

Mandatory folic acid fortification of wheat flour for bread making

National compliance survey of flour mills producing wheat flour for bread making (August 2017 - March 2018)

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Summary

Standard 2.1.1 - Cereal and cereal products, in the *Australia New Zealand Food Standards Code* (the Code), requires all wheat flour for bread making to be fortified with between 2 and 3 mg of folic acid per kg of wheat flour, apart from flour represented as 'organic'.

To assist enforcement agencies and industry with compliance and enforcement issues related to the mandatory folic acid fortification provisions contained in Standard 2.1.1, the Implementation Subcommittee for Food Regulation (ISFR) developed the *Mandatory Fortification Compliance and Enforcement Model* (the Model). Because of inherent difficulty in achieving a consistent blend when adding small quantities of folic acid to large quantities of flour in industrial conditions, the Model recognises that folic acid concentration alone should not be used to determine how a mill operator is managing compliance with provisions of Standard 2.1.1. The Model requires mills to implement a quality assurance arrangement (QAA) which contains elements to control, verify and validate folic acid concentrations in wheat flour for bread making.

This survey has been undertaken as part of ISFR's 2016-19 Coordinated Food Survey Plan which was endorsed at ISFR7 in August 2017. The objective of this survey was to assess compliance of Australian flour mills with Standard 2.1.1. This was done by testing the folic acid concentration in a sample of wheat flour for bread making taken at a mill and by assessing whether a mill's QAA effectively managed folic acid concentrations in bread flour.

Five Australian jurisdictions, Queensland, South Australia, Tasmania, Victoria and Western Australia, participated in this survey which investigated twelve mills. Results showed that folic acid concentrations in wheat flour for bread making ranged between <1.0 and 4.3 mg/kg. After consideration of the QAA at each mill, only one mill was considered as non-compliant with Standard 2.1.1. The folic acid concentration in the flour sample from this mill was <1.0 mg/kg, and unlike the other eleven mills, this mill was not independently audited.

The current survey was a follow up of the ISFR *National Mandatory Folic Acid Fortification of Wheat Flour for Making Bread Compliance Survey* (October 2010 - March 2011), which used the same methodology as the current survey. Results showed that all 21 mills assessed in 2010-2011 complied with the provisions of Standard 2.1.1.

Both surveys were point in time snapshots of folic acid levels in bread flour. The high level of compliance with Standard 2.1.1 in both surveys is evidence that Australian flour mills are successfully implementing in-process controls to achieve prescribed concentrations of folic acid in wheat flour for bread making.

1. Background

Australia and New Zealand have introduced several initiatives to increase the folic acid intake of women planning to or who may become pregnant to reduce the risk of Neural Tube Defects (NTDs) in their babies. These have included health claims on food labels, education programs, voluntary folic acid fortification of foods such as breakfast cereals and bread, and encouraging women to take folic acid supplements.

Mandatory folic acid fortification of bread making flour was introduced in Australia in 2009 to provide additional protection against NTDs. 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 demographics. The addition of folic acid to wheat flour for bread making was selected as the preferred route to add folic acid to bread because flour mills were already mandatorily fortifying bread flour with thiamin. Consequently, Standard 2.1.1 - Cereal and cereal products in the *Australia New Zealand Food Standards Code* (the Code) was amended to require that all bread flour, apart from flour represented as 'organic,' must be fortified with folic acid. The level of fortification required is between 2 and 3 mg of folic acid per kg of wheat flour (i.e. 200-300 µg folic acid per 100g of wheat flour).

In New Zealand the fortification standard is voluntary and applies to 'bread', which must contain no more than 2.5 mg/kg of folic acid. An industry Code of Practice has been developed which outlines industry's commitment to fortify between 25% and 50% of breads (by volume) with a target level of 2.0 mg of folic acid per kg of bread. New Zealand industry and enforcement agencies preferred a fortification standard for bread rather than flour because New Zealand, unlike Australia, does not have a history of mandatory thiamin fortification and therefore does not have existing infrastructure for mandatory fortification of wheat flour.

The 2016 Australian Institute of Health and Welfare report identified that mandatory folic acid fortification in Australia resulted in an increase of folic acid in bread from 20-29 µg/100g to 134-200 µg/kg. Folic acid intakes of women of childbearing age increased from 102 µg/day to 247 µg/day. There was a statistically significant (14.4%) decrease in the rate of NTDs.

State and territory enforcement agencies are responsible for assessing compliance with the Code. To assist enforcement agencies and industry with compliance and enforcement issues related to the mandatory folic acid fortification provisions contained in Standard 2.1.1, the Implementation Sub Committee for Food Regulation (ISFR) developed the *Mandatory Folic Acid Fortification of Wheat Flour for Making Bread - Compliance and Enforcement Model* (March 2009). It was developed on a national basis in consultation with industry and was endorsed by the Food Regulation Standing Committee (FRSC) and noted by the Australia and New Zealand Ministerial Forum on Food Regulation. ISFR has since expanded the scope of the original model to become a broad base for the implementation of all future mandatory fortification standards including iodine. Reflecting the change in scope, the original model has been renamed the *Mandatory Fortification Compliance and Enforcement Model* (the Model).

There is inherent difficulty in achieving a consistent blend when adding small quantities of folic acid to large quantities of flour in industrial conditions. Consequently, the Model recognises that there is potential for analysed samples to be outside the required fortification range on occasions, and that folic acid concentration alone should not be used to determine how a mill operator is managing compliance with Standard 2.1.1. The Model requires mills to incorporate

into their quality assurance arrangements (QAA) elements which are designed to control compliance with mandatory folic acid fortification, including sampling and analysis protocols. The QAA should be audited to demonstrate that the QAA is in place and achieving stated outcomes. All Australian jurisdictions agreed to use the Model for compliance and enforcement of the mandatory folic acid fortification of wheat flour for bread making provision contained in the Code.

Between October 2010 and March 2011, the *National Mandatory Folic Acid Fortification of Wheat Flour for Making Bread Compliance Survey*, commissioned by ISFR, was undertaken. This survey assessed the effectiveness of QAAs implemented by flour mills in achieving compliance with Standard 2.1.1. Wheat flour produced by eleven, of 21 mills surveyed, contained between 2 and 3 mg of folic acid per kg of flour. Five other mills produced flour which contained folic acid levels within the measurement of uncertainty (MOU) range of the test method (i.e. between 1.7 to 3.4 mg/kg). The remaining five mills produced flour containing between <0.5 and 1.2 mg/kg of folic acid. Although below the mandatory folic acid limit, these mills were considered compliant with Standard 2.1.1, following further assessment of their QAA documentation.

The current survey is a follow up of the 2010/2011 survey. It is being undertaken as part of the ISFR 2016-19 Coordinated Food Survey Plan endorsed at ISFR7 (August 2017).

2. Objective

The objective of this survey was to assess compliance of Australian flour mills with Standard 2.1.1 by testing the folic acid concentration in a sample of wheat flour for bread making taken at a mill, and assessing whether the mill's QAA incorporated the necessary controls to deliver prescribed folic acid concentrations.

3. Methodology

3.1 Overview

Five Australian jurisdictions, Queensland, South Australia, Tasmania, Victoria and Western Australia, participated in the survey (Appendix 1). A total of twelve mills were surveyed across jurisdictions. Only flour mills producing wheat flour for bread making were included in the survey. Each jurisdiction collected one sample of wheat flour for bread making from a flour mill during production and arranged for the sample to be tested for folic acid concentration at a NATA accredited laboratory. Each jurisdiction also assessed the mill's QAA (or equivalent) using a pre-agreed questionnaire.

3.2 Sample collection and folic acid analysis

Three subsamples of wheat flour for bread making, weighing at least 500 g, which were representative of the final flour produced by the mill prior to storage, were collected from each mill during production. The sampling point(s) was established in consultation with the mill operator. Subsamples were combined and mixed to make a composite sample, which was

then divided into two parts. One part was submitted to a laboratory for analysis for folic acid concentration; the other part was given to the mill as a retention sample.

Provided the laboratory participated in a proficiency test program for folic acid analysis and was NATA accredited for this test, the choice of testing laboratory was at a jurisdiction's discretion. The laboratory was requested to provide a measurement of uncertainty for the test method, determined in accordance with NATA guidelines, with results on the Certificate of Analysis.

Each mill was provided with folic acid results in the flour it produced.

3.3 Questionnaire

Each jurisdiction assessed a flour mill's QAA using the questionnaire provided in Appendix 2. The questionnaire was based on the Model and included questions about folic acid addition, procedures used to verify folic acid concentrations in flour, corrective actions undertaken when incorrect concentrations of folic acid in flour were found, and audit arrangements. The assessment required the mill operator to produce documented procedures and monitoring records for review.

3.4 Risk management strategy

To ensure consistency in enforcement action between jurisdictions when samples of flour were found to contain noncompliant concentrations of folic acid, a risk management strategy was developed for the project. This strategy involved adjusting the upper and lower prescribed limits for folic acid concentration (2 mg/kg and 3 mg/kg respectively) using the MOU associated with the test method, as follows:

$$\text{Adjusted lower limit (mg/kg)} = 2 \text{ mg/kg (lower prescribed limit)} - (2 \text{ mg/kg} \times \text{MOU} \%)$$

$$\text{Adjusted upper limit (mg/kg)} = 3 \text{ mg/kg (upper prescribed limit)} + (3 \text{ mg/kg} \times \text{MOU} \%)$$

For example, using mill 1 with an MOU of 20% associated with the test method:

$$\text{Adjusted lower limit (mg/kg)} = 2 \text{ mg/kg} - (2 \text{ mg/kg} \times 20/100) = 2 - 0.4 = 1.6$$

$$\text{Adjusted upper limit (mg/kg)} = 3 \text{ mg/kg} + (3 \text{ mg/kg} \times 20/100) = 3 + 0.6 = 3.6$$

If the result fell within the adjusted range, the sample was considered compliant with Standard 2.1.1. If the test result was outside this adjusted range, additional evidence would be sought from the mill to determine the reason for the non-compliance. If necessary, follow-up tests for folic acid concentration would be undertaken. Regulatory action would be considered if the mill did not have an appropriate QAA or had not appropriately implemented it.

4. Results

Folic acid concentrations ranged between <1.0 and 4.3 mg/kg (Table 1) in the twelve samples of wheat flour for bread making tested. Eight mills produced bread flour with folic acid concentrations between 2 and 3 mg/kg. A further three mills produced flour with compliant folic acid concentrations, after adjusting upper and lower prescribed limits for folic acid concentration using the MOU associated with the test method. Three analytical laboratories undertook testing for folic acid in this survey, with each reporting a different MOU associated

with their results (Table 1). Two samples of different types of flour were submitted for analysis by mill 1. Although one sample had a folic acid concentration of 4.3 mg/kg, the other contained 2.6 mg/kg. Consequently mill 1 was considered to produce flour compliant with Standard 2.1.1.

Mill 12 produced flour containing <1.0 mg/kg of folic acid. According to the questionnaire, this mill had implemented procedures for verification of the folic acid delivery system, including sampling, and for taking corrective action when folic acid concentrations are out of specification (Table 1). However, this mill was the only mill, of the twelve surveyed, which was not independently audited. The relevant regulatory agency was alerted to this potential non-compliance for follow-up action.

All twelve mills had a documented QAA in place (question 1) with records demonstrating correct pre-mix calculations and folic acid addition formulae (question 2), a validated pre-mix delivery system (question 6), and a corrective action procedure (question 17). Sampling and analysis was routinely undertaken to check that the flour contained the required amount of folic acid (question 8). All but one mill (mill 10) had records showing that the feeder was working properly and set at an appropriate rate to deliver folic acid with the defined range (question 3). All mills, except mill 6, undertook effective stocktakes to verify the correct dosing of flour with folic acid (question 7). Only one mill (mill 10) did not retain retention samples for retest purposes (question 13). Mill 10 was also the only mill which did not keep records to demonstrate that sampling frequency was appropriate to the quantity of flour produced (question 14). As discussed, only one mill (mill 12) was not independently audited (question 18). Four mills sampled flour using the grab method, with the remainder using composite sampling.

5. Discussion

Folic acid results and assessment of a mill's QAA found that all but one of the twelve mills surveyed had successfully implemented a systems-based approach which achieved levels of folic acid in wheat flour for making bread consistent with the requirements of Standard 2.1.1. The current survey is a follow up to an earlier national compliance survey, undertaken between October 2010 and March 2011, which found that all 21 mills assessed complied with the provisions of Standard 2.1.1.

Both surveys are point in time snapshots of folic acid levels in bread flour using results from a single, composite (three part) sample of flour. There is inherent difficulty in achieving a consistent blend when adding small quantities of folic acid to large quantities of flour in industrial conditions. Consequently, the high level of compliance with mandatory folic acid levels found in both surveys, undertaken seven years apart, provides further evidence that most Australian flour mills are successfully implementing in-process controls to achieve prescribed concentrations of folic acid in wheat flour for bread making.

Table 1 Summary of results

Flour Mill		1	2	3	4	5	6	7	8	9	10	11	12
Folic acid results													
Folic acid (mg/kg)		2.60- 4.30¹	2.44	2.40	2.40	2.40	2.30	2.20	2.05	1.80	1.77	1.70	<1.00
Measurement of uncertainty (MOU) associated with test method (±%)		20	14.4	5.0	20	20	20	5.0	14.4	20	14.4	20	20
Compliant folic acid concentration (mg/kg) lower limit after adjustment for MOU of test method		1.60	1.71	1.9	1.60	1.60	1.60	1.9	1.71	1.60	1.71	1.60	1.60
Compliant folic acid concentration (mg/kg) upper limit after adjustment for MOU of test method		3.60	3.38	3.15	3.60	3.60	3.60	3.15	3.38	3.60	3.38	3.60	3.60
Responses to questionnaire													
1	Is there a documented QAA or equivalent in place?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Folic acid addition													
2	Are there records to demonstrate that correct pre-mix calculations & defined addition formulas are recorded?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
3	Are there records to demonstrate that feeder is working properly & set at appropriate rate to deliver folic acid within defined range?	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y
4	Are there records to demonstrate that feeder is calibrated?	Y	Y	Y	Y	Y	Y	Y	N	Y	N	Y	N
5	Are there records to demonstrate that feeder is maintained?	Y	Y	Y	Y	N	Y	Y	N	Y	N	Y	Y
6	Are there records to demonstrate that pre-mix delivery system has been validated?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y
Verification - Stocktake													
7	Are there records to show that stocktake is performed on relative quantities of pre-mix added versus wheat flour produced?	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y
	If yes, are there records to show that stocktake is undertaken at a suitable time to show that correct amount of pre-mix is added?	Y	Y	Y	Y	Y	NA	Y	Y	Y	Y	Y	Y
Verification – Sampling and analysis													
8	Are there records to show that sampling & analysis are routinely done to check if wheat flour contains the required amount of folic acid?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y

Unofficial

Flour Mill		1	2	3	4	5	6	7	8	9	10	11	12
9	Are there records to demonstrate that samples are drawn from a point that is a fair representation of the wheat flour that is dispatched?	Y	Y	Y ²	Y	Y	Y	Y	Y	Y	N	N	Y
10	Sample type - single 'grab' (G) or composite (C) representative of lot?	C	C	C	G	C	C	C	G	C	G	C	G
11	For a lot sample are there records to demonstrate that subsamples are taken from pre-determined point/s in milling process?	Y	Y	Y ²	NA	Y ³	?	Y	NA	Y	NA	Y	NA
12	For a lot sample are there records to demonstrate that at least 3x subsamples, each >500 grams, are taken over course of the run?	NA	Y	N ²	NA	?	Y	Y	NA	N	NA	N	NA
13	Is a matching sample usually retained by the mill?	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	Y
14	Are there records to demonstrate that sampling frequency is appropriate to quantity of wheat flour produced?	Y	Y	Y ^{2.5}	Y ⁵	Y ⁵	Y	Y	Y	Y ⁵	N	Y ⁵	Y
15	Are there records to demonstrate that laboratory is accredited for testing for folic acid in wheat flour?	Y	Y	Y ²	?	?	?	Y	Y	Y	Y	?	Y
16	Are there records to demonstrate test method has been validated?	N	Y	Y	?	?	?	Y	Y	Y	NA	?	Y
Corrective action													
17	Is there a documented system for corrective action if verification procedures confirm product is potentially out of specification?	Y	Y	Y ²	Y	Y	Y	Y	Y	Y	Y	Y	Y
Audit arrangement													
18	Are there records to show that QAA or equivalent is assessed through 3rd party or alternative audit arrangement?	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	N

Y, yes; N, no; NA, not applicable; ?, response not recorded on questionnaire - in the case of mill 4, the mill could not answer the question

¹Mill 1: Two samples from the same mill were tested for folic acid.

²Mill 3: Procedures are undertaken correctly, but not documented. This is a work in progress.

³Mill 5: Procedure is undertaken, but not documented.

⁴Question 11 There is only one sampling point after folic acid addition at mills 3, 7, 9 and 11.

⁵Question 14 Sampling frequency: Mill 3, every 40 tonnes; mill 4, weekly; mill 5, every 6 months; mill 9, quarterly - 600 tonnes of flour are produced per week; mill 11, quarterly - 200 T/week

Appendix 1 Number of samples of wheat flour for bread making tested by each jurisdiction

Jurisdiction	Number of flour mills	Total number of samples per jurisdiction
Queensland	2	2
South Australia	3	3
Tasmania	1	1
Victoria	3	3
Western Australia	3	3

Appendix 2 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

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

3. Are there records to demonstrate that the feeder is working properly and set at the appropriate rate to deliver folic acid within the defined range? Yes No

4. Are there records to demonstrate that the feeder is calibrated? Yes No

5. Are there records to demonstrate that the feeder is maintained? Yes No

6. Are there records to demonstrate that the pre-mix delivery system has been validated? Yes No

Verification

Stocktake -

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

Sampling & Analysis –

8. Are there records to demonstrate that sampling and laboratory analysis is routinely conducted to check that the flour contains the required amount of folic acid? Yes No

9. Are there records to demonstrate that samples are drawn from a point that is a fair representation of the flour to be dispatched? (e.g. final point of production) Yes No

10. 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)

11. For a lot sample – are there records to demonstrate that sub-samples are taken from predetermined point or points in the milling process? Yes No Not applicable

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

Yes No Alternative method (please specify).....

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

14. Are there records to demonstrate that the frequency of sampling is appropriate to the quantity of flour produced? (e.g. once every 1000 tonnes of flour produced may equate to once every two days for large mills and monthly for small mills) Yes No

15. Are there records to demonstrate the analytical laboratory is capable of conducting tests for the presence and level of folic acid in wheat flour for bread making? Yes No Not applicable

16. Are there records to demonstrate the test method has been validated?
 Yes No Not applicable

Corrective action

17. Is there a documented system in place for corrective action if verification procedures confirm a product is potentially out-of-specification? Yes No

Audit Arrangement

18. Are there records to show that the QAA or equivalent arrangement is assessed through a third party or alternative audit arrangement? Yes No

References

Food Standards Australia New Zealand (February 2009) Australian User Guide Mandatory Folic Acid Fortification Implementing the Requirements of the Mandatory Fortification with Folic Acid under Standard 2.1.1 - Cereals and Cereal Products.

The Implementation Sub-Committee Mandatory Fortification Working Group Mandatory Fortification Compliance and Enforcement Model
<http://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Compliance-and-Enforcement-model-for-Mandatory-Folic-Acid-Fortification> Downloaded 4 May 2018