



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

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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

Email: FoodUnit@health.wa.gov.au
Ph: (08) 9388 4999
Fax: (08) 9382 8119
Website: www.public.health.wa.gov.au



Stan Goodchild
Manager - Food Unit
Email: FoodUnit@health.wa.gov.au
Ph: (08) 9388 4920 Fax: (08) 9382 8119
Department of Health
PO Box 8172
Perth Business Centre WA 6849
www.public.health.wa.gov.au

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 is 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.

