Regulatory Monitoring of National Food Fortification Programs:
A Policy Guidance Document

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This Policy Guidance Document on Regulatory Monitoring began as a response to the needs and priorities identified in the 2015 Arusha Statement of the #FutureFortified Global Summit on Food Fortification. Since that time, a Regulatory Monitoring Working Group formed within the Global Fortification Technical Advisory Group (GF-TAG) and consisted of a core group of individuals representing Project Healthy Children (PHC), the Global Alliance for Improved Nutrition (GAIN), the Food Fortification Initiative (FFI), and Smarter Futures. The Working Group focused on identifying barriers and enablers to improving the oversight, monitoring, and enforcement of food fortification standards and regulations. Two technical meetings were held to this end with participants from national, regional, and global bodies including governments, private sector, and development partners to discuss and agree on the principles included in this document.

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Executive Summary

Food fortification is the addition of essential vitamins and minerals (micronutrients) to foods during the manufacturing process to enhance the nutritional content of the end product for consumers. When fortified staple foods and condiments are appropriately produced, widely available, and regularly consumed by the population, a public health benefit is expected.[a]

In many countries, government leaders have established food fortification programs as one strategy to improve the nutrition status of their populations. To facilitate widespread coverage of adequately fortified foods, these leaders often enact legislation that requires food manufacturers to fortify their products with clearly defined levels of specific micronutrients. Despite the existence of legislation, however, only a small proportion of countries have realized the desired public health outcomes of national food fortification programs. Three interrelated factors that contribute to the lack of widespread success include insufficient micronutrient levels in the fortified products, inconsistent monitoring by regulatory authorities at food production facilities and border control sites, and limited enforcement of regulations and standards.

Though food producers are accountable for fortifying their products, the sustainability and nutritional impact of food fortification programs are highly dependent on the long-term commitment of government stakeholders as well. Lawmakers set the foundation for success by developing clear and achievable regulations and standards for the program, and once the initiative has started, regulatory agencies commence monitoring and enforcement activities. External evaluations of national programs have revealed, however, that government regulatory agencies are often burdened by challenges, such as limited budget allocations, poorly equipped laboratories, and overlapping agency duties. These impede ongoing regulatory monitoring efforts. Likewise, some food producers fail to add the proper levels of micronutrients to their products due to obstacles such as the recurrent cost of purchasing vitamins and minerals and a lack of clarity about the requirements of the regulations and standards. Additionally, the absence of a standardized, feasible approach for determining whether a food production facility and its products are compliant increases the risk for program inefficiencies, confusion among government and private sectors, and inconsistent and/or limited enforcement.

Recognizing these hindrances to success, the objectives of this Policy Guidance Document are:

1. To propose a standardized, feasible approach to determining compliance; and
2. To offer country-specific examples for addressing common, ongoing challenges faced by the public and private sectors.

The document is divided into two main parts. The first proposes a systems-based approach to determining compliance within the context of a regulatory monitoring framework. It emphasizes the need for audits of food production facilities and imported fortified consignments coupled with less frequent product testing. This gives attention to the process of producing fortified foods, leveraging each company's internal monitoring activities. To facilitate accurate results when the product is analyzed quantitatively, compositing single product samples is recommended. The first section also discusses production-site, imported-consignment, and national-level compliance reporting. The second part of the document provides practical recommendations for addressing key challenges to sustain regulatory monitoring efforts and to maintain compliance by food manufacturers.

[a] The document does not address bio-fortified foods, fortification at small-scale food production facilities, fortified foods produced for target populations (such as refugees), or home fortification through micronutrient powders.

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Introduction

Scope and Purpose

The overarching aim of this publication is to help countries achieve the target public health outcomes that are established by stakeholders at the outset of food fortification programs.

To facilitate success, this policy guidance document proposes a standardized systems-based approach for determining compliance built upon a foundation of realistic, feasible food fortification standards. Furthermore, it addresses common challenges faced by government regulatory agencies that are designated to monitor the program and by food manufacturers as they seek to fortify appropriately.

This guidance document aims to reflect consensus among food fortification stakeholders and to serve as a resource for those responsible for food fortification policy development and implementation. It will especially benefit individuals who are working in countries that have struggled to carry out regulatory monitoring activities on a consistent basis and where the lack of compliance with fortification regulations and standards is an ongoing issue.

Relevant Terms and Definitions

Food fortification is the addition of essential vitamins and minerals (micronutrients) to foods during the post-harvest, manufacturing process to enhance the nutritional content of the end product for consumers. Commonly fortified staple foods are edible salt, vegetable oil, sugar, wheat and maize flours, rice, and condiments like soy sauce. When fortification is initiated to reach a significant proportion of a country's population, it is termed large-scale or mass fortification and implementation efforts are often concentrated on industrial-sized food production facilities.

When the vast majority of a country's population regularly eats adequately fortified foods, fewer people will become deficient in key vitamins and minerals and the risk of morbidities caused by micronutrient deficiencies will decrease over time. A large-scale food fortification program is just one option for addressing micronutrient deficiencies. Government leaders may establish food fortification as a stand-alone program or they may implement it in conjunction with other nutrition-based initiatives such as vitamin and mineral supplementation, micronutrient powders, and dietary diversification. One key advantage of food fortification, however, is that it does not require consumers to change their behavior to receive the nutritional benefits.

During the planning stage of a food fortification program, stakeholders develop a standard for each food vehicle that will deliver added micronutrients to the population. **Standards** specify the micronutrient compounds that food manufacturers must use for fortification and the micronutrient levels that must be present in the finished product at the end of the manufacturing process. These standard specifications are based on country-specific food consumption or food availability data with consideration for micronutrient deficiency rates to the extent possible. They should also align with the latest fortification guidelines published by the World Health Organization (WHO)[b].

[b] The guidelines published by the WHO on the topic of food fortification focus on the following micronutrients: iron, folic acid, vitamin A, vitamin B12, and zinc. Stakeholders do not have to include all the micronutrients presented by the guidelines in a country's fortification standard. However, for each one included, stakeholders are highly encouraged to follow the recommendations for micronutrient levels and compound types, adjusting accordingly if the same micronutrient is added to multiple food products.

Wheat flour: http://www.who.int/nutrition/publications/micronutrients/wheat_maize_fortification/en/
Maize flour and corn meal: http://www.who.int/elena/titles/flour_fortification/en/

Standards form the foundation for the program's impact, so it is important to get the specifications correct. Fortification standards can be voluntary or mandatory. However, when government stakeholders initiate fortification to achieve target public health outcomes, they are advised to enact **legislation** that requires food producers to add micronutrients as specified in the standards. These standards should be maintained as documents that are separate from but referenced in the fortification legislation. This enables government stakeholders to modify the micronutrient levels and compound types with relative ease should the need arise.

Compliance is broadly defined as adhering to or obeying a request, order, regulation, or law. In the case of fortification, all food production facilities within the scope of the fortification regulations must ensure that their products conform to the micronutrient specifications detailed in the nationally adopted standards and to other food quality, safety, packaging, and labelling requirements. The legislation should encompass fortified foods that are imported into the country in addition to those that are domestically produced. Where fortification is voluntary, food manufacturers that choose to fortify are also expected to comply with any existing standards. Determining whether a food manufacturing facility and its products are compliant is based upon the monitoring activities conducted by regulatory authorities.

Regulatory Monitoring includes four subtypes of monitoring: internal, external, import, and commercial, which collectively aim to provide consumers with fortified foods that are of high quality, safe, and adequately fortified. Data collected during regulatory monitoring activities should be collated, analyzed, and interpreted to inform fortification stakeholders about the program's current status and progress over time. Furthermore, if stakeholders are concerned that certain details of the program need to be revised to enhance its impact, regulatory monitoring data can provide evidence of the problem(s) and serve as catalysts for change.

Internal Monitoring is executed by food producers at food manufacturing sites. It has two primary components: quality assurance and quality control. **Quality assurance (QA)** activities facilitate the production of fortified foods that contain adequate micronutrient levels, are of high quality, and are safe to consume. The focus is on the manufacturing process (including fortification). **Quality control (QC)** activities are concentrated on the finished product. They verify that fortified foods actually contain adequate micronutrient levels, are of high quality, and are safe to consume before marketing them to consumers.

External monitoring is conducted by government food inspectors at food production sites. It has two primary components: the audit and the inspection. During an **audit**, government food inspectors review the process by which fortified foods are manufactured to ensure that producers proactively address potential issues that could affect product quality, safety, and fortification adequacy. Specifically, they confirm that internal monitoring protocols are established and followed. They also review the site's records, observe the fortification process, and conduct critical location checks. **Inspections**, on the other hand, verify that the finished product actually adheres to the specifications of the fortification standard and other food quality and safety requirements. This is done through qualitative and quantitative tests of collected fortified food samples, also known by some as **corroborating trials or tests**. The audit closely relates to the QA activities conducted by food producers whereas the inspection aligns with the QC activities.

Import monitoring occurs when a product consignment arrives at the border to be imported into a country. It is generally the responsibility of import regulatory agencies and customs authorities, which are tasked with ensuring that the product adheres to applicable regulations and standards before it is

sold in the marketplace. In relation to fortification, the assessment should include a review of the product's labels, packaging, and Certificate of Analysis (CoA)[c]. Periodically, import monitoring includes product sampling for corroborating trials as well. This type of monitoring is also applicable to imported premix, the mixture of micronutrients and other specialty ingredients used to fortify foods.

Commercial monitoring is typically the responsibility of government food inspectors. It occurs in the marketplace where consumers purchase or otherwise obtain fortified foods and emphasizes a review of product labels and packaging. When resources are available, government food inspectors should also collect product samples for qualitative and quantitative testing. The analysis results are indicative of how well the foods are fortified at the production level and thus may serve to identify sites that require an additional audit and inspection visit. They also reveal the amount of micronutrients that are generally delivered to consumers who consistently eat the fortified food. However, commercial monitoring should never take the place of external and import monitoring for the following reasons:

Fortification standards specify the micronutrient levels that must be present in fortified products at the production level, not the commercial level. For this reason, commercial level findings are not valid for compliance determination or legal enforcement of fortification regulations and standards.

At the commercial level, inspectors are not able to adequately review the complete process by which fortified foods are produced, which is of vital importance for compliance determination.

Food producers aim to provide consumers with the micronutrient levels intended to provide a public health impact, first by adding the proper levels of vitamins and minerals to the target product and then by packaging and storing the fortified product in a manner that is expected to retain those micronutrients. However, during transportation and storage, fortified foods may be subjected to natural elements, such as water, heat, and sunlight, which have the potential to negatively impact product quality. Given that food producers do not have control over the entire food distribution system, they cannot be automatically penalized for issues noted at the commercial level.

Background to Development of this Policy Guidance Document

This policy guidance document stems from the Global Summit on Food Fortification, which took place in Arusha, Tanzania, in September 2015. The event culminated with the Arusha Statement on Food Fortification, which was delivered on behalf of the organizers by the Commissioner for Rural Economy and Agriculture of the African Union. Among other things, the Statement set forth five recommendations for fortification in low- and middle-income countries (see Figure 1).

A regulatory monitoring working group was established based on the second recommendation to understand the challenges that hinder regulatory monitoring and enforcement of fortification regulations and standards and to identify enabling factors that facilitate consistent regulatory monitoring practices and industry compliance. An outcome of the group's efforts from October 2015 – March 2016 was the recommendation to develop a *Regulatory Monitoring Policy Guidance Document* to

[c] Certificates of Analysis (COAs) endorse the content of the product and should align with the product label. It is the responsibility of the receiving party to verify that the COA matches the details of the product order and aligns with the requirements of the fortification standard.

share country-specific examples for addressing challenges to sustained regulatory monitoring and industry fulfillment of fortification regulations and standards. The document would also offer a standardized approach for compliance determination.

Figure 1:

Arusha Statement Recommendations for Improving Large-Scale Food Fortification Programs (2015)

1. Obtain modest but new investments
2. Improve oversight (regulatory monitoring) and enforcement of food fortification regulations and standards
3. Generate more evidence to guide fortification policies and program design
4. Increase program transparency and global reporting
5. Continue advocacy

To inform the development of the document, the Bill and Melinda Gates Foundation, Project Healthy Children, and the Global Alliance for Improved Nutrition convened a meeting of 35 fortification technical experts and national program leaders in London, the United Kingdom, from 26-27 April 2017. The objectives of this workshop were to define compliance and identify best practices for compliance determination, taking into consideration the role of both technical audits and factory inspections (specifically quantitative testing). A second workshop was held 17 August 2017 using virtual technology to examine, discuss, and agree upon ways to improve existing regulatory monitoring systems and expand industry compliance.

Evidence of Opportunities to Strengthen Regulatory Monitoring and Compliance

Despite the widespread momentum to establish food fortification programs worldwide, realization of the desired public health outcomes has been jeopardized, in part, by limited execution of regulatory monitoring activities and related compliance issues. Based on data from 20 national fortification programs in 12 countries, it was estimated that less than half of the analyzed samples complied with relevant standard specifications [1]. Although this data came from country analyses that may have faced undocumented and/or unaccounted-for variations, the information remains indicative of inadequate fortification practices. Improving compliance, however, is not just a matter of determination and motivation in most cases. Significant challenges hinder the actualization of regulatory monitoring protocols established by stakeholders during the program planning stages and industry adherence to the fortification standard specifications once the program starts. A publication by Luthringer et al. [1], based on interviews and surveys conducted with food fortification stakeholders representing the public and private sectors, identified common barriers to compliance (see Table 1).

Speakers at the aforementioned London technical meeting substantiated the common barriers. For example, a miller from eastern Africa explained that government food inspectors are scheduled to visit food production sites semi-annually. However, they rarely fulfil that duty. On the occasion that they

do visit, their findings are not shared for a long time. Also, the government established a central collection center to track monitoring data. However, it had not been utilized for a year at the time of the presentation. The miller stated that his food production facility struggles given limited laboratory capacity onsite and varied quantitative results when portions of the same sample are sent to different external laboratories. Additionally, the company faces competition from unfortified (noncompliant) products that remain in the marketplace.

Table 1: Common Barriers to Compliance with Fortification Regulations and Standards

Private Sector (Industry)	Public Sector (Government)
Price of premix Competition with producers who do not fortify Poor laboratory capacity Lack of clarity about regulations and standards Lack of functioning fortification equipment Lack of market demand Lack of technical knowledge	Perceived political risk of taking action against industries Lack of trained inspectors and laboratory analysts Overlapping roles; poor coordination Lack of fiscal resources Industry composition and distribution throughout the country

Top priorities to improve compliance, as identified by Luthringer et al. were vastly different between respondents of the private and public sectors. Whereas those representing the government felt clearer regulations, a better regulatory structure, a larger cadre of trained inspectors, and increased budget allocations for fortification should be prioritized, industry respondents felt incentives and penalties, communication between sectors, food industry engagement, and better laboratory capacity were most important.

To improve the consistency of satisfactory fortification processes and outcomes and to increase the sustainability of thorough yet feasible regulatory monitoring procedures, practical guidance is respectively needed for food producers and government food inspectors. A standardized approach for determining compliance that is well informed, transparent, and that leverages the internal monitoring QA/QC practices of food producers should serve as the backbone of each country's regulatory monitoring framework because it helps stakeholders to prioritize activities and resources. Part I of this document discusses a recommended methodology for compliance determination. It seeks to prompt conversations and direct stakeholders on this matter without being overly prescriptive. Part II of this document offers best practices for maintaining regulatory monitoring activities and industry commitment while addressing challenges that are common to low- and middle-income countries. Throughout the paper, country-based examples are included where available and relevant.

Highlighted Recommendations from this Policy Guidance

1. Implement a standardized, realistic systems-based approach to determine compliance, emphasizing the *process* of fortification over regular testing of fortified food samples.

2. Develop a comprehensive audit checklist that covers food quality, food safety, *and* food fortification.

3. Use the premix reconciliation calculation to determine whether the manufacturing (fortification) *process* is sufficiently adding micronutrients to foods. This equation compares whether the amount of premix used correlates appropriately to the amount of fortified food produced over a set time period. Premix reconciliation is one task conducted during an audit at a food production site.

4. Within the country's fortification standards, express each micronutrient specification as a target value[d] encompassed by actionable limits[e].

5. Analyze composite[f] samples of fortified foods quantitatively only periodically and as a means to *validate* the findings of an audit.

6. Implement a user-friendly, computerized management information system (MIS) to make the process of data collection, collation, analysis, interpretation, and results dissemination more efficient and effective.

7. Establish incentives that appeal to the food industry in addition to meaningful and enforceable penalties that drive consistent compliance among food manufacturers.

8. Involve non-traditional stakeholders in monitoring fortification programs at the commercial and household[g] levels to extend resources and expand public engagement in the initiative.

[d] The target value can be a target average, meaning that the results of multiple tested samples should hover around the specified amount, or a target minimum, meaning each sample must achieve at least the specified amount. It is the prerogative of fortification stakeholders to make this decision. The target value, however, should never be a target maximum because that would, in theory, permit food producers to skip fortification.

[e] Actionable limits, the lower and upper bounds outside of which a fortified food sample is classified as not compliant with the standard specifications, account for multiple types of variation that affect quantitative test results. Actionable limits are synonymous with the term "acceptable range of variation" which is not used in this document.

[f] Composite samples are comprised of equal parts of multiple single samples (usually at least three) that are collected from the facility.

[g] Household monitoring is not discussed in this document.

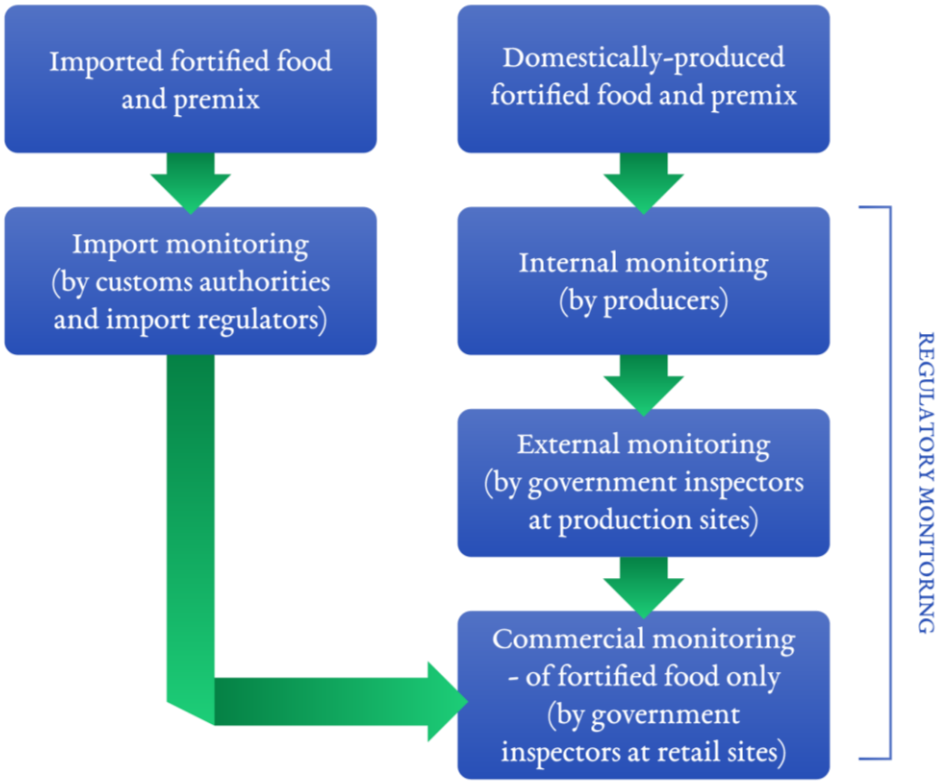
Part I: Recommended Method for Determining Compliance within a Regulatory Monitoring Framework

Challenges addressed: lack of communication and negative rapport between sectors, lack of regulatory clarity, limited personnel and financial resources, and poor laboratory capacity

1.1 Introduction to the Systems-Based Approach for Monitoring

The systems-based approach for monitoring, as recommended in this policy guidance document, is conducted in the context of a regulatory monitoring framework as shown in Figure 2.[h]

Figure 2: Regulatory Monitoring Framework



Though the regulatory monitoring framework highlights multiple types of monitoring, this document emphasizes external monitoring at food production sites with some focus on import monitoring, predominantly in Section 1.6[i]. Commercial monitoring is only touched upon given that it is not directly relevant for compliance determination.

[h] This diagram was adapted from the framework printed on page 179 of the book, *Guidelines on Food Fortification with Micronutrients,* a publication of the World Health Organization and the Food and Agriculture Organization of the United Nations (2006).

[i] The intricate details of import monitoring can get complex and are likely to vary between countries, so they are not provided in this document. Stakeholders who are tasked with developing the protocols for monitoring imported fortified foods may find that it is helpful to build upon procedures that exist for monitoring other consumables that are frequently imported and contain added micronutrients, such as vitamin and mineral supplements and baby formula.

The philosophy of the systems-based approach is to control the food *manufacturing process* appropriately so the end product will – with relative certainty – achieve the necessary food quality, safety, and fortification parameters. As such, this policy guidance document emphasizes audits of food production facilities to infer compliance with confidence coupled with less frequent qualitative and quantitative testing of fortified foods to verify the audit results.

Audits compliment the internal monitoring procedures that food manufacturers regularly implement and track. Specifically, the inspector will observe the fortification process, conduct critical location checks (ex: inside the feeder[j] and inside the premix storage area), confirm that internal monitoring QA/QC protocols are established and followed, and review records that document internal monitoring practices.

To guide the data collection process and facilitate parallel assessments across food production sites, inspectors should apply an audit checklist that includes items about food quality, safety[k], and fortification. A checklist framework, available in Appendix I, is meant to guide stakeholders who are responsible for the checklist development process. They should keep in mind the level of industry sophistication when preparing the checklist to avoid instant failure by any small- and medium-sized food production facilities that are required to fortify. Before implementing such a checklist, stakeholders need to determine which items are vital for all facilities to achieve.

Including a scoring system can help mitigate subjectivity in compliance determination. For example, stakeholders may assign a point value to each checklist item based on its relative importance to the overall audit. The inspector awards the full point value for the items that are fulfilled and zero points for the items that are not satisfied. At the end of each audit, s/he adds up the total score and compares it against the pass/fail parameters developed for the checklist.

A robust, field-tested audit checklist should serve as the primary means for determining whether a food production site is compliant if implemented by a cadre of inspectors who are trained to carefully and comprehensively assess each item. If a scoring system is utilized, the inspectors should undergo periodic peer evaluations to ensure points are awarded consistently and objectively. Section 2.1 will expand upon the topic of the audit checklists.

1.2 Premix Reconciliation Calculation – One Component of an Audit

An effective way for government food inspectors to infer whether the fortification process is functioning adequately is by conducting a premix reconciliation calculation as part of the facility audit. The data points needed for the exercise include: starting premix inventory, amount of premix purchased (if any), ending premix inventory, and the amount of fortified product produced over a specified period of time. The remaining data points are calculated using simple math (see Table 2).

Food manufacturers should always aim to achieve the target premix addition rate (ex: 250 grams of premix per metric ton of flour) as specified by the premix producer. At the beginning of the program, however, it is expected that food manufacturers will be a few percentage points over or under as they

[j] Feeders (aka: dosifiers) add the vitamin and mineral premix to the food during the manufacturing process.

[k] Food safety is an important consideration when assessing facilities that manufacturer fortified foods. A food production facility should not be considered compliant if its system for controlling food safety is not adequately developed or executed.

come to understand the technicalities of the fortification process. In the example that follows (see Table 3), the food producer is approximately 15% under the target premix addition rate. This is significant for a month's time and should raise notable concerns about whether adequate fortification process controls are implemented at the food-manufacturing site, even if the program is newly established.

Table 2: Premix Reconciliation Equation: Step-by-Step

Item	Unit	Where to Locate
A. Starting inventory of premix	MT[l]	See facility records
B. Amount of premix purchased	MT	See facility records
C. Ending inventory of premix	MT	See facility records
D. Amount of premix used	MT	Calculate: A+B-C
E. Fortified product produced	MT	Facility records
F. Actual premix addition rate	g[m]/MT	Calculate: D/E x 1000
G. Target premix addition rate	g/MT	Provided by premix producer
Result: Percent of target addition rate	%	Calculate: F/G x 100

Table 3: Premix Reconciliation Calculation: An Example

Mill producing 350 metric tons (MT) of fortified wheat flour per day, for 27 days	
Item	Quantity/Answer
A. Starting inventory of premix	1,700 MT
B. Amount of premix purchased	2,300 MT
C. Ending inventory of premix	2,000 MT
D. Amount of premix used *(A+B-C)*	2,000 MT
E. Fortified flour produced	9,450 MT *(350 MT/day for 27 days)*
F. Actual premix addition rate *(D/E x 1000)*	212 g/MT
G. Target premix addition rate *(Per the premix producer)*	250 g/MT
Result: Percent of target premix addition rate *(F/G x 100)*	Approximately 85% (15% below the target)

The premix reconciliation calculation is also relevant for food producers and should be integrated into each company's daily quality assurance activities. When the premix reconciliation calculation is conducted on a daily basis, only items D through G, as shown in Tables 2 and 3, are needed. The result serves as an indicator for whether that day's output would comply with the country's fortification standard specifications. The data should be recorded and made available to government food inspectors upon request.

[l] Metric tons

[m] Grams

1.3 Verification of Added Micronutrients: Qualitative Analyses

Even though the systems-based approach emphasizes proper control of the fortification process, testing the finished product remains important. Food manufacturers and government food inspectors alike should prioritize rapid qualitative tests, which are low-cost and user-friendly. These tests confirm that fortified foods contain test-specific vitamins and minerals.

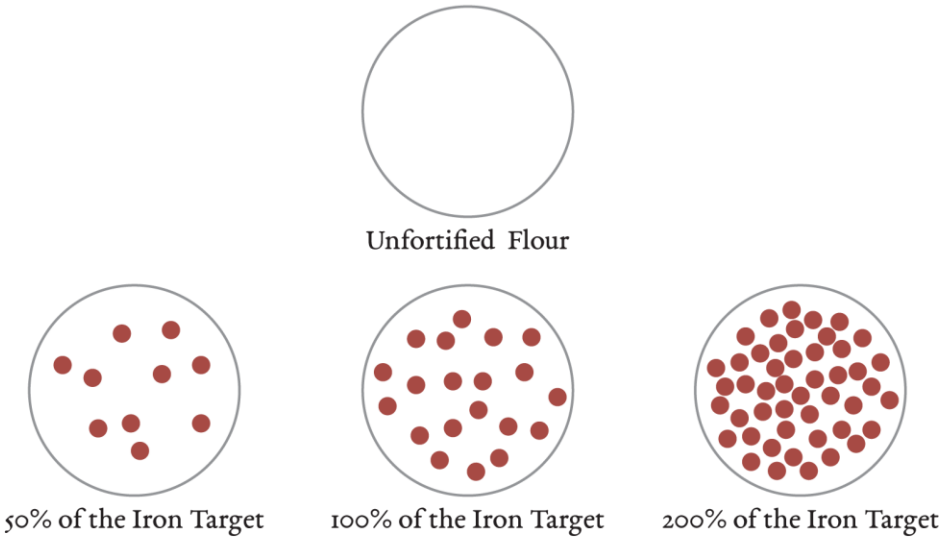
A common rapid qualitative test for fortified wheat and maize flour and fortified rice is the iron spot test, which exhibits the presence of added iron [2]. This test was developed by the American Association of Cereal Chemists International, and is also known as AACCI 40:40. Using the iron spot test, fortified samples of flour will display red spots after the necessary reagents are added. Fortified rice will display red kernels. Unfortified samples may develop a red hue from iron that is intrinsic to wheat, maize, and rice but no red spots or kernels. Qualitative tests are also available for indicating the presence of added iodine in salt ("rapid test kits") and added vitamin A in flour, vegetable oil, and sugar [3]. In most cases, these qualitative tests can function as semi-quantitative analyses when the results are compared to a colorimetric chart, similar to what is described below for the iron spot test. Food manufacturers should conduct qualitative analyses on single samples of fortified product multiple times per day as part of their quality control protocols. Government food inspectors should test each fortified food sample they obtain at food production sites in this manner as well.

Before a fortification program commences, food manufacturers should develop a results-comparison chart. To do so, a small amount of the food product is fortified at 50%, 100%, and 200%[n] of the target micronutrient levels as shown in Figure 3. Single samples are collected and tested qualitatively. Pictures are taken of the results and made into a chart for display, with a picture of the unfortified product for comparison. Each time a qualitative test is run on a sample of the fortified food, staff are encouraged to compare the result with the chart as a semi-quantitative assessment. Though they will not be able to determine exactly how much iron was added, they will be able to *estimate* whether the target value was achieved based on the density of red spots that appear.

When government food inspectors collect samples of fortified products at manufacturing sites, they should do so from the production line and the warehouse to respectively account for product quality at present and product quality over time. The total number of samples to obtain and the quantity of each is based on the underlying intent of use. For instance, if the samples will be used for both qualitative and quantitative analyses, the quantity of each will need to be greater than if the sample will only undergo qualitative testing. The same is true for the total number of samples. If the government food inspector is only required to conduct qualitative tests during the visit, the sample size will be smaller than if the site assessment also requires the inspector to send samples to a laboratory for quantitative testing. The desire to have high confidence and high reliability in the quantitative results increases the sample size; this is elaborated upon on Appendix II.

[n] The treatment levels for this exercise can be altered.

Figure 3: Results-Comparison Chart for the Iron Spot Test



1.4 Actionable Limits

This guidance document advises government stakeholders to establish fortification standards that express each micronutrient specification as a target value[o] encompassed by lower and upper actionable limits[p]. Practically, the actionable limits stipulate the boundaries for quantitative test results, outside of which samples collected from food production sites are classified as noncompliant and follow-up steps by regulatory authorities, such as an additional inspector visit, should be considered.

Actionable limits are recommended because they account for:

1 The varying levels of micronutrients inherently found in the food products[q];
2 The varying distribution of micronutrients within the premix;
3 The varying capacity of equipment at food production sites to adequately combine the premix and the food product;
4 The analytical variation inherent in chemical assays and the methodology by which they are performed; and
5 The variability inherent in measuring very small amounts of micronutrients.

[o] The target value can be a target average, meaning that the results of multiple tested samples should hover around the specified amount, or a target minimum, meaning each sample must achieve at least the specified amount. It is the prerogative of fortification stakeholders to make this decision. The target value, however, should never be a target maximum because that would basically permit food producers to skip fortification.

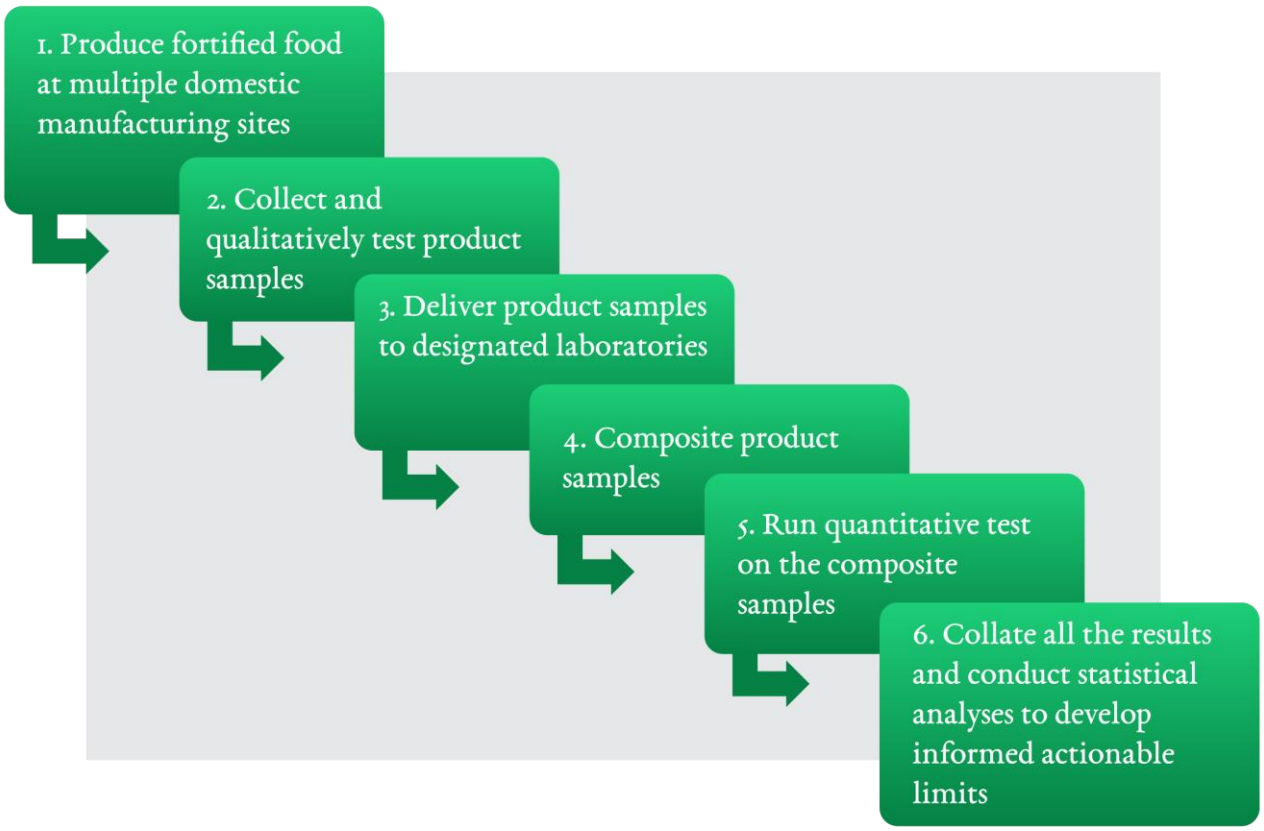
[p] Actionable limits, the lower and upper bounds outside of which a fortified food sample is classified as not compliant with the standard specifications, account for multiple types of variation that affect quantitative test results. Actionable limits are synonymous with the term "acceptable range of variation" which is not used in this document.

[q] Stakeholders may choose to reference country food composition tables to gain an understanding about the inherent micronutrient content of staple foods used in fortification programs. The figures presented in such tables are typically based on several quantitative analyses.

Formulating actionable limits during the program's planning stage makes it easy to include them in the country's fortification standards and facilitates compliance determination after any fortification grace period[r] granted by the government. This option necessitates support of food producers and laboratory staff to conduct fortification trials and government stakeholders to analyze the data as explained in the next paragraph and summarized in Figure 4.

The first step in developing actionable limits during the planning stage of a fortification program is to identify multiple appropriately equipped food production sites across the country to participate in the food fortification trials. Each should be tasked with fortifying batches of product using the target premix addition rate specified by the premix producer as a guide. Next, a designated, trained individual from the regulatory agency should collect and qualitatively test single samples of the fortified food from each of the multiple sites.

Figure 4: Steps to Establish Actionable Limits During the Program Planning Stage



Subsequently, s/he should either combine the single samples into one or more composite samples or take the single samples to the appropriate laboratory where they will be composited. In both cases, the samples should be appropriately packaged, sealed, and labelled. Only laboratories accredited in the proper analysis techniques for quantitative testing of relevant micronutrients or laboratories that have

[r] In some countries, the government provides a grace period after the law that stipulates fortification goes into effect to allow food producers time to obtain the necessary materials and adjust their practices before full compliance with the regulations and standards is expected.

shown similar competence based on the standard ISO/IEC 17025[s] should be elected to support the fortification trials.

Equipment validated for analyzing micronutrients in food products must be utilized. Analytical procedures published in peer-review journals or manuals should also be prioritized. For instance, AACCI and the Association of Official Analytical Chemists (AOAC) have published well-accepted procedures for determining micronutrient levels in flour. Methodologies that are not peer-reviewed should first be validated for fitness of purpose. Lastly, the quantitative results of all samples in this exercise should be statistically analyzed to inform the establishment of attainable actionable limits for each micronutrient. Conducting these fortification trials with the support of food production sites throughout the country helps to ensure that the industry, as a whole, has the capacity to fortify satisfactorily. Likewise, the studies capture the readiness of the laboratories in addition to the laboratory-based variations mentioned earlier. If any outliers are identified during the exercise, the associated food production sites or laboratories may require additional staff training, fresh reagents for testing or, in rare cases, new equipment.

If stakeholders choose to develop actionable limits after the program is underway (during the implementation stage) because they are not included in the country's original standards or because the existing actionable limits were devised incorrectly, the process differs. Rather than conduct fortification trials, stakeholders will formulate actionable limits by collating and statistically analyzing numerous quantitative test results that were obtained as part of external monitoring activities. In countries where the actionable limits were developed during the planning stage, this methodology can be used a few years into the program to reevaluate the achievability of the established boundaries. Under both approaches for formulating actionable limits, stakeholders need to emphasize consistent, validated methods for sampling, compositing, and testing the fortified product.

In **Canada**, flour fortification commenced in the 1950's [4]. The relevant actionable limits were developed much later and came into effect in 2012. Based on analytical reports of more than 3,000 flour samples that were tested over the course of many years by the Canadian Millers Association, the Canadian Food Inspection Agency, and Health Canada, country leaders determined through statistical analysis that the actionable limits for wheat flour would be no less than 80% and no more than 175% of each micronutrient's minimum specification (see Table 4). [5] It was noted that these limits "will not pose a risk to the Canadian consumer, will meet the policy intent…will comply with applicable health and safety requirements, and will be consistently achievable based on current industry practices" [5]. This is an example of a country that chose to develop actionable limits many years after the program commenced because they were not included in the fortification standard.

[s] ISO/IEC 17025 offers general requirements for the laboratories that provide testing and calibration services.

Table 4: Actionable (Legal) Limits based on the Canadian Regulation B.13.001 for Flour and Flour Products

Micronutrient	Minimum Specification mg/100 g	Minimum Actionable Limit (80%) mg/100 g	Maximum Actionable Limit (175%) mg/100 g
Vitamin B1 (thiamine)	0.64	0.51	1.12
Vitamin B2 (riboflavin)	0.40	0.32	0.70
Vitamin B3 (niacin)	5.3	4.24	9.63
Folic acid	0.15	0.12	0.26
Iron	4.4	3.52	7.70

It is not recommended for one country to simply adopt the actionable limits approved by a neighboring country given that the equipment utilized by the food production sites and laboratories will likely differ and because the capacity of laboratory staff to appropriately execute and interpret quantitative tests will vary. However, if resources are not available to carry out the recommended fortification trials or analyses, the standard specifications from a country with the most similarities can be assumed.

Before the actionable limits are published, government regulators need to agree upon and document the actions that will take place when quantitative results indicate that samples collected by inspectors from food production sites fall outside of the actionable limits.

1.5 Verification of Added Micronutrients: Quantitative Analyses

While qualitative analyses demonstrate the presence of test-specific micronutrients, quantitative analyses provide numerical results for each micronutrient assessed. Examples of "gold-standard" (most-trusted) quantitative techniques include high performance liquid chromatography to measure folic acid in flour and mass spectrometry to measure iron in flour, among others. Rapid quantitative tests also exist. Examples include iCheck Fluoro for assessing the amount of vitamin A in flour and sugar and the WYD Iodine Checker for iodine in salt.

There is a common misperception among fortification stakeholders that quantitative tests are the best indicator of compliance because they offer numerical results that can be compared (directly or indirectly) to the micronutrient specifications listed in the fortification standards. However, quantitative analyses should be thought of as a means for confirming the results of the audit checklist not as a stand-alone method for determining compliance given the following notable limitations:

1 They are costly to conduct and burdensome for laboratory staff, especially when requested frequently.
2 Many do not differentiate between intrinsic and added micronutrients. This can pose a problem if a country's standards stipulate the amount of each micronutrient to *add* rather than the total amount that should be present in the sample.
3 They are subject to human error, especially when staff lack adequate training or are overworked.
4 They are not able to sufficiently detect very small amounts of micronutrients in a fortified sample. This problem is exacerbated when single samples are analyzed instead of composite samples.

5 They have an inherent (sometimes wide) margin of error, which is not consistently taken into account when the results are interpreted by regulators or laboratory personnel.
6 Their turn-around time tends to be a couple of weeks, hindering timely modifications at food production sites when problems are noted.

To maximize the reliability and precision of quantitative test results, food manufacturers, food inspectors, and laboratory technicians should all receive training on proper sample collection, handling, and storage. Laboratories designated to analyze samples of fortified foods should be appropriately staffed and equipped for fortification purposes. Laboratory technicians should be competent in performing validated quantitative testing procedures for micronutrients and in interpreting quantitative results [6, 7, 2]. Furthermore, they should adhere to the accepted timeline for reporting results to the inspector (where applicable) and to the relevant government agencies. Clear instructions for product sampling and laboratory analyses should be included in the country's fortification monitoring plan.

The following paragraph offers a recommended product sampling methodology. Stakeholders may choose to adopt and implement it, or they can simply use the methodology as a prompt for further discussions about devising a realistic sampling methodology for their country, taking into consideration the capacity of laboratories to analyze samples and properly interpret the results.

When government food inspectors collect single samples with the intention of testing the product qualitatively and quantitatively, each should amount to 400-500 grams. For production-line samples, the inspector should collect the fortified food from the end of the production line.[t] At this point, the premix and product should be adequately integrated. S/he obtains the single samples at 10-minute intervals in order to capture production-based variations. A total of 12 single samples is recommended; see Appendix II for an explanation of this number. Next, the inspector should divide each sample into three parts. One part of each should undergo a qualitative test, ideally onsite. After the result is documented, the tested product is thrown away. The other two parts of each single sample should be of an equal amount. They should be placed in containers, sealed, and labeled with the following: product name, brand name, facility address, identification code, batch number, and date collected. Twelve parts (containers), each representing a different sample, should remain at the food production site as a reference samples in case third-party evaluation is needed in the future. The inspector should transport the other twelve to a laboratory for compositing and quantitative testing[u] of one or two marker micronutrients[v]. Inspectors should follow the same methodology for warehouse samples,

[t] If a closed-system is used to fortify the product, samples can be collected in the site's packaging or load-out area.

[u] Alternatively, the inspector can composite the single samples at the food production facility. This will result in one composite reference sample and one composite laboratory sample representing the production line and one composite reference sample and one composite laboratory sample representing the warehouse. This method is easier for government food inspectors because they have fewer samples to keep track of during transportation to the laboratory; just two composite samples instead of 24 single samples. However, if the quantitative results of a composite sample are not compliant with the country's standard specifications, it will not be feasible to then stratify the composite sample to identify the single samples that actually contributed to the problem. Such information may or may not be important to country stakeholders.

[v] A marker micronutrient is one that is chosen as an indicator for the other micronutrients in the premix. For quantitative assessments, if the analysis demonstrates that the marker micronutrient complies with the relevant standard specifications then the food producers and government food inspectors can surmise that the other added micronutrients will as well.

except they will collect the samples (or product packages) at random from various parts of the warehouse.

Recall from Section 1.3 that production-line samples point to a site's fortification quality in the present whereas warehouse samples demonstrate the site's fortification quality over time. The latter may be more important because they represent what takes place when government food inspectors are not at the facility.

1.6 Compliance with Food Fortification Regulations and Standards

There are three primary decisions related to compliance that government stakeholders should agree upon and put into writing, ideally before any fortification program begins. They include:

1 The approach for determining compliance at food production sites and among imported consignments, if applicable;
2 The manner for reporting compliance at food production sites and among imported consignments, if applicable; and
3 The method for reporting national-level compliance.

These will be elaborated upon in turn.

1.6.1 Recommended Steps for Determining Compliance at Food Production Sites and Among Imported Consignments

The following compliance determination methodology balances the desire to thoroughly evaluate food production sites and their fortified products with the need for a protocol that is mindful of resource challenges and the limitations of quantitative analyses. As such, it includes implementation of an audit checklist and corroborating trials. However, it only recommends quantitative testing periodically. For instance, if a country's monitoring plan stipulates that regulatory authorities monitor each manufacturing site quarterly, government stakeholders might only require sample collection for the purpose of quantitative testing on a biannual basis. The same approach can be applied to import monitoring.

Step 1: Audit Checklist

Production Sites[w]:

Upon entering a food production facility, the government food inspector should give his/her full attention to completing the audit checklist, which ideally addresses food quality, safety, and fortification adequacy. A total score should be tallied and compared against the predetermined pass/fail parameters for the audit checklist.

[w] Some countries require audits of foreign food production facilities before the fortification program begins and/or annually as part of each company's process of registering as a trade partner. In these cases, government food inspectors should implement the checklist that is typically used to evaluate domestic food production sites.

Imports:

Designated authorities should assess imported fortified products at border entry points using an audit checklist that is developed specifically to ensure the imported products meet national requirements for imported fortified foods. Similar to the checklist used to evaluate food production sites, this checklist should address food quality, safety, and fortification adequacy to verify that the compliance evidence presented by importers is acceptable. This is done through a review of the Certificate of Analysis. A total score should be tallied and compared against the predetermined pass/fail parameters for the checklist.

See Sections 1.1 and 2.1 for more information about the audit checklist.

Step 2: Qualitative Testing

A. "Passing" Audit Checklist Results:

Production Sites:

If the food production site passes the checklist portion of the visit (inclusive of the premix reconciliation calculation), the inspector obtains single samples of the product from the production line and warehouse. S/he then tests each qualitatively.

Imports:

If the imported consignment receives a passing score on the checklist, the relevant authority obtains single samples from packages (or a bulk container) of finished product per the sampling plan adopted for imports. S/he then tests each qualitatively. Enumeration of a country's import sampling plan is critical since it may not be possible to test every import consignment.

See Sections 1.3 and 1.5 for more information about qualitative testing.

B. "Failing" Audit Checklist Results:

Production Sites:

If the food production site fails the checklist portion of the visit, qualitative and quantitative sample analyses for fortification purposes do not need to be performed. The government food inspector continues with any remaining tasks related to food quality and safety. When ready to exit the facility, s/he gives a detailed verbal report of the findings to the site manager and leaves a copy of the completed checklist (electronic or paper) for reference purposes.

Imports:

If the imported consignment receives a failing score on the checklist, qualitative and quantitative sample analyses for fortification purposes do not need to be performed. The relevant authority continues with any remaining tasks related to food quality and safety. When all tasks are finished, s/he should immediately inform the importer and the responsible foreign food production site of the issues verbally to facilitate quick and appropriate corrective actions. The imported product should not enter the marketplace until the cause of failure is remedied, if possible. An example of a failure that can be resolved is a shipment that arrived without a complete COA.

Step 3: Quantitative Testing

A. "Passing" Qualitative Test Results:

Production Sites and Imports:

If all single samples indicate the presence of added micronutrients based on the results of the qualitative tests, packaged, sealed, and labelled samples (single or composited) are sent to a laboratory for quantitative testing[x]. The pass/fail parameters for quantitative test results must be agreed-upon and documented by government stakeholders, ideally during the planning phase of the program.

See Section 1.5 for more information about quantitative testing.

B. "Failing" Qualitative Test Results:

Production Sites:

If the food production facility fails the qualitative portion of the visit, quantitative testing is not warranted. The government food inspector should work with the production manager or other employees involved in the fortification process to locate a reason for the failure, which s/he should then document. The inspector subsequently proceeds with his/her responsibilities as described in Step 2B.

Imports:

If the imported consignment fails the qualitative portion of the assessment, quantitative testing is not warranted. S/he subsequently proceeds with his/her responsibilities as described in Step 2B. When finished with all tasks, the relevant authority should immediately notify the importer and the foreign food production site about the failure in order to facilitate quick and appropriate corrective actions. The consignment should not be permitted to enter the marketplace[y] and future consignments from that production site should be scrutinized more closely going forward.

Step 4: Determining Compliance

A. Classification as "Compliant"

Production Sites and Imports:

Food production sites and imported consignments that pass all three of the previous steps are classified as compliant for that assessment.[z]

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[x] If single samples are sent to the laboratory, they should be appropriately composited before testing.

[y] Stakeholders should determine, during the program planning stage, how to handle imported consignments that are not suitable for consumption.

[z] If the country's regulatory monitoring plan shows that quantitative testing is not a factor for this assessment/visit, compliance determination may be based on the results of the audit checklist and qualitative analyses only.

B. Classification as "Non-compliant"

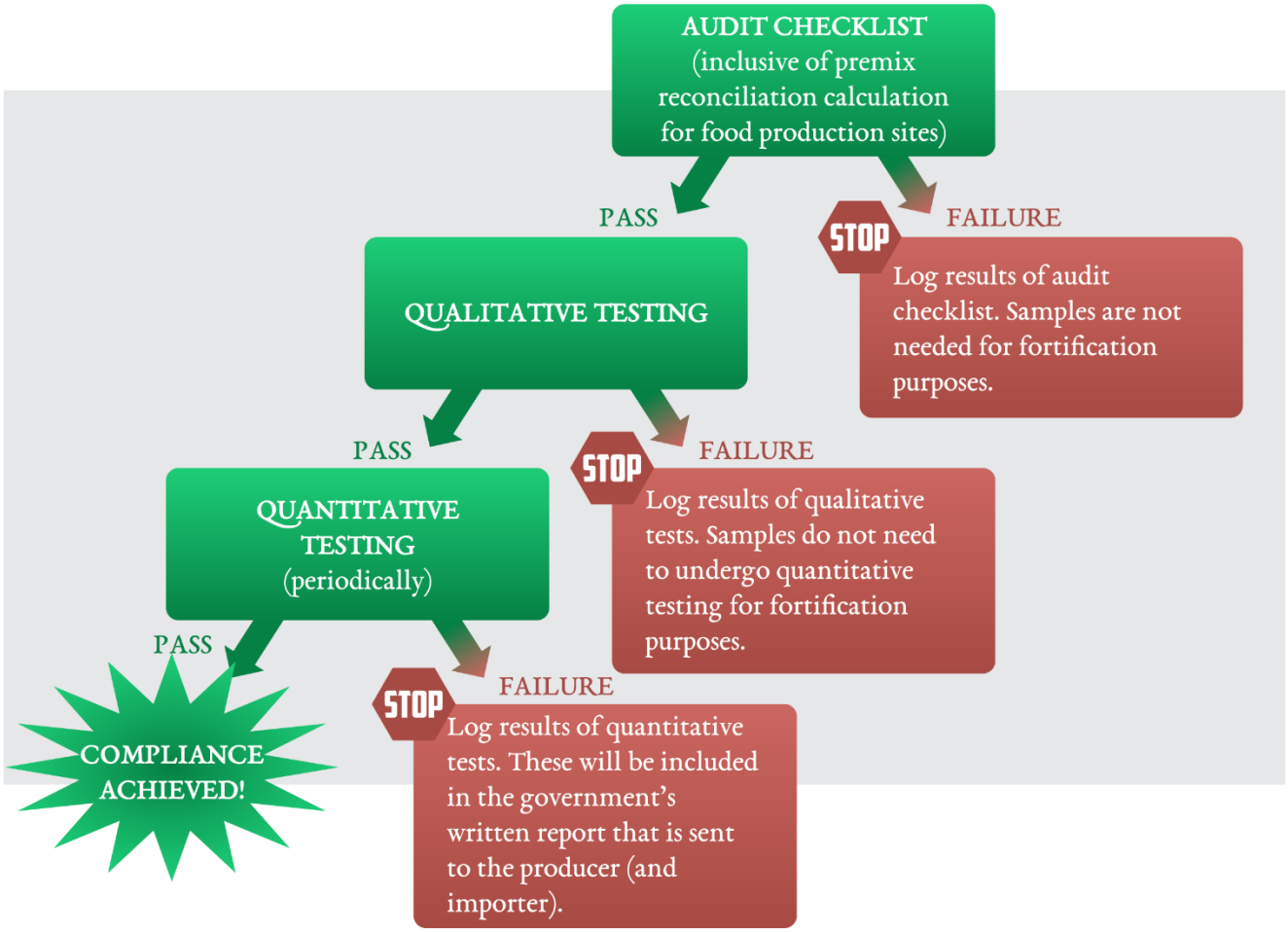
Production Sites:

If composite samples representing the site's production line and warehouse fail to fulfill the criteria established for "passing" the quantitative analyses, the site is classified as non-compliant for that assessment.[aa] The site should be promptly notified in writing as described further in Section 1.6.2.

Imports:

If the composite sample collected at the border fails to fulfill the criteria established for a consignment to "pass" the quantitative portion of the assessment, the consignment is classified as non-compliant. It should not be allowed to enter the marketplace. The importer and foreign production site should be promptly notified in writing as described further in Section 1.6.2.

Figure 5: Stepwise Approach for Compliance Determination



[aa] The food producer can decide to send the stored reference sample(s) for quantitative testing at a third-party laboratory to refute the classification.

Implementing a stepwise approach (Figure 5) for determining compliance inherently places emphasis on the process of fortification since qualitative and quantitative tests on the end product are not conducted if the food production facility or the imported consignment receives a failing score on the checklist. This lends itself to increased efficiency and ensures that personnel, supplies, and financial resources are not wasted on testing product samples that may fail based on poorly managed quality assurance and control measures at food production facilities. The results of audits and inspections are then utilized to report compliance as explained in Sections 1.6.2 and 1.6.3.

All qualitative and quantitative testing for domestic production sites and imports should be in line with a national sampling plan.

1.6.2 Reporting Food Production Site and Imported Consignment Compliance

As described above, compliance determination should be based on the results of the audit checklist, the qualitative tests, and the quantitative tests for the individual food production sites and for each imported fortified consignment, where relevant.

Following every audit and inspection visit, a final written report should be sent to the respective food producer. It is the prerogative of government stakeholders to stipulate the allowable timeframe for delivery. A general recommendation is between two and four weeks after samples are collected, depending on the sophistication of the country's established monitoring system and laboratories. The written report should list the site's classification – compliant or noncompliant - along with the results of the audit checklist, the qualitative tests, and the quantitative tests (when relevant) as illustrated in Figure 6. Furthermore, it should include recommendations for improvement, any necessary corrective actions, and a timeframe for a follow-up visit (as required). In the case of an imported consignment, government regulators may provide a written report to each respective importer and foreign food producer, though the items included in the reports will differ slightly from those provided to domestic food producers.

Figure 6: Production Site Compliance Reporting, Key Elements

Food Manufacturing Site: Best Flour Mill
Site Visit Date: 10 December 2017
Inspector: Tom Jones
Overall Classification: Compliant

Compliance Details:

Audit Checklist Score: 92% - Pass
Criteria: Must receive 76% or higher to pass

Qualitative Tests: Pass
Test type: Iron spot test
Criteria: Test must indicate presence of iron (red spots) in all samples to pass

Quantitative Tests: Pass
Test type: Mass spectrometry – iron
Criteria: All samples must comply with the fortification standard specifications for relevant micronutrients to pass

This information should be included as part of the larger written report of the site visit

1.6.3 Reporting National-Level Program Compliance

National-level compliance reporting is reliant upon the compliance determination data collected from all food production facilities that are expected to observe the food fortification regulations and standards. For countries that import fortified foods, national-level compliance reporting should include compliance determination findings relevant to imported consignments as well.

Assuming stakeholders choose to adopt the stepwise method for determining compliance at food production sites and among imported consignments as outlined in Section 1.6.1, the following primary indicators are recommended to serve as the main statistics for reporting national-level compliance:

1. Percent of assessed domestic food manufacturing sites that "pass"[bb] the entire audit and inspection visit (during a specified period of time).
2. Percent of assessed imported fortified food consignments that "pass" the entire audit and inspection (during a specified time period) – where relevant.[cc]Specifically, this includes how many consignments arrive with accurate Certificates of Analysis and labelling ("audit") and how many consignments have passing test results based on the import sampling plan ("inspection")

[bb] Food manufacturing sites that "pass" the audit may still be required to make corrective actions.

[cc] Note that the compliance determination methodology for imported consignments will differ slightly from that used for domestic food production sites given that regular access to the foreign facilities for auditing purposes is not possible. However, the methodology needs to be equitable.

In publications, the primary indicators should be accompanied by additional information to provide a basis for the numbers presented. Some key elements to include in a report of the country's food fortification program are listed in Figure 7. Each is followed by an example in blue. The report should present statistics about production sites and imported consignments separately.

Figure 7: National-Level Compliance Reporting, Key Elements

1. Type of food – Wheat flour fortified with folic acid and iron
2. Time period for the report - 1 January – 31 December
3. Percent of food production sites and/or imported consignments under the purview of the fortification regulations that were actually assessed during the specified time period. If the report does not encompass 100% of the relevant food production sites and imported consignments, it should explain the selection process.

   100% of food production sites that are required to add micronutrients

   100% of imported consignments that are required to have added micronutrients
4. Primary indicator(s) used to report national-level compliance.
   a. Percent of assessed domestic manufacturing sites that passed the entire audit and inspection, encompassing the audit checklist, qualitative tests, and quantitative tests (when relevant).

      68 % of assessed food production sites
   b. Percent of assessed imported consignments that passed the entire audit and inspection, encompassing the audit checklist, qualitative tests, and quantitative tests (when relevant).

      80% of assessed imported consignments
5. Description of the pass/fail parameters for the primary indicator(s) and any components thereof. The report should also identify the testing techniques used.

   Audit checklist: Need to receive 76% or higher to pass

Qualitative tests: All results must demonstrate the presence of the marker fortificant (iron) to pass; iron spot test utilized

Quantitative tests: All results must comply with the fortification standard specifications for relevant micronutrients (iron) to pass; mass spectrometry of iron utilized

Note that the remaining tables in this section are relevant for national-level compliance reporting of any fortified product. However, to vary the food items highlighted in this document, those presented below pertain to *iodized salt that is domestically produced*; imported consignments are therefore not applicable.

If the country does not require all sites that manufacture the target product to fortify (i.e.: village processing plants), a descriptive table similar to Table 5 will help the reader to gain a better understanding of the industry landscape and the program's potential impact.

Table 5: Industry Landscape for Country A, Iodized Salt

Category of Production Sites	Number of Salt Production Sites n (% of total sites)	Percent *Total* Salt Market Share Represented
Domestic salt processing plants	85 (100%)	100%
Domestic salt processing plants required to fortify[dd]	30 (35.1%)	81% *(all fortifiable)*
Domestic salt processing plants required to fortify that had an audit and inspection visit this reporting period	30 (35.1%)	81% *(all fortifiable)*

Furthermore, the program report should include a summary table that presents compliance statistics by performance category in addition to the fortifiable market share held by each group (see Table 6). **Fortifiable market share** is the proportion of a particular staple food that can realistically undergo (adequate) fortification. It is highly influenced by the technological sophistication of the targeted industry. For example, row three, column two specifies that 19 out of the country's 30 salt processing plants under the purview of the fortification regulations and standards (63.3%) complied with the audit checklist, the qualitative tests, *and* the quantitative tests. This is a primary statistic used for national-level compliance reporting. Those 19 sites make up 56% of the fortifiable salt market share in the country, as indicated in row three, column three. The 19 compliant sites hold 45% of the country's *total* salt market share (inclusive of iodized and non-iodized salt) as shown in row three, column four.

Table 6: Annual Compliance Summary Table[ee] for Country A, Iodized Salt

Number of salt production sites included in reporting period: 30

Compliance Assessments	Compliant Salt Processing Plants, n (% of total sites required to fortify)	Percent *Fortifiable* Market Share Represented	Percent *Total* Salt Market Share Represented
Audit Checklist *	25 (83.3%)	87%	70%
Audit Checklist + Qualitative Tests	23 (76.6%)	64%	52%
Audit Checklist + Qualitative Tests + Quantitative Tests	19 (63.3%)	56%	45% *(.81 from Table 5 x .56 from row 3 column 3)*

* Common issues for sites this reporting period: improper storage of premix and additives, inconsistent monitoring records, and lack of adequate pest control

Given that the audit checklist is the gateway tool for compliance determination, stakeholders may benefit from further illumination of the checklist scores as demonstrated in Table 7. For instance, if many of the noncompliant food production facilities missed the passing score threshold by just a few points, it's likely that a few minor adjustments to their internal monitoring practices would solve the problem. Inspectors should explain the issues before leaving each site to enable the food producers

[dd] Non-industrialized salt processing plants are exempt from fortification in this case.

[ee] Figures presented are hypothetical and for demonstration purposes only.

to address them in a timely and appropriate manner. However, if a significant proportion of the noncompliant food production facilities earned scores well below the passing threshold, that could signify a pervasive problem at food production sites that needs to be better understood and addressed. If the checklist is new, stakeholders should also revisit the scoring system to be sure it is appropriately designed and implemented. An example of the latter situation is presented below. Note that the data presented in Tables 5 and 6 are unrelated to the data presented in Table 7 given the desire to demonstrate a high failure rate with numerous sites in the lowest category.

Table 7: Annual Audit Checklist Summary Table[ff] for Country B, Iodized Salt

Number of salt production sites included in reporting period = 40

Checklist Score	Compliant Food Production Sites, n (% of total sites required to fortify)	Percent *Fortifiable* Market Share Represented
<25 (fail)	15 (37.5%)	30%
25-50 (fail)	2 (5.0%)	5%
51-75 (fail)	5 (12.5%)	16%
76-100 (pass)	18 (45.0%)	49%

[ff] Figures presented are hypothetical and for demonstration purposes only.

Part II: Aiming for Success: Effective Practices for Overcoming Common Challenges

To increase the consistency of regulatory monitoring activities and compliance with fortification regulations and standards, an enabling environment should be prioritized. An actionable way to lay the foundation for an enabling environment is for stakeholders to agree upon the most significant issues that hinder the program's success and to work cohesively to address them in an efficient and effective manner. Part II of this document supports that aim by outlining six practical actions that will help stakeholders to overcome challenges that are common to countries worldwide.

2.1 Add Food Fortification Activities to the Existing Methodology for Monitoring Food Quality and Food Safety

Challenges addressed: Lack of trained inspectors, limited funding/budget allocations, broad geographical distribution of industry, and negative rapport between regulators and industry

Food safety programs are essential for maintaining consumer safety and satisfaction. They are also important for government leaders and food manufacturers alike who desire to advance foreign trade arrangements. For those reasons, food safety programs have become an increasing priority worldwide. Once established, they are usually maintained and even improved over time. With this in mind, industrial food producers often institute one of the following management systems focused on food quality and safety:

1. ISO 9001:2015[gg] which is part of the ISO 9000 series;
2. ISO 22000:2005[hh] which is part of the ISO 22000 series and Food Safety System Certification (FSSC) 22000;
3. Hazard Analysis and Critical Control Points (HACCP); and
4. Good Manufacturing Practices (GMPs)[ii].

Each of these management systems requires food manufacturers to establish and execute internal monitoring QA/QC procedures to facilitate the production of foods that are high in quality and safe to consume. When a food fortification program commences, the QA/QC procedures pertaining specifically to the new public health initiative should be integrated into each site's existing management system.

Similar to what takes place at food production facilities at the start of a fortification program, government regulatory agencies should integrate fortification-monitoring activities into existing mechanisms for monitoring food quality and safety at food production sites. For example, instead of conducting two visits - one for monitoring food fortification and another for monitoring food safety and quality - a single visit is suggested. This is expected to increase the sustainability of regulatory monitoring efforts.

With this integration approach in mind, stakeholders should develop an audit checklist that addresses food quality, safety, *and* fortification. A checklist framework, found in Appendix I, can be used as a

[gg] This standard was developed by the International Organization for Standardization. As the name suggests, this entity develops voluntary, internationally recognized standards, which help to make companies worldwide comparable in terms of business practices and product quality, safety, and reliability. ISO is not an acronym; it is derived from "isos" in Greek, meaning equal. In every language, ISO is used.

[hh] Ibid

[ii] The specifics of GMPs may vary by region or country.

guidance tool for this process. Alternatively, any existing mechanism for assessing food quality and food safety can be modified to include key fortification items/questions. Prior to finalizing the checklist, government stakeholders should review the document with industry representatives. This ensures that the checklist captures the internal monitoring (QA/QC) procedures conducted by food manufacturers. It also guarantees that the proposed checklist items are both relevant to the program and technically feasible. Prior to using the audit checklist for monitoring and compliance determination, it is imperative to field test the tool and thoroughly train government food inspectors.

While the approach to combine the visit for monitoring food fortification with the visit for monitoring food quality and safety requires upfront planning and inspector training, it is ultimately expected to decrease the burden on the lead government agency and its inspectors. Though more time will be required for each production site visit, the facilities will be assessed less frequently overall. Inspectors will thus travel less, which gains them time to do other work and saves on transportation costs. Food manufacturers will be satisfied because the combined visit will decrease staff and production interruptions.

Government stakeholders need to determine the appropriate number of visits and the level of detail required for each. At the beginning of a program, inspectors may need to visit food production facilities frequently. When a fortification program is running appropriately and at-scale, however, two or three times per year is generally sufficient.

2.2 Develop a Computerized Management Information System for National and Subnational Record-Keeping

Challenges addressed: Delayed or nonexistent feedback after inspector visits (which plays a role in negative rapport between sectors) and lack of timely responses to problems

Regulatory monitoring activities capture a significant amount of information about the fortification program, which can be used to identify problems, determine compliance, track trends, and infer the likely program impact, among other things. Given the illuminating role of regulatory monitoring activities and the resources required to carry out such activities appropriately and on a reoccurring basis, the collected data should be held to a high regard.

Under manual monitoring schemes, data and relevant reports are transferred by hand or by mail. There is a risk of losing the information before it reaches the intended recipient. Additionally, manual monitoring schemes are relatively slow, resulting in delayed feedback to food producers. Finally, the amount of time required to manually input data obtained from food producers and laboratories into a computer at the lead government agency is burdensome. As such, employees are less likely to spend additional time collating, analyzing, and interpreting data on a national scale to inform program changes.

To tackle these challenges, some countries have developed management information systems (MISs), which are platforms used to digitize the monitoring process and facilitate rapid data collection, collation, and analysis. Data are entered in real time as authorized personnel gather the information from food production facilities, import sites, and laboratories. In addition to the benefits of increased speed and efficiency, an MIS can alert regulatory authorities to potential problems, thus facilitating swift corrective action. Most systems auto-generate graphs and charts from the data entered. This enables easy interpretation of the program's status and progress, thus catalyzing more-appropriate

program adjustments. Additionally, since an MIS connects all stakeholders, written reports following audit and inspection visits can be shared in a timely, more cost-effective manner.

Each MIS must be well designed, user-friendly, secure, and adaptable. All relevant entities should be involved in the planning process to ensure feasibility, create buy-in, and foster trust. The system outputs need to be practical. Those charged with inputting the data must be adequately trained and have access to a computer or another hand-held device with at least periodic access to the Internet. The lead government agency may consider providing a subsidy to individuals who use their own mobile devices to log onto the MIS for reporting purposes rather than purchasing laptops and hand-held devices for the program. Finally, those responsible for analyzing and interpreting data to inform program improvements must do so at least on an annual basis.

In **Egypt**, a web-based MIS for the country's wheat flour fortification program was launched in 2011 as an alternative to the laborious and unreliable manual procedure of data processing. Once it was established, wheat flour millers were expected to input the following information on a daily basis: premix inventory, premix reconciliation calculation, feeder calibration records, and qualitative test results. Note that the required indicators were predominantly focused on the process of fortification as opposed to the end product. At laboratories, designated staff entered quantitative test results into the system as well. When the MIS received data indicative of low premix inventory or over/under fortification at a food production site, it generated alerts for the relevant parties. Only those individuals who had active login credentials were granted access to the MIS, and only to applicable sections of the system. These security measures were put into place to avoid disclosure of production data to competitors and the general public. An initial challenge to the MIS in Egypt was computer illiteracy. Although political instability in the country halted the wheat flour fortification program, when in use, the MIS helped to improve data collection and analysis [8].

Stakeholders from countries without a computerized data aggregation system in place may consider a virtual MIS designed by Project Healthy Children and the Global Alliance for Improved Nutrition called *FortifyMIS*. Developed in 2017, *FortifyMIS* captures favored characteristics of existing MISs, which were elucidated during a global mapping exercise [9], while also addressing common implementation barriers. *FortifyMIS* is available worldwide for country-specific use and can be adapted to capture data on any food vehicle. See Appendix III for more details.

2.3 Clearly Define Government Agency Responsibilities

Challenges addressed: Lack of coordination among government stakeholders and limited financial and human resources.

In many countries, monitoring foodstuffs is the responsibility of more than one government agency. To effectively utilize personnel time and resources and to facilitate consistent implementation of monitoring activities, relevant agency representatives should work cohesively to map out and document the responsibilities of each entity. Agency duties can be written into the country's fortification monitoring plan or can form the foundation for a signed multi-agency memorandum of understanding, for example.

Stakeholders in the **Solomon Islands** have drafted national guidelines for the control of domestically milled and imported foods. In the case of imports, a Memorandum of Understanding aims to be established, which specifies the duties of Customs, Agricultural Quarantine, the Department of Health and Medical Services, and food importers. In this case, involving multiple agencies and creating clear

responsibility distinctions are deemed important because of the high level of food imports in the Solomon Islands and the limited number of food inspectors to carry out food control tasks.

In the **United States**, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) are both tasked with food control. The distinction of efforts is related to the type of food, irrespective of whether it is fortified. The FDA regulates 80% of food products in the United States. The USDA only oversees processed egg products, domestic and imported meat and poultry (except game meat), and most products that contain those items (such as pizza).[jj]

If clear responsibilities are not determined during the program's planning stage, it will be necessary to do so prior to implementing any MIS in order to maintain strict data security. For instance, if one ministry oversees import monitoring activities and another oversees external monitoring activities, they should not be able to access or alter each other's data.

2.4 Develop and Implement Realistic Penalties for Industry Noncompliance

Challenges addressed: Lack of will to fortify and high competition with producers that do not fortify their products

Given that non-compliant food production sites and imported consignments impact the overall success of a food fortification program, stakeholders need to develop and enforce realistic penalties on poor performers. In some countries, government stakeholders may determine it is in the best interest of the program to involve food producers when establishing penalties. At the very least, government stakeholders need to inform food manufacturers about all potential consequences before the fortification program begins and whenever a new food production facility is established.

Regulatory agencies should apply penalties progressively based on the severity and duration of each violation. A first-time offender should receive a notice of shortcomings, but generally a heavy penalty is not warranted. Instead, the inspector should help company staff understand the problem thoroughly, so they can implement the appropriate corrective measures. The inspector should then grant a reasonable amount of time for the producer to remedy the issue before returning to assess the situation again.

If non-compliance persists after two follow-up visits, especially if management is deliberately challenging the legal requirements for fortification, the designated regulatory agency should impose penalties as indicated in the country's regulatory framework for the program. Consequences may include fines, public naming of the company at fault, seizure of warehouse stock, and food production facility closure, to name a few. Individual personnel may also be held responsible and penalized in certain cases. Fines need to be in excess of the costs food production facilities save by not fortifying for a significant period of time. Otherwise, the food manufacturer may choose to pay the fine instead of fortifying. Public naming should be used with caution given that consumers may retain a negative view of the company long after it improves its practices. Where facility closure is likely to severely interrupt the food supply chain, this consequence should be used as a last result. Regulatory agencies should enforce penalties objectively and consistently across the industry and in a timely manner.

[jj] For additional details, refer to https://ncfsma.ces.ncsu.edu/wp-content/uploads/2018/01/FDA-versus-USDA.pdf?fwd=no

The following penalty examples were extracted with permission from a training manual, *Planning, Implementing, and Monitoring National Food Fortification Programs*, which was developed by the Food Fortification Initiative.

In **Liberia** [10], penalties can include one or a combination of the following:

1. Civil fine of no less than US$1000, taking into account the severity of the violation, the amount of product impacted, potential harm to consumers, and whether it is a repeat violation;
2. Order to cease and desist from activity that does not comply with the regulations;
3. Confiscation and destruction of food that does not meet requirements;
4. Publicity of unfavorable inspection; and
5. License restriction, suspension, or revocation.

In **Brazil** [11], health violations may be punished, alternately or cumulatively as follows: warning, fines, arrest of products, destruction of products, interdiction of products, suspension of sales and/or product manufacture, cancellation of product registration, partial or total interdiction of establishments, prohibition of advertising, cancellation of company's operating permit, etc. This applies to fortified flour and other foodstuffs.

In **Canada** [12], imported flour and flour-based products (such as crackers and pasta) that do not pass inspection are either returned to the manufacturer or confiscated and destroyed.

2.5 Develop and Implement Realistic Incentives to Encourage Industry Compliance

Challenges addressed: Lack of will to fortify, high financial input required by industry, low industry engagement, lack of technical knowledge within the industry, and negative rapport between sectors

Though penalties can – and in certain cases should - be leveraged to increase industry compliance with fortification regulations and standards, government leaders must also recognize the power of positive incentives. Food fortification does not occur without the ongoing commitment of food manufacturers. They allot time for their staff to implement and monitor the program. They also provide financial resources to cover the cost of equipment, premix, and product testing. The vital contribution of food manufacturers should be recognized by the public sector. As with penalties, incentives should be discussed during the program's planning phase.

Given the costs associated with purchasing fortification equipment and the ongoing procurement of premix, economic incentives are well received by industry leaders from a practical standpoint. Economic incentives also send a message to food manufacturers that the national government is willing to share in the rewards and risks of the program.

In several countries, including **Rwanda, Burundi, and Liberia**, premix is part of the government's list of essential drugs [13]. It was given this designation based on the critical role of vitamins and minerals in maintaining healthy lives. Under the arrangement, premix is exempt from import duties, which would otherwise range from 15-45% of the total premix cost [14]. Government representatives leading the effort to exempt premix from import duties need to make certain that all micronutrients to be included in the premix are on the essential drug list in the proper form. This will avoid contentious issues, for instance where electrolytic iron is on the essential drug list but where the fortification standard requires iron as ferrous sulfate. Some countries also categorize feeders,

qualitative testing supplies, and other fortification materials as duty free for the same reason. Where these incentives are provided, regulatory authorities need to inform all tax officers so confusion and wrongful collection of funds does not ensue.

National governments may also consider purchasing feeders for the food production facilities involved in fortification. This is a one-time expense for equipment that should be durable for many years. While such an incentive may get the industry to commence fortification, it may not, however, have the staying power to encourage ongoing compliance. Additionally, when feeders are provided at no cost, food producers may expect that other fortification inputs, such as premix, will be donated as well. On principal, donations of premix should be avoided as premix is a recurring cost and reductions or cessation of premix donations may negatively impact the sustainability of the entire program.

Another well-received incentive, for use once the program has broad coverage of adequately fortified foods, is commending food producers and importers publicly. This can be done by printing the names of all food production sites and/or importers that are classified as compliant on the website of the main regulatory agency or on social media. This approach helps consumers recognize compliant brands, which can influence purchasing patterns. To avoid distribution of incomplete information, however, public praise should only be used if all producers and importers have received a compliance classification during the specified period.

Government stakeholders can also offer praise to well-performing food production sites in the form of annual awards to be displayed in building lobbies and staff break rooms. These plaques, certificates, or posters should provide some basic information about the program and appreciate company employees for their dedication to supporting the public health initiative. Similarly, the Standards Organization of **Nigeria** has proposed a new quality marker in the form of a National Quality Award for food producers that consistently comply with the fortification regulations and standards as a way to keep industries accountable [15]. Along with this, producers should be informed whenever food fortification is associated with a positive health impact. For instance, if a national surveillance system shows that the country's birth defect prevalence is decreasing or a health survey demonstrates improvements in the population's micronutrient status since the start of the fortification program, relevant food producers should be notified and thanked for their efforts.

Another suggestion is for national governments, working in collaboration with other fortification stakeholders, to organize and fund trainings for industry employees with fortification responsibilities. For instance, prior to commencing fortification, relevant staff must be guided in equipment and premix procurement, feeder installation and calibration, the fortification process, relevant internal monitoring QA/QC procedures, and what to expect during inspector visits. They should also be well informed about the present health status of the population and the expected benefits of fortified foods.

General training recommendations include:

1. Keep each group to a manageable size, which may require hosting multiple training events throughout the country. Smaller group sizes promote interaction between hosts, facilitators, and participants.
2. Utilize multiple teaching methods such as discussions, demonstrations, worksheets, and practical activities during the trainings to increase understanding and retention of information.

3. Involve at least one individual who is highly experienced in fortification to offer instruction, share country-specific examples, and answer questions. This person should avail him/herself to further communication with the participants to assist them as the fortification program gets underway.
4. Involve at least one individual who can relate food fortification to health and humanity, such as a doctor or surgeon who treats individuals affected by the clinical consequences of micronutrient malnutrition or a parent who is raising a child born with spina bifida (a birth defect associated with low maternal folate levels around the time of conception).

Countries leaders may consider utilizing a training-of-trainers approach for the initial event to develop a sense of program ownership. If decided upon, participants would be expected to train colleagues upon returning to their respective food production facilities. Additionally, participants who are highly committed to the fortification program could be utilized as training facilitators. For instance, two individuals from the event held in Province A would be asked to facilitate (under the guidance of an expert), a few sessions of the training in Province B.

In addition to the government's role in organizing and funding the trainings, a representative of the designated regulatory agency should be present for the opening statement of each event to welcome the group and express support.

Trainings can also be done in the form of exchange visits whereby fortification stakeholders travel to another country to learn about successful program implementation and monitoring practices. This opportunity can include exchanges within a region or from one continent to another. For instance, employees of food companies in **Bangladesh** have visited Kenya and Tanzania to learn about the fortification process and fortification monitoring from local food producers [16]. Providing this opportunity demonstrates support from the government of Bangladesh and motivates industry representatives to maintain their program-related responsibilities upon returning. However, it is important to note that exchange visits may require significant funding for delegate travel and is time consuming for the host-country.

A final compliance incentive is for food manufacturers to develop partnerships with government institutions, such as the armed forces and public schools, along with food aid providers, such as the World Food Program (WFP) and World Vision, all of which need to acquire high quality, nutritious foods in large quantities on a consistent basis. Engaging bulk purchasers of locally produced fortified foods is an attractive option for food producers due to the inherent financial gains and to program managers since it strengthens compliance with fortification regulations and standards.

In **Rwanda**, under a voluntary fortification scheme, few millers expressed interest in adding vitamins and minerals to flour given concerns about market competition and costs. The one exception was the country's only producer of maize flour. When WFP approached this company to provide fortified maize flour for its food aid programs, management agreed given the economic boost this regular bulk purchaser would provide. As a result, production of adequately fortified maize flour from this producer commenced and is proving sustainable [17].

2.6 Facilitate Non-Traditional Partners to Obtain Program Performance Data

Challenges addressed: Lack of trained inspectors, limited funding/budget allocations, geographical distribution of industry, lack of public support for fortification, and high competition with non-fortifying producers

Food fortification programs are built upon a principle that multi-sector collaboration is a key to success. Though government agencies are typically responsible for carrying out external, import, and commercial monitoring activities, entities representing other sectors can be valuable partners in program monitoring efforts and in raising awareness about fortification among the public.

In **Guatemala**, university students were recruited to collect food product samples from retail stores throughout the country when the number of inspectors was limited due to a budget crisis. This helped to maintain regulatory monitoring efforts despite financial constraints, which in turn enabled stakeholders to assume the program's status despite the fact that samples collected from commercial sites are not viable for compliance determination. Additionally, involving university students helped to raise awareness about the fortification program among the young adult population and offered individuals valuable experiences that could be leveraged in the working world.

Consumer groups, community organizations, and locally based health facilities are other entities that can be called upon to support monitoring efforts. As with university students, these entities most often collect samples at commercial locations or even from households and schools (however, the latter two are not considered regulatory monitoring). This was the case in one region of **Kyrgyzstan** where volunteers from village health committees and employees of community-based Primary Health Care units supported monitoring and advocacy efforts [18]. The project had two key components. The *first* was for community members to visit households to test samples of salt for the presence of iodine and to inform inhabitants about iodine-deficiency disorders and their prevention. For the project, rapid qualitative test kits were used to indicate the presence of iodine. The *second* component targeted salt retailers. As with the household component, samples of salt were tested for the presence of iodine and the retailers were educated. However, in this component, retailers received their own test kits. They were encouraged to test salt at wholesale markets before purchasing any for resale at their stores. Follow-up visits to households and retail markets were conducted at 5-7 months and 18-21 months. In Area 1 (Jumgal District), the number of households with iodized salt increased from 71.0% initially to 97.5% at the second follow-up. In Area 2 (Ak-Tala, At-Bashy, and Naryn Districts), the percent of households with iodized salt increased from 65.2% initially to 90.2% at the second follow-up. The authors who wrote about this project concluded that implementing the rapid qualitative test in front of household members had a powerful effect coupled with the educational aspects of the visits. It is likely that testing salt in nearly two-thirds of households in the region within a short period of time played a role in disseminating the message to households that were not visited. The popularity of the test kits among retailers led to increased procurement of iodized salt (though sufficient iodization was not determined), and therefore more iodized salt purchases by individuals.

In **India**, the Voluntary Organization in Interest of Consumer Education (VOICE) raises awareness among the general population about the importance of nutrition, helping individuals to express their right to adequate intakes of essential vitamins and minerals. A campaign focused on vitamin A reached more than 20 large cities in the country. Additionally, volunteers facilitated the analysis of vitamin A in fortified edible oils available to consumers in the marketplace to evaluate the validity of the label claims [19].

Further Discussion and Dissemination

Areas Requiring Further Discussion

1. **Determining compliance when a country has food production sites of various sophistication levels**

The audit checklist is the initial means for assessing compliance at food production sites. Though fortification is most easily implemented and monitored at industrial facilities, certain countries also include small- and medium-sized production sites in the scope of their regulations. Some of the items alluded to in the audit checklist framework (Appendix I) may not be established at non-industrial facilities, however. In countries that require all manufacturers of the target product to fortify, it will be necessary to prepare a checklist that can be fairly and feasibly implemented across the industry – one that balances the importance of food quality, safety, and fortification with the reality of manufacturing food in facilities that may lack advanced technology, personnel, and comprehensive control systems.

2. **Further leveraging the internal monitoring practices of food producers to reduce the burden on regulatory agencies**

Food producers record a significant amount of data throughout each day as part of their internal monitoring QA/QC practices. In the case of Egypt, food manufacturers uploaded key indicators to the country's MIS on a daily basis to help regulators track the program. As more countries turn to virtual systems to aid in monitoring efforts, stakeholders should discuss the following questions:

1. How frequently should food producers be expected to share data with government regulatory agencies?
2. What basic indicators are most important for assessing fortification practices at food production sites?
3. Will regular submission of basic indicators through a virtual MIS lead to timely recognition of mistakes or miscalculations and therefore improve industry compliance?
4. Will regular submission of basic indicators through a virtual MIS decrease the burden on government food inspectors to visit food production sites?

3. **Using available resources wisely and obtaining the necessary budget allocations**

A commonly expressed barrier to consistent monitoring practices is a lack of sufficient resources. To address this challenge, stakeholders are encouraged to develop a realistic regulatory monitoring framework that balances best practices outlined in this document with the resources that are available. As part of this process, stakeholders need to consider how to maximize the use of accessible resources in order to minimize wasteful spending. For example, this guidance document appeals to government agencies to clearly differentiate their responsibilities to avoid duplication of efforts. It also recommends a single audit checklist that incorporates food quality, food safety, and food fortification to save on the transportation costs associated with monitoring and to make the best use of inspectors' working hours. Furthermore, a decreased emphasis on quantitative testing will lessen the burden on laboratories and lower related costs.

Even after government stakeholders prepare a detailed, economical budget for regulatory monitoring, they may still find that obtaining the necessary resources from year-to-year is a challenge. International partners committed to the success of national fortification programs should seek to better understand

funding barriers to inform discussions about how to realistically maintain regulatory monitoring activities under fluctuating budget allocations.

Dissemination and Use of this Policy Guidance Document

This policy guidance document will be disseminated through a broad network of international partners, donors, and implementing and coordinating agencies including:

- Ministries of Health
- National regulatory authorities
- Agencies of the United Nations
- Regional health communities
- Producers of fortified foods
- Producers of vitamin and mineral premixes
- Universities.

Stakeholders responsible for workshops and trainings pertaining to fortification monitoring are encouraged to use the guideline as a foundation for content development and participant discussion.

At the global level, the details of this policy guidance document will be used to update and inform existing manuals that guide food producers and government food inspectors through the protocols of regulatory monitoring and compliance determination.

As new food fortification programs are initiated and existing programs become more robust, further best practices related to regulatory monitoring and compliance will be revealed. To accommodate the latest information and offer continued support to program leaders, this document will be periodically revisited and revised.

Additional Resources

For additional tools designed to aid fortification stakeholders as they plan, implement, and monitor food fortification programs, refer to Annex I. Contact information is provided for each item. They include:

1. A population-level data-collection tool called *FORTIMAS*, which tracks trends in coverage of adequately fortified foods and the micronutrient status of the target population;
2. A virtual monitoring tool called *FortifyMIS*, which was introduced in section 2.2 as a means of tracking monitoring data and identifying problems in real-time;
3. Online training courses covering the topics of flour and rice fortification;
4. Training-of-trainers events addressing the topic of monitoring flour fortification programs; and
5. A service-focused platform called *ENABLE*, which is designed to help fortification stakeholders establish, optimize, and maintain food fortification and food safety programs.

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Appendices

Appendix I: Audit Checklist Framework

It is recommended for government stakeholders to use this basic framework as guidance for the development of an audit checklist - encompassing **food safety, food quality, and food fortification** - to be implemented by government food inspectors during their visits to food manufacturing sites. For countries that have an existing checklist, this framework should be referenced for adaptation purposes as in most cases food fortification items (at a minimum) will need to be added. The checklist should be designed to help government food inspectors efficiently yet comprehensively review each site's internal systems and the procedures established to produce high quality, safe, and appropriately fortified foods. In countries where food production sites vary in technological sophistication and size, the checklist will need to account for potential limiting factors at non-industrial facilities while still providing a thorough and appropriate evaluation of the aforementioned categories. Embedding a scoring system into the audit checklist is suggested to facilitate production site compliance determination.

Food Production Site Operations

Food authority approvals and third-party quality standards

- Operating licenses
- Access control & security
- Food safety and quality certifications (if applicable)

Food Production Site Design

Appropriate space and functionality for the intended purpose

- Exterior and interior construction and appearance
- Ventilation and temperature
- Production lines
- Storage areas
- Employee workspace and facilities

Quality Management System

Quality management system established to provide foundation for responsible food production

- System manual
- Internal audit
- Management review
- Non-conformance, corrective actions

Food Safety

Food safety management tools in operation and working effectively

- Food safety policy
- Food safety team
- Hazard Analysis and Critical Control Points (HACCP)/Good Manufacturing Practices (GMP)
- Critical control points for food safety

- Foreign body
- Glass, metal, and stone
- Metal detection, screens, and sieves utilized
- Microbiological contaminants
- Foodborne toxins
- Hazardous materials
- Cleaning agents, engineering chemicals, pest control materials

Process Control

Appropriate procedures, work instructions, and records for operational and monitoring activities

- Standard Operating Procedures (SOPs)
- Production records
- Monitoring records

Fortification

Activities specific to the controlled production of micronutrient-fortified foods

- Quality Assurance (QA)
- Microingredient feeder/dosifier installation
- Microingredient feeder/dosifier calibration
- Premix feed rate
- Premix reconciliation (premix use vs. production output)
- Product packaging and labelling
- Quality Control (QC)
- Qualitative testing
- Quantitative testing

Personnel

Items related to defining, screening, monitoring, and developing the workforce

- Job descriptions
- Training schedules and records
- Health checks

Hygiene

Management of an organized, hygienic, and safe working environment

- Zone control
- Cleaning protocols
- Cross contamination
- Protective clothing
- Housekeeping
- Handwashing
- Human and product waste disposal

Pest Control

Monitoring and control of specific pests

- Pest entry control
- Pest control within the facility
- Production and storage area observation

Services

Control of air and water for food production

- Water quality
- Air quality

Suppliers

Assured raw material and packaging supply lines

- Supplier approval process
- Approved supplier list

Raw materials

Managing ingredients and packaging

- Receiving and storage
- Clear labelling

Traceability

Maintaining the identity of all components

- Recall for raw materials

Warehousing

Appropriate storage of raw materials, packaging, and finished goods

- Raw material acceptance checks
- Raw material release
- Premix certificates of conformity (or analysis)
- Premix storage conditions
- Stock rotation
- Stock labelling
- Rejected & quarantined material handling
- Finished product release criteria

Maintenance

Ensuring equipment is operating correctly

- Equipment cleanliness and functionality review
- Maintenance plan (internal/external)

Testing

Raw material, in-process, and finished product analysis

- Internal laboratory testing
- External laboratory testing
- Retained reference samples

Product Standards

Finished product definition

- Product specifications

Appendix II: Probability and Sampling

Overview

Taking 12 samples, as explained in the main document, is based on the statistical probability (reliability) that 85% of a facility's production complies with the specifications of the fortification standard and stakeholders can be 85% confident of that assumption.

Rationale

No one can be 100% confident that 100% of a food manufacturer's product adheres to priority quality and safety specifications, even when a production facility's audit indicates that a well-controlled system is in place given a passing checklist score. If inspectors wish to further infer the product's quality and safety, they can triangulate data by testing samples of the fortified product taken from the production facility.

According to The Mirriam-Webster Dictionary, a sample[kk] is:

1. A representative part or a single item from a larger whole or group especially when presented for inspection or shown as evidence of quality; and
2. A finite part of a statistical population whose properties are studied to gain information.

The "part" referred to in bullet a. is that which is sent to a laboratory for analysis ("study"), as stated in bullet b., to gain information about the facility's current production quality (using production line samples) and/or past production quality (using warehouse samples). Given that fortified foods - especially those made of solid particles such as flours and salt - cannot be homogeneously mixed during production, one single sample is not "representative" of the larger production. Therefore, a single sample is not sufficient for compliance determination; composite samples are recommended instead.

Practically, product sampling and subsequent qualitative and quantitative testing enable stakeholders to estimate, with statistical probability (reliability), that a proportion of a food manufacturer's product adheres to priority quality and safety specifications at a particular confidence level.

Stated mathematically, product sampling plans are grounded in the Acceptance Quality Limit (AQL), a predetermined value that is based on the level of risk deemed acceptable to buyers (consumers) and sellers (producers). It is used as a reference point during internal or external inspections of food production sites and their products.

Considering the number of samples[ll] to obtain, stakeholders first have to decide whether:

1. The sample size will be the prime determinant (meaning stakeholders choose it); or
2. The sample size will be determined by the level of risk stakeholders are willing to accept, which then stipulates the level of confidence and reliability.

[kk] https://www.merriam-webster.com/dictionary/sample

[ll] Sample size specifies the number of single samples; however, they should be formed into one or more composite samples before quantitative testing.

CASE 1: The Sample Size is Chosen by Stakeholders

This method assumes that the micronutrient levels found in a collection of product samples (the "population" in this case) are normally[mm] distributed and takes the position that "any sample size is valid" when calculating confidence limits. Table 1 provides a partial example of a one-sided normal tolerance limit k table that is used for this sample size option, where n is total number of samples, 100 γ is the confidence level in percent, and 100(1-α) is the percent of the population above (or below) tolerance limits. The reliability of the test results increases as the sample size increases.

Table 1: Factor k for One-Sided Normal Tolerance Limits

	90% Confidence (100γ = 90%)			95% Confidence (100γ = 95%)			99% Confidence (100γ = 99%)		
n	% Above/Below Tolerance Limits 100(1-α)			% Above/Below Tolerance Limits 100(1-α)			% Above/Below Tolerance Limits 100(1-α)		
	90%	95%	99%	90%	95%	99%	90%	95%	99%
2	NA	NA	NA	20.58	26.26	37.09	103	131.4	185.6
3	4.258	5.310	7.340	6.156	7.656	10.55	14	17.17	23.9
4	3.187	3.957	5.437	4.162	5.144	7.042	7.380	9.083	12.39
5	2.742	3.400	4.666	3.407	4.203	5.741	5.362	6.578	8.939
6	2.494	3.091	4.242	3.006	3.708	5.062	4.411	5.406	7.335
7	2.333	2.894	3.972	2.756	3.400	4.642	3.856	4.728	6.412
8	2.219	2.755	3.783	2.582	3.187	4.354	3.497	4.285	5.812
9	2.133	2.649	3.641	2.454	3.031	4.143	3.241	3.972	5.389
10	2.065	2.568	3.532	2.355	2.911	3.981	3.048	3.738	5.074
11	2.012	2.503	3.444	2.275	2.815	3.852	2.898	3.556	4.829
12	1.966	2.448	3.371	2.210	2.736	3.747	2.773	3.41	4.633
13	1.928	2.403	3.310	2.155	2.671	3.659	2.677	3.29	4.472
14	1.895	2.363	3.257	2.109	2.615	3.585	2.593	3.189	4.337
15	1.866	2.329	3.212	2.068	2.566	3.52	2.522	3.102	4.222
16	1.842	2.299	3.172	2.033	2.524	3.464	2.46	3.028	4.123
17	1.820	2.272	3.136	2.002	2.486	3.414	2.405	2.963	4.037
18	1.800	2.249	3.106	1.974	2.453	3.37	2.357	2.905	3.960
19	1.781	2.228	3.078	1.949	2.423	3.331	2.314	2.854	3.892
20	1.765	2.208	3.052	1.926	2.396	3.295	2.276	2.808	3.832

The formula for using k tables in this manner is:

$$Observed\ k = \frac{|Sample\ average - nearest\ specification\ limit|}{Sample\ standard\ deviation}$$

For example, imagine a scenario where eight samples are collected. The average micronutrient content of those samples and the standard deviation are 23.9 mg/kg and 1.4, respectively. The standard's specification limit states that the micronutrient content of each sample should be above 20 mg/kg. Using the formula above, those figures compute to an observed k of 2.756.

Next, stakeholders look for k values in the table around 2.756 with eight samples (yellow highlighted box). In this case, stakeholders can claim that 95% of the samples were in specification and they can be 90% confident of that claim. In the case of 12 samples with the same observed k, stakeholders can

[mm] If the data is not normally distributed then reliability is typically under-estimated. Transform the data to a normalized population and use the transformed numbers in the equation instead.

claim that 95% of samples were in specification and they can be 95% confident of that claim (green highlighted box).

If the number of samples taken was fewer than eight, stakeholders can make no claims using this table and will have to find one with lower levels of confidence and reliability.

An alternative approach along the same lines is to implement the "BETA.INV" function in Excel using the formula reliability = BETA.INV (1 – C , N – F , F + 1) where:

C = confidence desired (expressed as a decimal fraction, i.e. 85% confidence would be 0.85)
N = sample size
F = # of failures seen in the sample (# of samples not in specification)

The formula outputs the lower 1-tailed "exact" binomial confidence limit on the percent in specification observed in the sample.

Examples:

1. If no failures in a sample of 299, then 95% confidence in…
   = BETA.INV(1 – 0.95 , 299 – 0 , 0 + 1) = 0.99 (99% reliability)

2. If 2 failures in a sample size of 30, then 95% confidence in...
   = BETA.INV(1 – 0.95 , 30 – 2 , 2 + 1) = 0.80 (80% reliability)

3. If 1 failure in a sample of 5, then 95% confidence in ….
   = BETA.INV(1 – 0.95 , 5 – 1 , 1 + 1) = 0.34 (34% reliability)

4. If 1 failure in a sample of 5, then 80% confidence in ….
   = BETA.INV(1 – 0.80 , 5 – 1 , 1 + 1) = 0.51 (51% reliability)

5. If no failures in a sample of 12, then 85% confidence in ….
   = BETA.INV(1 – 0.85 , 12 – 0 , 0 + 1) = 0.85 (85% reliability)

Note that these examples specify the total number of single samples in one composite sample, such as 12 single samples as shown in example 5. The 85% confidence and 85% reliability would also hold true if laboratory technicians tested all the single samples individually. However, that is not recommended as a first-line testing approach due to the costs and time involved.

CASE 2: The Sample Size is Determined Based on the Acceptable Level of Risk

Table 2 below is adapted from the American Society for Quality's magazine Quality Progress[nn] of November 2013

If dealing with a severity rating of 5, such as Salmonella in ready-to-use therapeutic food, stakeholders want 99% of production to be in specification, and they want to be 95% confident of that claim.

With fortification, stakeholders have no potential injury (severity rating 1), so they can use the 85/85 model from Table 2 in the following equation:

[nn] http://asq.org/quality-progress/2013/11/expert-answers.html

Table 2: Risk Analysis

Severity Rating	Potential Effect [What can realistically happen if the product fails in a way that the test is intended to detect?]	Required Reliability/Confidence [Acceptance criteria]
5	Death	99/95
4	Serious injury	95/95
3	Moderate injury	90/95
2	Minor injury	90/90
1	No injury	85/85

$$N = \frac{\ln(1 - confidence)}{\ln(reliability)}$$

Where 'ln' is the natural logarithm or logarithm base e (use Excel's ln function: =LN(Number)) and confidence and reliability are expressed as decimals.

$$12 = \frac{\ln(1 - 0.85)}{\ln(0.85)}$$

As expected, the result presented above is the same result obtained using the "BETA.INV" function (see #5 in the examples shared for Case 1).

The impact of changing either confidence (assurance of the result) or reliability (percent of product in specification) can be seen below:

$$8 = \frac{\ln(1-0.80)}{\ln(0.80)} \quad 9 = \frac{\ln(1-0.85)}{\ln(0.80)} \quad 22 = \frac{\ln(1-0.90)}{\ln(0.90)} \quad 32 = \frac{\ln(1-0.95)}{\ln(0.95)} \quad 90 = \frac{\ln(1-0.99)}{\ln(0.95)}$$

NOTE: The United States Food and Drug Administration, working under Title 21 Code of Federal Regulations CFR, takes 12 samples of fortified flour during flour mill inspections.

Conclusion

When considering sample size, confidence, and reliability, stakeholders must first determine whether they will specify a specific sample size or whether the sample size will be determined by the risk they are willing to accept. The k tables and "BETA.INV" function in Excel are used by stakeholders who wish to specify the sample size, the former being slightly restrictive as the lowest confidence and reliability in most k-tables is 90%. When risk is the primary determinant of sample size, stakeholders choose the confidence and reliability they are willing to accept and plug those figures into the logarithm formula, which results in the necessary sample size.

This appendix was generously contributed by Philip Randall with input from Quentin Johnson.

Appendix III: Additional Regulatory Monitoring Tools and Resources

The following table outlines existing tools and resources specific to regulatory monitoring, which fortification stakeholders can take advantage of as they plan, implement, and monitor fortification programs.

Regulatory Monitoring Tool / Resource	Objective	Targeted Users	Primary Implementer / Owner and Contact Information
FORTIMAS	A population-level data-collection approach based on sentinel site surveillance that tracks trends in a) household coverage of appropriately fortified foods and b) the micronutrient status of those regularly consuming appropriately fortified foods.	Program managers	Smarter Futures For more information, contact: Anna Verster at anna@annagram.nl or info@smarterfutures.net
FortifyMIS	FortifyMIS is a virtual management information system that can be accessed via a desktop computer, laptop, or handheld device wherever monitoring data are collected (e.g. production sites, import sites, and market sites). Data entry can occur while offline; data will be uploaded to the system once Internet is accessed. FortifyMIS simplifies the process of data collection for government food inspectors and food producers and enables food control agencies to remain informed about fortification practices and challenges.	Food producers, government food inspectors, laboratory staff, and program managers.	Project Healthy Children and the Global Alliance for Improved Nutrition (GAIN) For more information, contact: Laura Rowe at lrowe@phcmail.org or Corey Luthringer at cluthringer@gainhealth.org
Distance-learning courses about monitoring flour and rice fortification programs	The online courses guide participants in planning for monitoring; engaging in internal, external, import, and commercial monitoring activities; and collating, reporting, and using monitoring data. Videos, photos, and examples enhance the monitoring concepts introduced in the courses. Data collection forms are provided to facilitate country-level monitoring activities. The courses are available for groups of 10 or more people and are hosted on a virtual platform of Kansas State University.	Representatives of government ministries and partner organizations, flour and rice millers, food inspectors, and laboratory staff.	Food Fortification Initiative (FFI) and GAIN For more information, contact: FFI's Sarah Zimmerman at szimme2@emory.edu

Regulatory Monitoring Tool / Resource	Objective	Targeted Users	Primary Implementer / Owner and Contact Information
Training of trainers (ToT) for flour fortification	The goal of this TOT opportunity is twofold. First, it aims to increase the capacity of flour fortification stakeholders to plan, implement, and monitor well developed, sustainable flour fortification programs. Second, it trains participants about how to effectively share their fortification-related knowledge and skills with others. Prior to attending the TOT, participants are expected to complete an online training course (see row above for details) so that all arrive with a baseline level of knowledge. Topics covered at the training include: fortification and monitoring basics, multi-sector alliances, legislation and standards, premix, monitoring plans, equipping a mill for fortification, internal monitoring, and external monitoring.	Representatives of government ministries and partner organizations, flour millers, food inspectors, and laboratory technicians.	Food Fortification Initiative (FFI) For more information, contact: FFI's Sarah Zimmerman at szimme2@emory.edu
ENABLE Platform	The ENABLE platform is a set of integrated services designed to help stakeholders establish, optimize, and maintain food fortification and food safety programs. GAIN's Premix Facility provides affordable and quality-assured blends of vitamins and minerals. The Credit Facility provides access to finance for premix. The Audit and Assessment Facility is responsible for evaluating premix manufacturing sites, food production sites, food control agencies, and laboratories to identify capacity gaps. The Capacity Building Facility aims to fill the identified gaps through knowledge sharing and alliance building.	Representatives of government ministries and partner organizations, industry, food inspectors, and laboratory technicians.	Global Alliance for Improved Nutrition (GAIN) For more information, contact: Penjani Mkambula at pmkambula@gainhealth.org