

Mandatory Fortification Compliance and Enforcement Model

Background

The Implementation Sub-Committee (ISC) Mandatory Fortification Working Group was established to develop a National Implementation Strategy for mandatory fortification standards. The Working Group initially developed the Compliance and Enforcement Model for Mandatory Folic Acid Fortification and the scope of this Model has been expanded to become a broad base for the implementation of all future mandatory fortification standards, including iodine.

The revised Model focuses on manufacturers responsible for adding the required fortificant to the food vehicle and does not exclude manufacturers and suppliers from complying with all other relevant aspects of the *Australia New Zealand Food Standards Code*, such as labelling. Guidance on other compliance aspects will be developed where appropriate, in consultation with industry and enforcement agencies, and information provided in relevant supporting documents, such as a User Guide.

Compliance Model Principles

- Manufacturers implement a document system, such as a Quality Assurance Arrangement or an equivalent that is capable of being audited and is designed to control compliance. The documented system 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 to ensure that the level of fortification falls within the range prescribed in the relevant Standard; and
 - audit arrangements to demonstrate the documented system is in place and achieving the stated outcomes.
- Enforcement agencies agree that adherence to a documented system or equivalent alternative, assessed through either third party or alternative audit arrangements, is an acceptable means of demonstrating achievement of compliance with a specific mandatory fortification Standard.
- The documented system needs to specify the target fortification level 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 Model Principles

- Enforcement action may be triggered when manufacturers cannot show compliance with the relevant Standard through adherence to their documented system or equivalent alternative scheme. Examples of non-adherence could include: failure to take samples, inadequate record keeping; or failure to demonstrate corrective actions when problems are identified. However, additional evidence would be required to show that nonconforming product was being produced.
- The implementation and successful auditing of a documented system or equivalent alternative will not preclude enforcement agencies from taking a sample for analysis at any time, if needed.
- Enforcement agencies should ensure any samples taken within the manufacturing premises 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 within the manufacturing premises that demonstrates the correct amount of fortificant 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 that demonstrates compliance and due diligence.

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