

Improving compliance with food fortification standards

Meeting Report of a Technical Consultation on Regulatory Monitoring Policy Priorities for Improving Fortification Compliance, 26-27 April 2017 in London, UK

Correctly implemented food fortification is widely recognized as one of the most cost-effective strategies to reduce 'hidden hunger' and improve the health of populations and national economies. Today, over 140 countries implement national universal salt iodization (USI), 85 countries mandate at least one kind of cereal grain fortification, and over 40 countries mandate the fortification of edible oils. However, effectively verifying and enforcing the production of quality-assured fortified staple foods that meet national standards—a process known as regulatory monitoring—remains an ongoing challenge for many governments. With the exception of salt iodization, there are little good quality data on how compliant fortification programs are globally.

Although many factors can affect a country's ability to monitor, the lack of a realistic or consistent definition of product compliance is a dominant gap in global programs. Following on from the 2015 Arusha Summit Statement and the work of Technical Advisory Groups to consolidate the Summit's recommendations, a **Technical Consultation Meeting on Fortification Compliance** was convened with support from the Bill and Melinda Gates Foundation, Project Healthy Children, and GAIN. Attended by 35 technical experts and national program leaders, including representatives of the IGN, the meeting was the first in a series of workshops with the overall objective to produce a document that can realistically guide countries towards a practical means of measuring compliance. The goal of the meeting was to review existing practices and come up with a common approach to compliance that is flexible enough to take into account testing variations but robust enough to ensure the program stays on track. The following recommendations were made.

Key recommendations for an effective approach to compliance

The Challenge:

How can we make determining fortification compliance more effective and more realistic for both government food inspectors and food producers, so that programming can be improved?

The Recommendations:

1. Use a 'systems approach' or 'technical auditing' to determine compliance.

Include fortification monitoring indicators into HACCP/GMP protocols already used by industry and, in many cases, inspectors. Assessments should include but are not limited to:

- **Proper equipment:** feeder installation and calibration
- **Premix/fortificant procurement and storage:** supplier specifications, storage feed rates, proof of payment
- **Fortification process controls:** check weighing and timing, feed rate calculations
- **Record keeping:** quality assurance and quality control (QA/QC) sheets, log book or computer records

2. Use the 'Premix/Fortificant Usage Reconciliation Calculation'.

It is important to calculate whether the correct addition rate is being used to verify that the system is operating correctly over time.

A. Starting Inventory of Premix/Fortificant	[kg]
B. Amount of Premix/Fortificant Purchased	[kg]
C. Ending Inventory of Premix/Fortificant	[kg]
D. Amount of Premix/Fortificant Used (A+B-C)	[kg]
E. Fortified Product	[MT]
F. Actual Addition Rate (D/E x 1000)	[kg/MT]
G. Target Rate*	[kg/MT]
H. Percent of Target (F/G x 100)	[%]

* Based on supplier specifications

3. Verify that the micronutrient premix/fortificant is being added in a constant manner.

Factories should check frequently that the product they are manufacturing actually contains the micronutrient premix/fortificant. For this purpose, the use of qualitative rapid methods (such as the iodine rapid test kits) is very useful.

4. Generate a realistic variation/percent range for compliance when quantitative tests are used.

National programs should determine their own acceptable ranges of variation around the average micronutrient content that counts as compliant. This should be based on statistical analysis of actual results obtained in factories with acceptable performance. Based on the outcome, the actionable limits for fortified food can be determined (i.e. the levels at which legal action should be taken by food control inspectors if results fall outside the limit). This should be a joint effort by inspection agencies and food producers. The use of composite samples (a combination of similar amounts of single samples) may be needed to reduce variation of the analytically-determined micronutrient contents to a reasonable and enforceable range.

Moving forward, partners should place priority on a) working across agencies to identify indicators and regulatory monitoring approaches that can be scaled, and b) mobilizing required human and financial resources to this end.