Appendix 2

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

Questionnaire

Enforcement Agency	Flour Mill
Department: …… Officer Name: ……	Company: …… 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 -

<u>Folic Acid Addition System (Validation)</u>

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)

……..……

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