

**National mandatory folic acid fortification of wheat flour for making bread
compliance survey: of flour mills producing wheat flour for making bread in
October 2010 – March 2011**

Implementation Sub Committee
Co-ordinated Food Survey Plan

Uploaded April 2012

NATIONAL MANDATORY FOLIC ACID FORTIFICATION OF WHEAT FLOUR FOR MAKING BREAD COMPLIANCE SURVEY

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1.0 SUMMARY

The '*National mandatory folic acid fortification of wheat flour for making bread compliance survey*' (folic acid fortification survey) was commissioned under the Co-ordinated Food Survey Plan (CFSP) of the Implementation Sub Committee (ISC) to assess how effectively flour mills have implemented the Quality Assurance Arrangement (QAA) as a basis for demonstrating compliance with the folic acid requirements of Standard 2.1.1 of the *Australia New Zealand Food Standards Code* (the Code). Standard 2.1.1 of the Code prescribes the level of fortification between 2 and 3mg/kg of folic acid in wheat flour for making bread.

It is noted that all Australian jurisdictions have agreed to use the QAA as the basis for assessing industry compliance with the mandatory folic acid fortification requirements in the Code.

During October 2010 to March 2011 agencies represented on ISC from WA, QLD, NSW, VIC, SA and TAS carried out the survey at 21 flour mills producing wheat flour for making bread. At each mill an 'audit' (assessment) of the mills QAA or equivalent was undertaken, using a questionnaire that incorporated the elements of a QAA as provided in the ISC '*Mandatory Folic Acid Fortification of Wheat Flour for Making Bread - Compliance and Enforcement Model*' (Compliance and Enforcement Model). To further assist in the analysis of the QAA, one sample of wheat flour for making bread was collected from each mill and submitted for folic acid analysis.

Food regulatory agencies assessed the QAA documentation and supporting evidence provided by mills, in accordance with processes described in the ISC Compliance and Enforcement Model and the survey's Risk Management Strategy. It is noted that sample test results were also considered in reviewing each mill's QAA. The variability inherent in the analytical methodology used for flour sample analysis was also taken into account. Thus, a sample returning a result for folic acid between 1.7mg/kg [2.0mg/kg less a measurement uncertainty of 14.6%] and 3.4mg/kg [3.0mg/kg plus a measurement uncertainty of 13.0%] was considered to be within the uncertainty limits of the analytical methodology used in this study.

Outcomes of the assessments confirmed that all 21 mills were able to demonstrate satisfactory implementation of the QAA as the agreed approach to compliance with the mandatory folic acid fortification requirements of the Code. The QAA system provided industry with a documented means of applying systematic control over folic acid addition processes. It also provided a means of recording folic acid added to flour and allowed for monitoring through in-house testing.

The test results, used to support review of the mill's QAA, found that folic acid was present in all wheat flour samples, with a range of <0.5 to 3.3mg/kg detected. It is noted that although five test results were outside the maximum range of uncertainty for the test method used, these mills through assessment of QAA documentation, including validation data for dosing and further analytical analysis, were able to demonstrate effective implementation of a QAA. The final outcome of this study was that all 21 mills examined were assessed to be compliant.

Through the assessment of QAA's, it is noted that practical operational matters in mills impacted on the ability to provide consistent levels of folic acid in wheat flour for bread making. It is noted that adding small quantities of folic acid to large quantities of flour in industrial conditions presents difficulties in achieving a consistent blend. This required

mills to develop in-process controls to assist in managing effective addition of folic acid to flour and to provide for traceability mechanisms.

It is further noted that regulatory action was not considered to be a component of this work. However, under the agreed approach of the QAA, such action would only be considered after having proper regard to all available evidence concerning implementation of a QAA, as the agreed approach to compliance.

2.0 BACKGROUND

For more than ten years, Australia and New Zealand have introduced a number of initiatives to increase the folic acid intake of women planning to or who may become pregnant to reduce the risk of their babies developing Neural Tube Defects (NTD). These have included health claims on food labels, education programs and voluntary folic acid fortification of foods, such as breakfast cereals and bread and encouraging women to take folic acid supplements. Despite these initiatives, most women of child-bearing age are still not consuming sufficient folic acid, particularly when planning to become pregnant. Mandatory fortification of wheat flour for making bread with folic acid was introduced to provide additional protection against NTDs. Mandatory folic acid fortification is expected to reduce the number of NTD affected pregnancies by 14 to 49 (or up to 14%) each year in Australia (FSANZ, 2009).

Bread was chosen as the appropriate food vehicle for fortification as it is consumed regularly by a large proportion of women of child-bearing age across different socio-economic sub-groups. Women of child bearing age will however still need to take a folic acid supplement to ensure that they achieve the recommended intake of folic acid. The addition of folic acid to wheat flour for bread was selected as the preferred route to add folic acid to bread.

In May 2004, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) asked Food Standards Australia New Zealand (FSANZ) to investigate mandatory fortification with folic acid as a possible means of reducing the incidence of NTD.

In December 2004, FSANZ sought advice from the Food Regulation Standing Committee (FRSC) on whether mandatory fortification was the most effective public health strategy as FSANZ believed that this issue was more appropriately addressed by FRSC and the Ministerial Council. This issue was considered by the Ministerial Council who sought advice from the Australian Health Ministers' Advisory Council (AHMAC).

In October 2005, FSANZ was asked to progress mandatory fortification with folic acid as a matter of priority, taking into account safety and cost effectiveness. Under *Standard 2.1.1 – Cereals and Cereal Products* of the Australia New Zealand Food Standards Code (Code) Australian manufacturers were already adding thiamin to flour used for making bread. Subsequently FSANZ developed a standard for the mandatory folic acid fortification of wheat flour for making bread by amending Standard 2.1.1 of the Code. The Ministerial Council then approved the proposed amendment to the Code which was gazetted on 13 September 2007 and included an implementation date of 13 September 2009.

In Australia, Standard 2.1.1 of the Code requires all wheat flour for making bread to be fortified with folic acid, with the exception of flour represented as 'organic'. The level of fortification required is between 2 and 3 milligrams of folic acid per kilogram of wheat flour for bread making.

In New Zealand the fortification standard is voluntary and applies to bread. It is noted that mandatory fortification of bread will be enacted in New Zealand on 31 May 2012.

Currently, state and territory food regulatory agencies are responsible for assessing compliance with the Code within Australia and the Ministry of Agriculture and Forestry carry out the same function in New Zealand. To assist food regulatory agencies and industry in Australia with compliance issues related to the mandatory folic acid fortification

standard in the Code, the FRSC ISC developed the '*Mandatory Folic Acid Fortification of Wheat Flour for Making Bread - Compliance and Enforcement Model*' (Model) (see Appendix 1). The Model was developed on a national basis in consultation with industry and has been endorsed by FRSC and ISC and noted by Ministerial Council.

The Model is based on mills incorporating a systems based approach to compliance, through implementation of a quality assurance arrangement (QAA) into their business. Monitoring arrangements (e.g. internal and external audit) may then be applied to demonstrate that the QAA is in place and is achieving the stated outcomes. All Jurisdictions in Australia have agreed to use the Model to demonstrate compliance with the requirements for mandatory folic acid fortification in the Code.

The folic acid fortification survey was commissioned under ISC Co-ordinated Food Survey Plan (CFSP). WA Health was the lead agency for the development and co-ordination of the survey with FSANZ, QLD and the Commonwealth Department of Health and Ageing represented on the working group. Assistance with finalising the survey proposal was also provided by the Flour Technical Advisory Group, Food Surveillance Network and ISC/Industry Folic Acid Working Group.

It is noted that the intent of the survey is a preliminary fact gathering exercise on the QAA as an approach to compliance and not a formal food regulatory activity. Therefore enforcement was not contemplated by the design of the survey. Due to the inherent differences between flour mills and variability in approaches to dosing, testing methods available, testing accuracy, accuracy limitations and sample homogeneity, the Model recognises that there is potential for analysed samples to be outside the required fortification range on occasions. Therefore, sample results will be considered in conjunction with other information available at the mill (e.g. a review of the flour mills' QAA documentation along with appropriate sampling and analysis protocols), to assess whether a business's QAA as an approach to compliance, may be considered compliant with the folic acid fortification standard in the Code.

3.0 OBJECTIVES

The objectives of this survey were to –

- Assess the effectiveness of the QAA as an approach to compliance with the folic acid fortification standard in the Code by conducting a survey questionnaire of flour mills QAA documentation or equivalent arrangement, including reconciliation and sampling and analysis protocols for wheat flour used for making bread.
- Assess the level of folic acid fortification in wheat flour for making bread at flour mills (with the exception of flour represented as organic), by conducting sample collection and analyses to determine whether test results fall within the variability range established by the mills as part of their QAA.
- Identify practical operational matters impacting on flour mills ability to comply with the limits contained in the mandatory folic acid fortification standard provided in the Code.
- Review the QAA for its effectiveness as an approach to compliance with the mandatory folic acid fortification standard.

4.0 METHOD

All states and territories used their own resources to –

- Conduct an assessment of flour mills QAA documentation or equivalent arrangement, including sampling and analysis protocols and available records for wheat flour used for making bread.
- Collect and analyse one sample of wheat flour for making bread from flour mills producing wheat flour for making bread.
- Assess the outcomes of the review of documented evidence of each mill's QAA in conjunction with the sample test result.

4.1 QAA assessment

Each food regulatory agency conducted an assessment of the flour mills QAA system or equivalent arrangement to review the mills folic acid addition system. A questionnaire (see Appendix 2) was used to assist in providing regulatory agencies with consistency in approach. The questionnaire was based on the elements of the Compliance and Enforcement Model and required millers to produce documented evidence and monitoring records of their QAA for review.

Information gathered was used to assess whether industry had successfully incorporated a QAA that included all elements in the ISC Compliance and Enforcement Model into their business, and whether sufficient procedures and records were available to demonstrate that the requirements of the mills QAA were being achieved. The elements required to be incorporated into a QAA include –

- Sampling protocols including sampling point and frequency, the target folic acid level that the mill is aiming to achieve and the range of variance that is likely to occur from the target level. Variation is expected to occur, however the potential variance needs to be known and controlled.
- Verification processes including reconciliation of the folic acid addition system, this would include monitoring of depletion of folic acid stocks with respect to quantity of flour processed by a mill;
- Audit arrangement to demonstrate the QAA is in place and achieving the stated outcomes. Adherence to the QAA assessed through either third party or alternative audit arrangements, is an acceptable means of demonstrating achievement of compliance with the mandatory folic acid fortification Standard.

4.2 Sample collection & analysis

4.2.1 Sample collection

The food regulatory agency with the assistance of the flour mill collected 5 sub-samples of wheat flour for making bread for analysis (excluding organic wheat flour and wheat flour intended for export). Each sub-sample was a minimum of 500g in weight and was drawn from product representative of the final stage of mill production prior to storage. The location of sub-samples was established in consultation with the mill. These sub-samples were combined to make a composite sample which was then divided into two equal halves, with one half retained by the mill and the other half submitted for analysis of folic acid content.

The following information was recorded at each flour mill when a sample was taken –

- Date of sampling
- Premises name & address
- Product name
- Brand
- Batch code
- Best-before / use-by date
- Sub-sample number & collection location
- Weight of each sub-sample
- Weight of composite sample
- Weight of sample for analysis
- Weight of sample to be held by the mill

4.2.2 Analysis

All analyses were carried out by Advanced Analytical Australia Pty Ltd located in NSW which undertakes proficiency testing and is NATA accredited for folic acid analysis. A single laboratory that met the requirements of this survey was chosen to reduce the variability of test results by different laboratory methods.

Analysis by Liquid Chromatography-Mass Spectrometry and Liquid Chromatography-Tandem Mass Spectrometry (LC-MS-MS) was chosen to measure folic acid concentration in flour samples. This method is ISO/IEC 17025 quality system accredited for wheat flour, biscuits and breads. The method involves quantitative determination of folic acid in wheat and wheat products using extraction with 75mM Ammonium Acetate (~pH 7.0) for LCMSMS analysis. Separation of folic acid is performed on C-18 column and detected by mass selective detector on LCMSMS using positive electrospray ionization and monitored for two Multiple Reaction Monitoring (MRM) transitions. For accurate quantification, Folic acid-*d4* is used as internal standard. For each batch of analysis a method blank, duplicate for every 10 samples, spike for every twenty samples and at least 3 point calibration are performed. The standards are prepared in the most appropriate matrix similar to that of samples.

The method detection limit (LOD) is 0.1mg/kg and limit of reporting (LOR), also known as practical quantitation limit (PQL) is 0.5mg/kg. The maximum measurement uncertainty at 0.5mg/kg is $0.5 \pm 0.19\text{mg/kg}$ at 2.0mg/kg is $2.0 \pm 0.29\text{mg/kg}$ and at 3.0mg/kg is $3.0 \pm 0.39\text{mg/kg}$. The matrix spike recovery is in between 90-120% and duplicates read within 20% relative percentage difference for the mean of the two results.

The analyst was asked to include in their report a value for the uncertainty inherent in the method of analysis that was used. This measurement of uncertainty, determined in accordance with NATA guidelines², was reported to be 14.6% for 2.0mg/kg

(+/- 0.29mg/kg) and 13.0% for 3.0mg/kg (+/- 0.39mg/kg). Therefore the maximum measurement uncertainty range provided by the analyst for the test method used was between 1.7 and 3.4mg/kg.

4.3 Assessment of results

To ensure consistency across the 21 mills reviewed in this study all food regulatory agencies agreed to utilise the Compliance and Enforcement Model and the survey proposal's Risk Management Strategy in considering results. The information gathered from the assessments using the questionnaire was reviewed in conjunction with the sampling results to establish whether industry had implemented a QAA into their business, and whether sufficient procedures and records were available to demonstrate that the requirements of the mills QAA were being achieved.

Food regulatory agencies further considered all test results from flour samples in reviewing QAA's. Noting the range of uncertainty provided by the testing laboratory for the analytical work, this equated to results within the range 1.7mg/kg [2.0mg/kg less uncertainty of 14.6%] and 3.4mg/kg [3.0mg/kg plus uncertainty of 13.0%] being considered within the 2 to 3mg/kg requirement of the Code.

4.4 When results of analysis were outside the range allowing for the measurement uncertainty

Where test results were outside the 1.7 to 3.4mg/kg range further validating evidence was sought from flour mills taking into account the following –

- Analytical results are only one component of a mill's QAA. Results need to be considered with other evidence supplied by the miller concerning aspects of the QAA (e.g. dosing regime, evidence of dosing rates, sampling protocols and records, analytical reports and any other evidence) to properly assess a mill's QAA.
- Results of samples should be considered in conjunction with the mill's specified target folic acid level and potential variance levels which are specified in the mills QAA. It is known that variation will occur, however the potential variance should be specified and controlled. Therefore, documents relating to the procedures in place to monitor, control and correct variation, should be examined along with records of any internal or external audits.
- Identification of practical operational issues within mills that may impact on a miller's ability to consistently meet the prescriptive limits for folic acid provided in the Code (e.g. processes for flour mixing).
- Results of follow-up tests if required.

After additional evidence was sought from flour mills, theoretically, should the food regulatory agency not be satisfied that a QAA had been appropriately implemented, regulatory action may be considered. It is noted in this study that all mills were shown to have successfully implemented QAA's. However should action be required, it is noted that all available evidence would be reviewed before action is undertaken. Any action taken should occur in accordance with the Australia and New Zealand Food Regulation Enforcement Guideline.

5.0 RESULTS

The results from the 21 mills surveyed in this study are shown in Table 1. Table 1 displays results from the questionnaire as well as analytical work undertaken, in assessing whether mills had implemented appropriate QAA's.

Table 1: Summary of Results

Column I.D	A	B	C	D	E
Flour mill & Sample I.D	QAA or equivalent in place, incorporating folic acid addition system	Folic acid test result (mg/kg)	Folic acid level within 2 to 3mg/kg range and within the measurement uncertainty range 1.7 to 3.4mg/kg	Outside the range and not within the measurement uncertainty range; Additional evidence sought from the flour mill including follow-up tests if required	Compliance with the folic acid fortification standard in the Code
1	✓	3.3	✓		✓
2	✓	3.1	✓		✓
3	✓	3.1	✓		✓
4	✓	2.9	✓		✓
5	✓	2.9	✓		✓
6	✓	2.7	✓		✓
7	✓	2.7	✓		✓
8	✓	2.2	✓		✓
9	✓	2.2	✓		✓
10	✓	2.2	✓		✓
11	✓	2.1	✓		✓
12	✓	1.9	✓		✓
13	✓	1.9	✓		✓
14	✓	1.8	✓		✓
15	✓	1.7	✓		✓
16	✓	1.7	✓		✓
17	✓	1.2		✓	✓
18	✓	1.2		✓	✓
19	✓	0.9		✓	✓
20	✓	0.6		✓	✓
21	✓	<0.5		✓	✓

Column A of table 1 shows that all flour mills surveyed had a QAA or equivalent in place which incorporated a folic acid addition system.

Column B provides the 21 folic acid test results in descending order. The test results ranged from <0.5 to 3.3mg/kg folic acid which indicated that folic acid was present in all samples analysed.

Column C shows that 16 of the 21 test results were assessed to be within the uncertainty range of 1.7 to 3.4mg/kg for the analytical method used in this study. Due to this inherent uncertainty, these 16 test results were considered to be within the 2 to 3mg/kg range prescribed in the Code and consistent with the testing laboratory's proficiency testing program.

Column D shows five test results were assessed to be outside the measurement uncertainty range of 1.7 to 3.4mg/kg. In accordance with the Compliance and Enforcement Model and the survey's Risk Management Strategy, additional evidence was sought from each of these mills to allow an informed decision to be made on each mill's QAA. This evidence included an assessment the mill's documented folic acid dosing regime as well as a review of sampling protocols and records, analytical reports and any other evidence to support the requirements of the mills QAA. Further sampling was also conducted where required.

Column E shows that following review of additional evidence provided by the 5 mills whose analytical results were outside the limits of uncertainty that all 21 mills were shown to have implemented appropriate QAA's and may therefore be considered to meet the folic acid fortification requirements in the Code. This was established through the assessment of the mills QAA, supported by the sample test results. It was confirmed that the mills were able to incorporate a systems based approach to compliance with the folic acid requirements of the Code and that QAA documents and monitoring records provided by mills were able to demonstrate that the requirements of the mill's QAA were being achieved.

6.0 DISCUSSION

The assessment of QAA documentation and evidence gathered from the mills in conjunction with the consideration of sample test results and the variability of the test method used for the survey, found that millers were able to incorporate a systems based approach to compliance with the folic acid requirements of the Code, and that QAA documents and monitoring records provided by the mill were able to demonstrate that the requirements of the mill's QAA were being achieved.

An 'auditing' approach to the mills QAA was found to be an effective method of assessing compliance, particularly as each mill differed in their methods of management, fortification processes and techniques, and size of production. Although each mill is inherently different, 'auditing' of industry's QAA allows an outcomes based approach to be applied to assessments of compliance, whilst providing millers with the flexibility to maintain their own business.

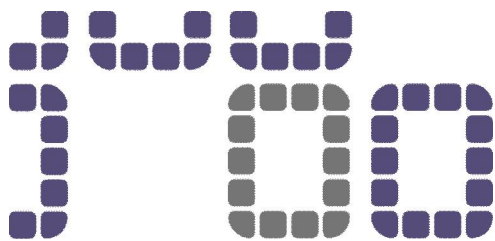
It should be noted that this survey will be different to ongoing compliance activities that may be instituted by ISC or by individual food regulatory agencies. The principle intent of this survey was to evaluate the effectiveness of the QAA as an approach to compliance. Based on the preliminary data reviewed in this study, it may be stated that this work has allowed this to be shown. In considering any further work (whether by ISC or by a food regulator), there may need to be an agreed method of identifying non-compliances, applying corrective actions and where necessary developing a process to allow escalation to formal regulatory

action, if required. For example, development of a consistent approach for responding to multiple failures to meet the analytical limits provided in the Code (where such results are consistently falling outside the known limits of uncertainty) may be necessary as part of the design of future survey work in this area.

It may be also be useful to consider the development of comprehensive guidelines for food regulatory agencies to apply in the event that multiple non-conformances are detected in a businesses QAA.

7.0 REFERENCES

1. Food Standards Australia New Zealand. (2009). *Australian User Guide Mandatory Folic Acid Fortification*. Retrieved March 27, 2010 from:
http://www.foodstandards.gov.au/_srcfiles/Mandatory%20Folic%20Acid%20Fortification%20User%20Guide%20final.pdf#search=%22users%20guide%20folic%20acid%20
[2](http://www.foodstandards.gov.au/_srcfiles/Mandatory%20Folic%20Acid%20Fortification%20User%20Guide%20final.pdf#search=%22users%20guide%20folic%20acid%20)
2. National Association of Testing Authorities (2009) *NATA Technical Note 33: Guidelines for estimating and reporting measurement uncertainty of chemical test results*. Retrieved 19 May 2011 from:
http://www.nata.asn.au/phocadownload/publications/Technical_publications/Technote_s_Infopapers/technical_note_33.pdf.



FOOD UNIT NOTICE

SUBJECT: MANDATORY FOLIC ACID FORTIFICATION OF WHEAT FLOUR FOR BREAD MAKING - STANDARD 2.2.1 – CEREALS AND CEREAL PRODUCTS – COMPLIANCE AND ENFORCEMENT MODEL

Notice Number: 09.03

Date of Issue: 05/03/2009

Distribution of Notice:

Flour Milling Industry

Purpose:

This Notice is to advise the flour milling industry of the implementation requirements of Standard 2.1.1 – Cereals and Cereal Products, in relation to the mandatory fortification of wheat flour for bread making with folic acid.

Actions:

Food businesses involved in the production of wheat flour bread making are required to comply with the Standard effective from 13 September 2009.

The Standard requires that all wheat flour for bread making with the exception of flour represented as 'organic' must be fortified with folic acid from 13 September 2009. The level of fortification required is between 2 and 3 milligrams of folic acid per kilogram of wheat flour.

Background:

In May 2004, the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) asked Food Standards Australia New Zealand (FSANZ) to investigate mandatory fortification with folic acid as a possible means of reducing the incidence of Neural Tube Defects.

In December 2004, FSANZ sought advice from the Food Regulation Standing Committee (FRSC) on whether mandatory fortification is the most effective public health strategy as FSANZ considered that this issue was more appropriately addressed by FRSC and the Ministerial Council. This issue was considered by the Ministerial Council who sought advice from the Australian Health Ministers' Advisory Council (AHMAC).

In October 2005, FSANZ was asked to progress mandatory fortification with folic acid as a matter of priority, taking into account safety and cost effectiveness.



Subsequently Food Standards Australia New Zealand developed a standard for the mandatory folic acid fortification of wheat flour for bread making by amending *Standard 2.1.1 – Cereals and Cereal Products* of the Australia New Zealand Food Standards Code (Code). Ministerial Council then approved the proposed amendment to the Code which was made on 13 September 2007 and included an implementation date of 13 September 2009.

To assist industry with compliance and enforcement issues related to the mandatory folic acid fortification of wheat flour for bread making provisions contained in *Standard 2.1.1 – Cereals and Cereal Products*, the Implementation Sub Committee (ISC) of the Food Regulation Standing Committee (FRSC) developed the *Mandatory Folic Acid Fortification of Wheat Flour for Making Bread Compliance and Enforcement Model* (Model). The Model was developed on a national basis in consultation with industry and has been endorsed by ISC and FRSC and noted by Ministerial Council.

A copy of the Model is attached for your information. All Jurisdictions in Australia, including Western Australia, have agreed to use the Model and the Model will be used for the compliance and enforcement of the mandatory folic acid fortification of wheat flour for bread making provision contained in *Standard 2.1.1 – Cereals and Cereal Products* in Western Australia.

Useful Resources and Websites:

- Department of Health WA www.public.health.wa.gov.au
- Food Standards Australia New Zealand <http://www.foodstandards.gov.au>
- Food Regulation Secretariat <http://www.health.gov.au>

Contact the Food Unit:

Any feedback or concerns please utilise the “Food Unit Query” form which can be downloaded from our website:

http://www.public.health.wa.gov.au/2/786/3/food_informatio.pm

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Note: The information contained in this document covers the food legislation requirements for Western Australia. It is current on the date of publication but may change without notice. The Department of Health is not liable for any costs arising from or associated with decisions based on information here and users should obtain expert advice to satisfy all requirements of the relevant food legislation applicable.

Attachment to Food Unit Notice 09.03

Mandatory Folic Acid Fortification of Wheat Flour for Making Bread Compliance and Enforcement Model

The Standard

Standard 2.1.1 – Cereals and Cereal Products requires that all wheat flour used for making bread, with the exception of flour represented as 'organic', must be fortified with folic acid from 13 September 2009. The level of fortification required is between 2 and 3 milligrams of folic acid per kilogram of wheat flour.

Compliance Model Principles

- Industry is required to incorporate into a quality assurance arrangement (QAA) certain components designed to control compliance with the mandatory folic acid fortification Standard. The QAA is expected to contain key aspects including:
 - sampling protocols – including sampling point and frequency, sampling and analysis protocols and target level and variance;
 - verification processes; and
 - audit arrangement to demonstrate the QAA is in place and achieving the stated outcomes.
- A QAA needs to specify the target folic acid level a process is aiming to achieve and the range of variance that is likely to occur from the target level. Variation will occur; however the potential variance needs to be known and controlled.
- Enforcement agencies agree that adherence to the QAA, assessed through either third party or alternative audit arrangements, is an acceptable means of demonstrating achievement of compliance with the mandatory folic acid fortification Standard.
- The implementation and successful auditing of a QAA will not however, preclude enforcement agencies from taking appropriate samples for analysis at any time should a need arise to take such action; however it recommended that such samples be based on a composite that is representative of a 'lot'.

- Compliance will be monitored in late 2010 through the ISC Coordinated Survey Plan, which will include an assessment of mills' QAA documentation, and appropriate sampling and analysis protocols for flour used for making bread.

Note: Guidance on appropriate sampling and analysis protocols, including representative sampling, will be provided in the Mandatory Folic Acid Fortification Industry User Guide.

Enforcement Model Principles

- Enforcement may be triggered when millers cannot show adherence to their QAA compliance scheme. Additional evidence would be required to show that non-conforming product was being produced.
- The implementation and successful auditing of a QAA will not preclude enforcement agencies from taking a sample for analysis at any time.
- Enforcement agencies should ensure any samples taken at a mill are reflective of product being produced and should include a composite sample that is representative of a 'lot' and should account for laboratory and analytical variability.
- Results of samples taken by enforcement agencies should be considered in conjunction with information available at the mill that demonstrates the correct amount of folic acid is being added e.g. by examining sampling records and processes and evidence the required range was being achieved to the appropriate level.
- A follow-up test may be required. If the second test returns a non-compliant result, legal action may be considered having regard to any information held at the mill that demonstrates compliance and due diligence.

Appendix 2

National Mandatory Folic Acid Fortification of Wheat Flour for Making Bread Compliance Survey

Questionnaire

Enforcement Agency	Flour Mill
Department:	Company:
Officer Name:	Address:
	Contact Name:
	Contact No:

Please tick ☒ the appropriate box

Survey Date:

1. Is there a documented Quality Assurance Arrangement (QAA) or equivalent arrangement in place?

☐ Yes ☐ No

QAA Components:

For the following questions all documents or records should be sighted to confirm compliance has been demonstrated -

Folic Acid Addition System (Validation)

2. Are there records (e.g. Certificate of analysis - CoA or testing results) defining the purity of the folic acid or its proportion in the premix?

3. Has the required addition rate been determined? (e.g. 2 to 3 mg/kg of folic acid to wheat flour for making bread) ☐ Yes ☐ No

4. Are there records to demonstrate that correct pre-mix calculations are recorded (e.g. 2 to 3 mg/kg of folic acid to wheat flour for making bread)? ☐ Yes ☐ No

5. Are there records to demonstrate that defined addition formulas are recorded (e.g. 2 to 3 mg/kg of folic acid to wheat flour for making bread)? ☐ Yes ☐ No

6. Are there records to demonstrate that the feeder is set at the appropriate rate to deliver folic acid within the defined range? ☐ Yes ☐ No

7. Are there records to demonstrate that the feeder has been calibrated? ☐ Yes ☐ No

8. Is the potency of the resultant mix validated as being within the desired range? (either by CoA or testing) ☐ Yes ☐ No

9. What is the expected range of variance likely to occur from the target folic acid level set for the premix?

Reconciliation (Verification of Folic Acid Addition System)

10. Are there records to demonstrate that reconciliation is performed on the quantity of pre-mix added in relation to wheat flour for making bread? ☐ Yes ☐ No

11. Are there records to show that reconciliation is performed at an appropriate time to demonstrate that the correct amount of pre-mix has been added? (e.g. at the end of each shift, day, week)
☐ Yes ☐ No

12. Are there QAA documents and records to represent that utilisation of premix used against wheat flour for making bread produced over a period of time will provide a practical measure of rate of addition? ☐ Yes ☐ No

13. Are there QAA documents and records to represent that average rates of folic acid added to wheat flour for making bread are calculated on a regular basis and are reconciled against the range permitted in the Standard? ☐ Yes ☐ No

Sampling & Analysis (as required)

14. Are there records to demonstrate that appropriate sampling and laboratory analysis is conducted to demonstrate that the QAA system is producing wheat flour for making bread that contains the required levels of folic acid? ☐ Yes ☐ No

15. Are there records to demonstrate that samples are drawn from a point that is a fair representation of the wheat flour for making bread that is to be dispatched? (e.g. final point of production as produced by the mill, N.B. flour samples should NOT be removed from storage for this analysis) ☐ Yes ☐ No

16. Is the sample method –

- ☐ A single 'grab sample'
- ☐ A sample representative of 'a lot' (e.g. composite sample made up of a number of sub-samples)

17. For a lot sample – are there records to demonstrate that sub-samples are taken from a representative point or points in the milling process?

- ☐ Yes
- ☐ No
- ☐ Not applicable

18. For a lot sample - are there records to demonstrate that at least five sub-samples taken, each >500g over the course of the run?

- ☐ Yes
- ☐ No
- ☐ Alternative method (please specify)

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19. Is a matching sample usually retained by the mill? ☐ Yes ☐ No

20. Are there records to demonstrate that the frequency of sampling is appropriate? ☐ Yes ☐ No

21. Are there records to demonstrate the analytical laboratory is proficient in conducting tests for the presence and level of folic acid in wheat flour for making bread? (i.e. is the laboratory NATA accredited for folic acid analysis?) ☐ Yes ☐ No

22. Are the uncertainty measurements associated with the analytical technique used to measure folic acid concentration in wheat flour for making bread known to the laboratory and the miller?
☐ Yes ☐ No

23. Are there records to demonstrate that the test method has been validated? If so, what uncertainty measurements apply to the validated test method? ☐ Yes ☐ No

Corrective and Preventative Action

24. Is there a documented system in place for corrective action if verification procedures confirm a product is potentially out-of-specification (e.g. what does the mill do if premix is out of specification?) ☐ Yes ☐ No

Monitoring Arrangements (e.g. audit)

25. Are there records to show that the QAA or equivalent arrangement is assessed through a third party or alternative monitoring arrangement (e.g. audit)? ☐ Yes ☐ No