Health.

Russell DG, Parnell WR, Wilson NC. (1999). NZ Food:NZ people. Key results of the 1997 National Nutrition Survey. Ministry of Health.

TELARC (Testing Laboratory Registration Council of New Zealand) (1987). Precision and limits of detection for analytical methods. Auckland, New Zealand: Testing Laboratory Registration Council of New Zealand.

Whittaker P, Tufaro PR, Rader JI. (2001). Iron and folate on fortified cereals. American College of Nutrition; 20 (3):247-254.

Appendix 1: New Zealand and Australia RDIs and UILs for iron and folate (draft, NHMRC, 2004a)

Age/gender group		Iron mg/day		Folate (folate equivs. µg/day)	
		RDI	UIL	RDI	UIL
Infants	0-6 mo.	-	20	-	BM
	7-12 mo.	-	20	-	B/F
Children	1-3 yrs	9	20	150	300
	4-8 yrs	10	40	200	400
Boys	9-13 yrs	8	40	300	600
	14-18 yrs	11	45	400	800
Girls	9-13 yrs	8	40	300	600
	14-18 yrs	15	45	400	800
Men	19-30 yrs	8	45	400	1000
	31-50 yrs	8	45	400	1000
	51-70 yrs	8	45	400	1000
	>70 yrs	8	45	400	1000
Women	19-30 yrs	18	45	400	1000
	31-50 yrs	18	45	400	1000
	51-70 yrs	8	45	400	1000
	>70 yrs	8	45	400	1000
Pregnant	14-18 yrs	27	45	600	800
	19-30 yrs	27	45	600	1000
	31-50 yrs	27	45	600	1000
Lactating	14-18 yrs	10	45	500	800
	19-30 yrs	9	45	500	1000
	31-50 yrs	9	45	500	1000

BM = amount normally received from breast milk of healthy women; B/F = amount in breast milk and food

Appendix 2: Foods available in New Zealand that are fortified with iron or folate (Nutrition Services, 2003)

Food manufacturers have identified the following foods as being fortified with iron and/or folate. 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 2003 (Nutrition Services, 2003).

IRON

Baby Foods (13)

Heinz Watties NZ Ltd, Farex, Apricot porridge
Heinz Watties NZ Ltd, Farex,
    Baby muesli with oat flakes & apple
Heinz Watties NZ Ltd, Farex, Baby rice
Heinz Watties NZ Ltd, Farex, Mixed grain cereal
Heinz Watties NZ Ltd, Heinz, Teething rusks
Heinz Watties NZ Ltd, Wattie's, Baby muesli-finely groun
Heinz Watties NZ Ltd, Wattie's, Cheesy bread sticks
Heinz Watties NZ Ltd, Wattie's, Cheesymite bread sticks
Heinz Watties NZ Ltd, Wattie's, Muesli and Apple
Heinz Watties NZ Ltd, Wattie's, Rice cereal with apple
Nutricia Australasia, Robinsons, Baby rice
Nutricia Australasia, Robinsons, Banana & pear
Nutricia Australasia, Robinsons, Muesli

Biscuits (12)

Griffin's Foods Ltd, Griffins,
    Apricot shrewsbury (enriched with iron)
Griffin's Foods Ltd, Griffins,
    Calci Moo's very berry (enriched with iron)
Griffin's Foods Ltd, Griffins,
    Calci Moo's (enriched with iron)
Griffin's Foods Ltd, Griffins, Chocolate chippies
(enriched with iron)
    Mini cookie bear (enriched with iron)
Griffin's Foods Ltd, Griffins, Fruitli fingers-apricot
(enriched with iron)
(enriched with iron)
    (enriched with iron)
Griffin's Foods Ltd, Griffins,
    Shrewsbury (enriched with iron)
Griffin's Foods Ltd, Griffins,
    Shrewsbury numbers (enriched with iron)
Griffin's Foods Ltd, Griffins, Wee chocolate chippies:
    (enriched with iron)
Griffin's Foods Ltd, Well Grain,
    Essentials –spirulina & garlic crispbread

Breads (4)

Allied Foods Ltd, Holsoms, 9 Grain
Allied Foods Ltd, Holsoms, Soy, linseed, canola
Allied Foods Ltd, Holsoms, Sunflower & poppyseed
Allied Foods Ltd, Tip Top bread, Mighty white sandwich

Breakfast cereals (60)
Foodstuffs Auckland, Budget, Cornflakes
Foodtown/Countdown/Super Valu/Fresh Choice,
Basics, Cocoa rice poppas
Foodtown/Countdown/Super Valu/Fresh Choice,
Basics, Powergrain
Foodtown/Countdown/Super Valu/Fresh Choice,
Basics, Rice poppas
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range, Bran & Sultanas
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range, Cornflakes
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range, Honey nut flakes
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range, Power stars
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range, Rice poppas
Freedom Foods Aust. Pty. Ltd..
Freedom Foods, Rice flakes with psyllium
Freedom Foods Aust. Pty. Ltd..
Freedom Foods, Ultra-rice with psyllium
Goodman Fielder NZ Ltd, Uncle Tobys, Bran flakes
Goodman Fielder NZ Ltd, Uncle Tobys, Rice flakes
Hubbard Foods Ltd, Hubbards, Bugs ‘n’ mud
Hubbard Foods Ltd, Hubbards, Cocoa cornflakes
Hubbard Foods Ltd, Hubbards, Cornflakes
Hubbard Foods Ltd, Hubbards, Home Sweet Home
Hubbard Foods Ltd, Hubbards, Just the Bees Knees
Hubbard Foods Ltd, Hubbards, Rice pops
Kelloggs (Aust) Pty Ltd, Kellogg’s, All-bran
Kelloggs (Aust) Pty Ltd, Kellogg’s, Bran flakes
Kelloggs (Aust) Pty Ltd, Kellogg’s, Coco pops
Kelloggs (Aust) Pty Ltd, Kellogg’s, Coco pops K*pows
Kelloggs (Aust) Pty Ltd, Kellogg’s, Corn flakes
Kelloggs (Aust) Pty Ltd, Kellogg’s, Crunchy nut corn flakes
Kelloggs (Aust) Pty Ltd, Kellogg’s, Froot Loops
Kelloggs (Aust) Pty Ltd, Kellogg’s, Frosties
Kelloggs (Aust) Pty Ltd, Kellogg’s, Just Right
Kelloggs (Aust) Pty Ltd, Kellogg’s, Just right fruit n flakes
Kelloggs (Aust) Pty Ltd, Kellogg’s, Just right just grains
Kelloggs (Aust) Pty Ltd, Kellogg’s, Nutri grain choc malt
Kelloggs (Aust) Pty Ltd, Kellogg’s, Nutri grain smash
Kelloggs (Aust) Pty Ltd, Kellogg’s, Nutri-grain
Kelloggs (Aust) Pty Ltd, Kellogg’s, Rice bubbles
Kelloggs (Aust) Pty Ltd, Kellogg’s, Special K
Kelloggs (Aust) Pty Ltd, Kellogg’s, Special K peach n apricot
Kelloggs (Aust) Pty Ltd, Kellogg’s, Special K red
Kelloggs (Aust) Pty Ltd, Kellogg’s, Sultana bran
Kelloggs (Aust) Pty Ltd, Kellogg’s, Sustain
Prolife Foods Ltd, Alison’s Choice, Rise & shine cereal
Real Foods Ltd, Real Value, Tri-grain
Sanitarium the Health Food Co, Sanitarium, Corn flakes
Sanitarium the Health Food Co, Sanitarium, Fruity bix apricot
Sanitarium the Health Food Co, Sanitarium, Fruity bix strawberry
Sanitarium the Health Food Co, Sanitarium, Fruity bix wild berry

Sanitarium the Health Food Co, Sanitarium
 Fruity bix bars-apricot
Sanitarium the Health Food Co, Sanitarium,
 Fruity bix bars-fruit & nut
Sanitarium the Health Food Co, Sanitarium,
 Fruity bix bars-strawberry
Sanitarium the Health Food Co, Sanitarium,
 Fruity bix bars-tropical
Sanitarium the Health Food Co, Sanitarium,
 Fruity bix bars-wild berry
Sanitarium the Health Food Co, Sanitarium,
 Light 'n' tasty
Sanitarium the Health Food Co, Sanitarium,
 Light 'n' tasty berry
Sanitarium the Health Food Co, Sanitarium, Maximize
Sanitarium the Health Food Co, Sanitarium, Ricies
Sanitarium the Health Food Co, Sanitarium, Weet-bix
Tasti Products Ltd, Tasti, Blueberry morning
Tasti Products Ltd, Tasti, Cranberry bran
Tasti Products Ltd, Tasti, Tropicana sunrise
Tasti Products Ltd, Weight watchers,
 Weight watchers berry flakes
Tasti Products Ltd, Weight watchers,
 Weight watchers tropical breakfast

Extracts of meat, Yeast, or Vegetables (1)
Sanitarium The Health Food Co, Sanitarium, Marmite

Food Drinks (14)
Healtheries of NZ Ltd, Healtheries, Naturally slim-berry flavour
Healtheries of NZ Ltd, Healtheries,
 Naturally slim-chocolate flavour
Healtheries of NZ Ltd, Healtheries,
 Naturally slim-vanilla flavour
Healtheries of NZ Ltd, Healtheries, Vitaplan-Bountiful berry
Healtheries of NZ Ltd, Healtheries, Vitaplan-Classic chocolate
Healtheries of NZ Ltd, Healtheries, Vitaplan-Vital vanilla
Heinz Wattie's NZ Ltd, Complan, Complan chocolate
Heinz Wattie's NZ Ltd, Complan, Complan double chocolate
Heinz Wattie's NZ Ltd, Complan, Complan strawberry
Heinz Wattie's NZ Ltd, Complan, Complan vanilla
Nestle NZ Ltd, Milo, Milo tonic food
Sanitarium The Health Food Co, Sanitarium, Fast break
Sanitarium The Health Food Co, Sanitarium, Organics simply soy
Sanitarium The Health Food Co, Sanitarium, So Good Essential

Fruit Cordial (1)
Baker Hall (NZ) Ltd, Baker Halls Original,
 Cranberry & Blackcurrant fruit syrup

Miscellaneous (7)
Healtheries of NZ Ltd, Healtheries Kidscare,
 Real fruit waves-blackberry
Healtheries of NZ Ltd, Healtheries Kidscare,
Real fruit waves-raspberry
Mainland Products Ltd, Huttons,
 Ham and chicken luncheon with iron and vitamin C

McDonalds System of NZ Ltd, McDonalds, Croutons
Naturalac Nutrition Ltd, Horleys,
Meal Replacement HP Chocolate

Pasta (4)
Freedom Foods Aust. Pty.Ltd, Freedom Foods,
Enriched garlic pesto pasta-gluten free
Freedom Foods Aust. Pty.Ltd, Freedom Foods,
Enriched legume & rice pasta-gluten free
Freedom Foods Aust. Pty.Ltd, Freedom Foods,
Enriched rice pasta-gluten free
Freedom Foods Aust. Pty.Ltd, Freedom Foods,
Enriched spaghetti-gluten free

Protein Products (2)
Real Foods Ltd, Vitasoy, Vitality+
Bean Supreme Ltd, bean Supreme, vegetarian sausages
Nice & Natural Ltd, Chisel, Chocolate protein bar
Nice & Natural Ltd, Chisel, Yoghurt berry protein bar

FOLATE

Baby Foods (2)
Heinz Watties NZ Ltd, Wattie’s, Cheesy bread sticks
Heinz Watties NZ Ltd, Wattie’s, Cheesymite bread sticks

Biscuits (1)
Griffin’s Foods Ltd, Well Grain,
Essentials –spirulina & garlic crispbread

Breads (7)
Allied Foods Co Ltd, Burgen, Oat bran & honey
Allied Foods Co Ltd, Burgen, Soy Lin
Allied Foods Co Ltd, Holsoms, 9 Grain
Allied Foods Co Ltd, Holsoms, Soy, linseed, canola
Allied Foods Co Ltd, Holsoms, Sunflower & poppyseed
Allied Foods Co Ltd, Holsoms, Swiss bake
Healtheries of NZ Ltd, Healtheries, Gluten free bread mix

Breakfast cereals (53)
Foodstuffs Auckland, Budget, Cornflakes
Foodtown/Countdown/Super Valu/Fresh Choice,
Basics, Cocoa rice poppas
Foodtown/Countdown/Super Valu/Fresh Choice,
Basics, Powergrain
Foodtown/Countdown/Super Valu/Fresh Choice,
Basics, Rice poppas
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range,Bran & Sultanas
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range,Cornflakes
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range, Honey nut flakes
Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range, Power stars

Foodtown/Countdown/Super Valu/Fresh Choice,
Signature Range, Rice poppas
Freedom Foods Aust. Pty. Ltd..Freedom Foods, Rice flakes with psyllium
Freedom Foods Aust. Pty. Ltd..Freedom Foods, Ultra-rice with psyllium
Goodman Fielder NZ Ltd, Uncle Tobys, Bran flakes
Goodman Fielder NZ Ltd, Uncle Tobys, Rice flakes
Hubbard Foods Ltd, Hubbards, Bugs ‘n’ Mud
Hubbard Foods Ltd, Hubbards, Cocoa cornflakes
Hubbard Foods Ltd, Hubbards, Cornflakes
Hubbard Foods Ltd, Hubbards, Home sweet home
Hubbard Foods Ltd, Hubbards, Rice pops
Kelloggs (Aust) Pty Ltd, Kellogg’s, All-bran
Kelloggs (Aust) Pty Ltd, Kellogg’s, Bran flakes
Kelloggs (Aust) Pty Ltd, Kellogg’s, Coco pops
Kelloggs (Aust) Pty Ltd, Kellogg’s, Coco pops K*pows
Kelloggs (Aust) Pty Ltd, Kellogg’s, Cocoa Crispix
Kelloggs (Aust) Pty Ltd, Kellogg’s, Corn flakes
Kelloggs (Aust) Pty Ltd, Kellogg’s, Crispix
Kelloggs (Aust) Pty Ltd, Kellogg’s, Crunchy nut corn flakes
Kelloggs (Aust) Pty Ltd, Kellogg’s, Froot loops
Kelloggs (Aust) Pty Ltd, Kellogg’s, Frosties
Kelloggs (Aust) Pty Ltd, Kellogg’s, Just right
Kelloggs (Aust) Pty Ltd, Kellogg’s, Just right fruit n flakes
Kelloggs (Aust) Pty Ltd, Kellogg’s, Just right just grains
Kelloggs (Aust) Pty Ltd, Kellogg’s, Mini wheats milk choc
Kelloggs (Aust) Pty Ltd, Kellogg’s, Mini-wheats-blackcurrant
Kelloggs (Aust) Pty Ltd, Kellogg’s, Nutri grain choc malt
Kelloggs (Aust) Pty Ltd, Kellogg’s, Nutri grain smash
Kelloggs (Aust) Pty Ltd, Kellogg’s, Nutri-grain
Kelloggs (Aust) Pty Ltd, Kellogg’s, Rice bubbles
Kelloggs (Aust) Pty Ltd, Kellogg’s, Special K
Kelloggs (Aust) Pty Ltd, Kellogg’s, Special K peach n apricot
Kelloggs (Aust) Pty Ltd, Kellogg’s, Special K red
Kelloggs (Aust) Pty Ltd, Kellogg’s, Sultana bran
Kelloggs (Aust) Pty Ltd, Kellogg’s, Sustain
Real Foods Ltd, Lowan Whole Foods, Flake medley with wild berries
Sanitarium the Health Food Co, Sanitarium, Corn flakes
Sanitarium the Health Food Co, Sanitarium, Light ‘n’ tasty
Sanitarium the Health Food Co, Sanitarium, Light ‘n’ tasty berry
Sanitarium the Health Food Co, Sanitarium, Maximize
Sanitarium the Health Food Co, Sanitarium, Weet-bix
Tasti Products Ltd, Tasti, Blueberry morning
Tasti Products Ltd, Tasti, Cranberry bran
Tasti Products Ltd, Tasti, Tropicana sunrise
Tasti Products Ltd, Weight watchers, Weight watchers berry flakes
Tasti Products Ltd, Weight watchers,Weight watchers tropical breakfast

Extracts of meat, Yeast, or Vegetables (2)
Freedom Foods Aust. Pty. Ltd, Freedom Foods,
Vege spread-gluten free & yeast free
Sanitarium The Health Food Co, Sanitarium, Marmite

Food Drinks (19)
Healtheries of NZ Ltd, Healtheries, Naturally slim-berry flavour
Healtheries of NZ Ltd, Healtheries,Naturally slim-chocolate flavour
Healtheries of NZ Ltd, Healtheries,Naturally slim-vanilla flavour
Healtheries of NZ Ltd, Healtheries, Vitaplan-Bountiful berry

Healtheries of NZ Ltd, Healtheries, Vitaplan-Classic chocolate
Healtheries of NZ Ltd, Healtheries, Vitaplan-Vital vanilla
Heinz Wattie's NZ Ltd, Complan, Complan chocolate
Heinz Wattie's NZ Ltd, Complan, Complan double chocolate
Heinz Wattie's NZ Ltd, Complan, Complan strawberry
Heinz Wattie's NZ Ltd, Complan, Complan vanilla
Mainland Products Ltd, Naturalea, Smoothies-strawberry patch
Mainland Products Ltd, Naturalea, Smoothies-tropical breeze
Mainland Products Ltd, Naturalea, Smoothies-apricot grove
Sanitarium The Health Food Co, Sanitarium, Fast break
Sanitarium The Health Food Co, Sanitarium, So Good Essential
Sanitarium The Health Food Co, Sanitarium, Up & Go-Banana
Sanitarium The Health Food Co, Sanitarium, Up & Go-Choc Ice
Sanitarium The Health Food Co, Sanitarium, Up & Go-Strawberry
Sanitarium The Health Food Co, Sanitarium, Up & Go-Vanilla Ice

Fruit Cordial (1)
Baker Hall (NZ) Ltd, Baker Halls Original,
Cranberry & Blackcurrant fruit syrup

Fruit Juice (1)
Frucor Beverages Ltd, Citrus Tree, Orange with calcium and folate

Miscellaneous (5)
McDonalds System of NZ Ltd, McDonalds, Croutons
Naturalac Nutrition Ltd, Horleys, Meal Replacement HP Chocolate
Naturalac Nutrition Ltd, Horleys, Meal Replacement HP Vanilla

Pasta (4)
Freedom Foods Aust. Pty.Ltd, Freedom Foods,
Enriched garlic pesto pasta-gluten free
Freedom Foods Aust. Pty.Ltd, Freedom Foods,
Enriched legume & rice pasta-gluten free
Freedom Foods Aust. Pty.Ltd, Freedom Foods,
Enriched rice pasta-gluten free
Freedom Foods Aust. Pty.Ltd, Freedom Foods,
Enriched spaghetti-gluten free

Protein Products (1)
Nice & Natural Ltd, Chisel, Chocolate protein bar
Nice & Natural Ltd, Chisel, Yoghurt berry protein bar
Real Foods Ltd, Vitasoy, Vitality+

Appendix 3.1: Quality assurance data for iron

Intra-sample variability for iron

Food type	Analysis (mg/100g)						
	1	2	3	4	mean	Std dev	CV
Cereal, Product 9	8.3	7.8	8.3	8.1	8.13	0.24	2.9
Cereal, Product 22	11.9	12.4	11.9	11.9	12.0	0.25	2.1

These results were determined from 4 replicates tested as part of the same batch.

Duplicates and certified reference materials for iron (duplicates were tested as part of the same batch)

Sample	Analysis (mg/100g)				
	1	2	mean	Std dev	CV
Batch #1					
Cereal, Product 2	6.2	5.8	6.0	0.28	4.71
Cereal, Product 3	12.6	13.9	13.25	0.92	6.94
Cereal, Product 10	16.4	17.7	17.05	0.92	5.39
Food drink 3	28.8	29.4	4.5	0.42	9.43
Dietary supplement 2	835	809	29.1	0.42	1.46
Protein product	1.3	1.3	822	18.38	2.24
Meat extract	46	45.1	1.3	0.00	0.00
Batch #2					
Bread, Product 1 Ak	9.5	10.8	10.15	0.92	9.06
Cereal, Product 9	7.5	7.3	7.4	0.14	1.91
Cereal, Product 22	14.5	13.7	14.1	0.57	4.01
Food drink 2	0.9	1	0.95	0.07	7.44
Dietary supplement 2	812	818	815	4.24	0.52
Certified reference material			**Certified value**		
CRM-NIST 1568 Batch #1	6	7	7.4 ± 0.9		
CRM-NIST 1568 Batch #2	7	6	7.4 ± 0.9		

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

Spike recovery for iron samples spiked at 10 mg/kg

Food type	% Recovery
Cereal, Product 16	84
Supplement 3	122
Cereal, Product 6, Time 1	117
Food drink 2	98
Bread, Product 1 Ch	120
Cereal, Product 6, Time 2	95

Blind duplicates for iron analyses (both samples tested as part of the same batch).

Food sample	Result 1	Result 2	mean	Std dev	CV
Cereal, Product 20	11.9	11.9	11.9	0.00	0.0
Cereal, Product 2	6.6	7.1	6.85	0.35	5.2
Cereal, Product 9	8.3	8.1	8.2	0.14	1.7
Cereal, Product 15	19.3	18	18.65	0.92	4.9
Cereal, Product 18	17.7	13.7	15.7	2.83	18.0
Food drink 2	1.2	1.2	1.2	0.00	0.0
Dietary supplement 2	828	828	828	0.00	0.0
Bread, Product 3, Ak, T2	5.3	5.7	5.5	0.28	5.1
Dietary supplement 1, T2	290	271	280.5	13.44	4.8
Cereal, Product 24	5.1	5.7	5.5	0.36	6.6

Appendix 3.2: Quality assurance data for folate

Intra-sample variability for folate

Food type	Analysis (µg/100g)						
	1	2	3	4	mean	Std dev	CV
Cereal, Product 19	400	407	570	472	462	78.8	17.0
Cereal, Product 15	450	512	700	511	543	108.4	20.0

These results were determined on 4 replicates tested as part of the same batch of samples.

Duplicate analyses for folate (duplicates tested as part of the same batch)

Sample	Analysis (µg/100g)				
	1	2	mean	Std dev	CV
Batch #2					
Cereal, Product 6	240	277	259	26.2	10.1
Batch #3					
Cereal, Product 15	646	677	662	21.9	3.3
Food drink 2	70	63	67	4.9	7.4
Food drink 3	70	60	65	7.1	10.9

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

Blind duplicates for folate analyses (both samples tested as part of the same batch).

Food sample	Result 1	Result 2	mean	Std dev	CV
Cereal, Product 19	400	570	403.5	4.95	1.2
Cereal, Product 2	240	220	230	14.1	6.1
Cereal, Product 9	250	210	230	28.3	12.3
Cereal, Product 15	450	700	543	108.4	20.0
Food drink 2	33.1	44.6	38.85	8.1	20.9
Cereal, Product 14	330	390	360	42.4	11.8
Bread, Product 2 Ch	150	160	155	7.1	4.6
Bread, Product 4, Ak	150	160	155	7.1	4.6
Cereal, Product 23	780	760,870	803[1]	58.6	7.3
Dietary supplement 2	519	625	572	75.0	13.1

1 mean of 3 results

Appendix 4: Results for individual foods

Table 1A: Iron concentration (mg/100g)

Food		Label Claim (mg/100g)	Measured (mg/100g)	stdev	%CV	Acceptable range (mg/100g)	% overage
Baby food		4.3	6.3				
			8.1				
			6.8				
	mean		7.1	0.93	13	5.2 - 8.9	64
Bread, Product 1 Ch		6	7.4				
			7.5				
			8.0				
	mean		7.6	0.32	4.2	7.0 – 8.3	27
Bread, Product 1 Ak		6	9.5				
			8.6				
			1.1				
	mean		6.4	4.64	73	-2.9 – 15.7	6
Bread, Product 1 Wn		6	6.6				
			6.5				
			14.4				
	mean		9.2	4.53	49	0.1 – 18.2	53
Bread, Product 2 Ch		4.5	4.7				
			4.8				
			4.3				
	mean		4.6	0.26	5.7	4.1 – 5.1	2
Bread, Product 2 Ak		4.5	4.4				
			4.6				
			5.0				
	mean		4.7	0.31	6.7	4.0 – 5.3	3
Bread, Product 3 Ch		4.5	4.7				
			5.3				
			4.6				
	mean		4.9	0.38	7.8	4.1 – 5.6	8
Bread, Product 3 Ak		4.5	5.2				
			5.3				
			5.2				
	mean		5.2	0.06	1.1	5.1 – 5.3	16
Cereal, Product 1		6.7	13.7				
			15.5				
			14.9				
	mean		14.7	0.92	6.2	12.9 – 16.5	119
Cereal, Product 2		6.7	6.6				
			6.6				
			6.2				
	mean		6.5	0.23	3.6	6.0 – 6.9	-3
Cereal, Product 3		10	10.9				
			14.7				
			12.6				
	mean		12.7	1.90	15	8.9 – 16.5	27

Food		Label Claim (mg/100g)	Measured (mg/100g)	stdev	%CV	Acceptable range (mg/100g)	% overage
Cereal, Product 4		6.7	14.3				
			13.5				
			13.5				
	mean		13.8	0.46	3.4	12.8 – 14.7	105
Cereal, Product 6		6.7	10.0				
			9.6				
			11.7				
	mean		10.4	1.12	11	8.2 – 12.7	56
Cereal, Product 7		6	8.5				
			6.9				
			8.0				
	mean		7.8	0.82	10	6.2 – 9.4	30
Cereal, Product 9		6.7	8.3				
			8.1				
			7.6				
	mean		8.0	0.36	4.5	7.3 – 8.7	19
Cereal, Product 10		10	16.4				
			12.2				
			12.5				
	mean		13.7	2.34	17	9.0 – 18.4	37
Cereal, Product 11		10	12.3				
			13.6				
			13.2				
	mean		13.0	0.67	5.1	11.7 – 14.4	30
Cereal, Product 12		6.7	11.3				
			11.8				
			11.5				
	mean		11.5	0.25	2.2	11.0 – 12.0	72
Cereal, Product 13		6.7	17.3				
			18.5				
			17.6				
	mean		17.8	0.62	3.5	16.6 – 19.0	166
Cereal, Product 15		10	19.3				
			16.1				
			14.7				
	mean		16.7	2.36	14	12.0 – 21.4	67
Cereal, Product 16		7.5	11.8				
			12.5				
			11.7				
	mean		12.0	0.44	3.6	11.1 – 12.9	60
Cereal, Product 17		6.7	17.7				
			18.0				
			15.0				
	mean		16.9	1.65	9.8	13.6 – 20.2	152
Cereal, Product 18		10	14.8				
			15.4				
			15.3				
	mean		15.2	0.32	2.1	14.5 – 15.8	52

Food	Label Claim (mg/100g)	Measured (mg/100g)	stdev	%CV	Acceptable range (mg/100g)	% overage
Cereal, Product 19	6.7	11.9				
		11.6				
		14.9				
mean		12.8	1.82	14	9.2 – 16.4	91
Cereal, Product 20	10	10.7				
		9.7				
		11.4				
mean		10.6	0.85	8.1	8.9 – 12.3	6
Cereal, Product 21	10	14.6				
		16.5				
		15.9				
mean		15.7	0.97	6.2	13.7 – 17.6	57
Cereal, Product 22	6.7	9.7				
		12.1				
		11.2				
mean		11.0	1.21	11	8.6 – 13.4	64
Cereal, Product 23	no claim	4.8				
		4.9				
		4.7				
mean		4.8	0.10	2.1	4.6 – 5.0	NR
Cereal Product 24	12	10.5				
		6.0				
		7.4				
mean		8.0	2.30	29	3.4 – 12.6	-34
Meat extract meat	36	45.1				
		46.0				
		47.7				
mean		46.3	1.32	2.9	43.6 – 48.9	29
Food drink 1	5.5	5.6				
		5.5				
		5.5				
mean		5.5	0.06	1.0	5.4 – 5.6	1
Food drink 2	0.9	1.2				
		1.2				
		1.1				
mean		1.2	0.06	5.0	1.1 – 1.3	30
Food drink 3	27	28.8				
		33.6				
		31.4				
mean		31.3	2.40	7.7	26.5 – 36.1	16
Protein products	0.96	1.3				
		1.1				
		1.0				
mean		1.1	0.19	17	0.7 – 1.5	18
Dietary supplement 1*	4	3.9				
		3.8				
		3.6				
mean		3.8	0.13	3.6	3.5 – 4.0	-6
Dietary supplement 2*	12	11.7				
		11.8				

Food	Label Claim (mg/100g)	Measured (mg/100g)	stdev	%CV	Acceptable range (mg/100g)	% overage
		11.6				
mean		11.7	0.08	0.7	11.5 – 11.9	-3
Dietary supplement 3*	1	2.4				
		2.6				
		2.7				
mean		2.6	0.12	4.9	2.3 – 2.8	156

NR =no result as there was no label claim for this product even though it was included in the MDF as containing a low level of iron.
1=except for those products supplied in tablet form and marked * and expressed as mg/tablet

Table 2A: Folate concentration (μg/100g)

Food		Label Claim Folate (μg/100g)	T1 (μg/100g)[1]	stdev	% CV	Acceptable range (μg/100g)[1]	% overage
Baby foods		140	50				
			170				
			70				
	mean		97	64	67	-32-225	-31
Bread, Product 2 Ak		200	120				
			150				
			140				
	mean		137	15	11	106 - 167	-32
Bread, Product 2 Ch		200	120				
			130				
			150				
	mean		133	15	11	103 - 164	-33
Bread, Product 3 Ak		200	170				
			170				
			170				
	mean		170	0	0	170 - 170	-15
Bread, Product 3 Ch		200	200				
			170				
			160				
	mean		177	21	12	13 - 218	-12
Bread, Product 4 Ak		200	150				
			140				
			130				
	mean		140	10	7	120 - 160	-30
Bread, Product 4 Ch		200	140				
			160				
			140				
	mean		147	12	8	124 - 170	-27
Cereal, Product 1		333	390				
			280				
	mean		335	78	23	179 - 491	1
Cereal, Product 2		333	240				
			240				
	mean		240	0	0	240 - 240	-28
Cereal, Product 3		333	540				
			350				
	mean		445	134	30	176 - 714	34
Cereal, Product 4		333	290				
			470				
	mean		380	127	33	125 - 635	14
Cereal, Product 5		333	240				
			280				
	mean		260	28	11	203 - 317	-22
Cereal, Product 6		333	370				
			370				
	mean		370	0	0	370 - 370	11
Cereal, Product 7		200	320				
			260				

Food		Label Claim Folate (µg/100g)	T1 (µg/100g)[1]	stdev	% CV	Acceptable range (µg/100g)[1]	% overage
	mean		290	42	15	205 - 375	45
Cereal, Product 8		333	370				
		167	330				
	mean		350	28	8	293 - 407	5
Cereal, Product 9		333	230				
			250				
	mean		240	14	6	212 - 268	-28
Cereal, Product 10		167	250				
			190				
	mean		220	42	19	135 - 305	32
Cereal, Product 11		167	410				
			510				
	mean		460	71	15	319 - 601	175
Cereal, Product 12		222	880				
			880				
	mean		880	0	0	880 - 880	296
Cereal, Product 13		222	480				
			410				
	mean		445	49	11	346 - 544	100
Cereal, Product 14		333	450				
			490				
	mean		470	28	6	413 - 527	41
Cereal, Product 15		333	450				
			270				
	mean		360	127	35	105 - 615	8
Cereal, Product 17		333	190				
			270				
	mean		230	57	25	117 - 343	-31
Cereal, Product 18		333	490				
			570				
	mean		530	57	11	417 - 643	59
Cereal, Product 19		222	400				
			1000				
	mean		700	424	61	0- 1549	215
Cereal, Product 20		167	190				
			270				
	mean		230	57	25	117 - 343	38
Cereal, Product 21		167	370				
			340				
	mean		355	21	6	313 - 397	113
Cereal, Product 23		333	330				
			490				
			630				
	mean		483	150	31	183 - 784	45
Meat extract		2000	3790				
			3420				
			2800				
	mean		3337	500	15	2336 - 4337	67
Drink 1		90.9	140				

Food		Label Claim Folate (µg/100g)	T1 (µg/100g)[1]	stdev	% CV	Acceptable range (µg/100g)[1]	% overage
			130				
			130				
	mean		133	6	4	122 - 145	47
Drink 2		35	41				
			48				
			33				
	mean		41	8	18	26 - 56	16
Drink3		40	44				
			51				
			34				
	mean		43	9	20	26 - 60	8
Drink 4		40	70				
			56				
			62				
	mean		63	7	12	48 - 77	57
Protein products		32	79				
			72				
			115				
	mean		89	23	26	43 - 135	178
Dietary supplement 1*		200	307				
			314				
			375				
	mean		332	37	11	257 - 407	66
Dietary supplement 2*		300	388				
			478				
			402				
	mean		423	49	11	325 - 520	41
Dietary supplement 3*		300	384				
			312				
			382				
	mean		359	41	11	277- 442	20
Pharmacy medicine*		800	614				
			599				
			NR				
	mean		606	11	2	585 - 627	-24

na=not applicable, ND = not detected, NR= no result
1=except for those products supplied in tablet form and marked * that are expressed as µg/tablet