



**Food
Fortification
Initiative**

Enhancing Grains for Healthier Lives



Fortification : Evidence Based Regulatory Compliance

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Recent history of Canadian Flour Fortification Standards – Harmonization of Standards with USA

- Prior to the North American Free Trade Agreement (NAFTA) in 1994 there were slight differences between the USA and Canadian flour fortification standards.
- The added micronutrients included B₁, B₂, B₃, and Iron, the standards were harmonized in 1994 to facilitate free trade. Mexico also adopted the standard.
- In 1996 Folic Acid was included in the standards for flour and all three countries adopted the same standard.

2006 - 2017: Change from Fortification Range to Minimum Levels*

Shall contain in 100 grams of flour

- (i) 0.64 milligram of Thiamine,
- (ii) 0.40 milligram of Riboflavin,
- (iii) 5.30 milligrams of Niacin or Niacinamide,
- (iv) 0.15 milligram of Folic acid, and
- (v) 4.4 milligrams of Iron;

[http://laws-lois.justice.gc.ca/eng/regulations/C.R.C., c. 870/section-B.13.001-20120315.html#wb-cont](http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/section-B.13.001-20120315.html#wb-cont)

The USA uses a minimum standard as well at the same levels
(but expressed as mg per lb of flour)

Canadian Millers: Quality Assurance Requirements and Responsibilities (as part of HACCP requirements)

- Premix procurement and storage
- Feeder/Dosifier Installation
- Feeder Calibration
- Feed Rate Calculations
- Process controls (Check Weighing, standards and sampling schedule Iron Spot Test)
- Premix Storage and Usage Reconciliation (Record Keeping)
- Laboratory Analysis: Quantitative test for Iron and Vitamins
- **ALL OF THE ABOVE REQUIREMENTS AND RESPONSIBILITIES ARE PART OF THE SYSTEM AND AUDITABLE**

Quantitative Analysis of Fortified Flour by Canadian Millers

- Under HACCP, Canadian millers are required to provide evidence that samples of flour have been analyzed for fortification based on **quantitative** analysis.
- Under HACCP process controls are required to be carried out and proven to have been carried out (as per previous slide)
- Proof of purchase and proof of payment for premix must also be available for inspection.
- Typically monthly samples are sent out or tested in house for quantitative analysis for B₁, B₂, B₃, Folic Acid and Iron

Canadian National Millers Association (CNMA): Issue with minimum standard

- In 2009 - 10 the CNMA expressed concern to the Canadian Food Inspection Agency CFIA about the use of the minimum standard in the regulations.
- The issues were what were the actionable minimum level and maximum actionable level for fortification of flour that the member mills could be considered to be out of compliance by inspectors from the CFIA. (Legal enforcement)
- The CNMA and CFIA collaborated on a study of about 4000 analysis reports for fortification for B₁, B₂, B₃, Folic Acid and Iron that were submitted (without prejudice) by the CNMA member companies.

Compliance Example – Canada Canadian Food Inspection Agency (CFIA) and CNMA

- Collaborative study with Canadian National Millers Association
- Examples results of analytical tests on more than 4,000 samples
- Measuring B1, B2, B3, Folic Acid and Iron

Compliance Example – Canada Canadian Food Inspection Agency (CFIA) and CNMA

- The CFIA reviewed the analysis reports
- CFIA issued guidance document stating regulatory samples analyzed and having **levels greater 80% and less than 175% of the standard comply** with the Regulation B.13 Flour and flour products.

Actionable (legal) Limits based on the Current Canadian Standard

Micronutrient	Minimum Regulation (B.13.001) mg per 100g	Minimum Actionable Limit (80%) mg per 100g	Maximum Actionable Limit (175%) mg per 100g
Vitamin B ₁	0.64	0.51	1.12
Vitamin B ₂	0.40	0.32	0.70
Vitamin B ₃	5.3	4.24	9.30
Folic Acid	0.15	0.12	0.26
Iron	4.4	3.52	7.70

The Importance of Evidence to establish Actionable Limits in Food Standards

- The joint CFIA and CNMA assessment of actual analytical data on fortified flour is a strong example of scientific collaboration between the food industry and the food control authority.
- The joint study was used to establish actionable levels based on actual verifiable analytical data reports.
- The use of a legal minimum requirement as implemented by the USA and Canada, is a feasible alternative to the establishment of a legal range.

Actionable (legal) Limits based on the 85% - 150% range ECSA Standard - Maize flour

Micronutrient	ECSA Regulation Target mg per kg	Minimum Actionable Limit (85%) mg per kg	Maximum Actionable Limit (150%) mg per kg
Vitamin B ₁	6.5	5.2	9.8
Vitamin B ₂	4.0	3.2	6.0
Vitamin B ₃	30	24	45
Folic Acid	1.2	0.96	1.8
Vitamin B ₁₂	0.015	0.012	0.023
Vitamin A	1.0	0.8	1.5
Iron	31	24.8	46.5
Zinc	49	39.2	73.5

Conclusions

- Reliance on sampling and analysis of fortified food for micronutrient levels is **not** a satisfactory method of measuring compliance.
- The focus of auditing for compliance should be at food plant level and at the import entry point.
- A **systems based approach (Hazard Analysis and Critical Control Points and Quality Management System)** is the most effective way to ensure compliance at the food plant level.
- In regions where cross border flows of fortified foods is significant, the sharing of information between country level food control authorities is strongly recommended