Food Fortification in Latin America

Deep Dive on Practices of Food Fortification Compliance Systems in Costa Rica and Guatemala Based on Key Informant Interviews

UNIVERSITY OF WASHINGTON

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List of Acronyms

Abbreviation	Definition
LSFF	Large-scale food fortification
WHO	World Health Organization
PAHO	Pan American Health Organization
INCAP	Institute of Nutrition of Central America and Panama
ILSI	International Life Sciences Institute
MoH	Ministry of Health
INTA	National Institution of Nutrition and Food Technology
INCIENSA	Instituto Costarricense de Investigación y Enseñanza en Nutrición y Salud (Costa Rican Institute of Research and Teaching in Nutrition and Health)
WFP	World Food Programme
GAIN	Global Alliance for Improved Nutrition
USAID	United States Agency for International Development
UNICEF	United Nations Children's Fund
CONAFOR	Comisión Nacional para la Fortificación, Enriquecimientos y/o Equiparación de Alimentos (National Commission on Food Fortification, Enrichments and/or Equalization)
UCR	University of Costa Rica

Executive Summary

The Strategic Analysis Research and Training Center (START) was commissioned by the Bill & Melinda Gates Foundation (BMGF) to support the Nutrition Program Strategy Team (PST), a group focused on the implementation of large-scale food fortification (LSFF) to address micronutrient deficiencies across the globe. The previous phase of this project identified the key LSFF stakeholders and completed three case studies of exemplary LSFF programs in Latin America (Chile, Costa Rica, & Guatemala) that highlighted the attributes and common components of their compliance monitoring programs. In Phase I, we found that mandatory legislation on the fortification of all staple food products as well as sanctions for non-compliance was present in the three countries. Additionally, we identified the MoH as the central coordinating body for monitoring and compliance activities with support from other academic, industry, and non-governmental stakeholders.

In this phase of the project, the START team aimed to develop a deeper understanding of the practices of food fortification compliance systems in Costa Rica and Guatemala to enhance the findings from the previous phase of this project. The START team responded to the BMGF's request by conducting key informant interviews (KIIs) with leading professionals in industry, academia, government, and third-party non-government institutions (NGOs). Through these interviews, we aimed to describe industry and regulatory bodies' current Quality Assurance (QA)/ Quality Control (QC) practices, better understand coordination and cooperation between industry, academia, government, and NGOs, and, ultimately, inform what can be done to improve food fortification compliance in the Latin American market. This report summarizes these findings.

Key Findings

The compliance of large industry players in Costa Rica and Guatemala with food fortification standards is portrayed as voluntary and intrinsic, motivated by a sense of responsibility and goodwill towards the population. This compliance relies heavily on trust between government and industry, rather than strict enforcement. That said, smaller industry players lack the resources to comply with ease and consistency: while they supply less food and thus pose a lower risk to the population, they may require more assistance and monitoring rather than simply being trusted and left to their own devices. Large industry leaders prioritize collaboration with suppliers and international stakeholders to innovate on fortification practices, driven by profit motives and product improvement. Despite efforts, monitoring compliance faces limitations due to resource constraints, with reliance on slower governmental and academic testing services, prompting some industries to seek faster,

comprehensive testing abroad. In response, local entities resort to hiring students for assistance. We recommend further research into how small industry players fortify and monitor, how fortificant suppliers might be key to enabling all compliance upstream in the supply chain, and how scientific studies of fortification can be enabled such that there is more data to inform fortification practices.

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Introduction

Project Overview

This report is the product of analysis and interviews conducted by the University of Washington's Global Health Strategic Analysis and Research Training Program (START) team. The report was created in response to a request from the Bill and Melinda Gates Foundation's (the Foundation) Nutrition PST to characterize the critical components and practices of Latin American nations – namely Costa Rica and Guatemala – food fortification compliance systems and how they strengthen the sustainability of the compliance program. The goal of the project is to delve deeper into understanding the status of large-scale food fortification in Latin America. Specifically current quality assurance, quality control, and fortification testing methods, the state of fortification coordination and cooperation between industry, academia, and government, and what can be done to improve compliance in Latin America, given what we learned from stakeholders in Guatemala and Costa Rica.

Methodology

Key Informant Interviews

The START team conducted key informant interviews to get information on our areas of interest. We initiated KIIs through our client Dr. Claudia Pazlopez from the BMGF and Dr. Hannia Leon, the executive director of the International Life Sciences Institute (ILSI) Mesoamerica. We compiled the list of potential KIIs identified in the first phase of this project and included additional KIIs identified by the client to create a priority list from different sectors and countries (see Table 1). The interviews were conducted in English and Spanish depending on the KII preference.

The KII guide (outlined in the Appendix) was developed with input from the previous phase team members as well as the BMGF clients and included sections pertaining to the history and evolution of LSFF, current testing practices, monitoring efforts, technical assistance, enablement and sustainability, and innovations. The guide was further customized as needed to support specific KII and project requirements.

Table 1: Key informant interviews

6 Key Informant Interviews, 10 participants				
1	Maria Alexandra Sancho	Head of QA Operations	MASECA Flour Industry	Costa Rica
2	Jessie Usaga	Professor	University of Costa Rica Academia	Costa Rica
3	Elba Cubero-Castillo; Karolina Sanchez Alan; Carolina Cortes	Professor; Researcher, Chemist; Professor	University of Costa Rica, UCIMED Academia	Costa Rica
4	Carolina Martinez	Laboratory Lead	Institute of Nutrition of Central America and Panama Academia	Guatemala
5	Eugenia Ruiz; Oliver Tello	Lawyer; Engineer, QA Manager	Sugar Producer Association of GT Sugar Industry	Guatemala
6	Evelyn Meneses; Natalia Espinal	Nutritionist; Nutritionist	Ministry of Health Government	Guatemala

Thematic Analysis

The KIIs were recorded, transcribed, and translated (to English, as needed) for rapid thematic analysis. Stakeholder interviews were transcribed verbatim and imported onto an online collaborative digital whiteboard. Utilizing a deductive approach, data were organized into a priori themes derived from the discussion guide. Through iterative affinity mapping, themes were scrutinized across interviews to discern patterns and relationships. This method facilitated the identification of answers to predefined questions within the discussion guide. Additionally, emergent themes and narratives were identified through cross-referencing multiple conversations with diverse interviewees. This comprehensive approach ensured a thorough exploration of the data landscape, enabling a nuanced understanding of both anticipated and novel insight which became the basis for our delivered presentation as well as this report.

Findings

Overall Key Informant Interview Themes

THEME 1: Large, established industry players say their compliance is voluntary and intrinsically motivated, and sanctions are not strictly enforced on them.

Key informants from the flour industry in Costa Rica and from the sugar industry in Guatemala with whom we spoke said that they complied because they knew it was their responsibility to do so, and that they wanted to do well by the population. It is important to note that we spoke with industry representatives invested in maintaining a positive public appearance for their companies. For instance, this quote:

> *"The truth is that it is a privilege to be able to help the population."*
>
> –Eugenia Ruiz, Summary Producer Association (SPA), GT

We also note that while large industry players can proactively comply with ease, it is the smaller industry players who may struggle with resource compliance. This so-called "voluntary" compliance is predicated on mutual trust and collaboration between industry, academia, and government as there is seemingly little practice of legal enforcement or sanctioning if and when non-compliance is identified. Thus this system functions in "good faith."

THEME 2: The industry takes a proactive approach to monitoring food fortification compliance and engaging in collaboration with suppliers and other non-government stakeholders.

Our informants outlined that the industry actively seeks out knowledge, advice, innovation, and best practices in food fortification from other businesses, international organizations, and stakeholders in other countries such as the US, and beyond. Their motivation seemingly to find efficiencies, increase profits, and improve their products and services, they are always on the lookout for good ideas:

> *“We seek advice both abroad and here in Guatemala; currently, only INCAP is available, but we are always in search of overcoming the gaps that still exist.”*
>
> -Oliver Tello, Maquinas Exactas (ME), GT

Fortificant premix suppliers are a source that the industry mentions frequently. Suppliers, likely motivated to maintain strong relationships and to influence fortification processes, share fortificant dosage quantities, methods, and new technologies with industry.

THEME 3: Monitoring of food fortification compliance is constrained by limited testing resources, both material and human

Government and academic stakeholders lack the resources to measure compliance, whether when asked to do so by industry or when seeking to verify that food in the market accurately represents its levels of fortification. Academia’s testing services are often used by industry to test levels of fortification, but their services are often slower than private testing options:

> *"[Private testing is] faster for sure than [the University of Costa Rica], a public institution. But they're going to be more expensive...it depends on what you need and what you can pay for, especially for…small companies."*
>
> -Jessie Usaga, UCR, CR

The industry seeks to monitor in faster, cheaper ways. Still, there is a tradeoff between speed and cost. Given that local labs either lack experience, or only offer some tests, not a comprehensive panel of testing, some industries send their testing to the United States where labs are better outfitted. Academies and the government, wishing to test compliance with a limited workforce, sometimes hire students to aid with testing.

Country-Specific KII Findings

Interviews with key stakeholders from the government, industry, and academia from the countries of interest – Costa Rica and Guatemala – were done to deep-dive into the country-specific food fortification practices, quality assurance and quality control (QA/QC) processes, and technical assistance.

Costa Rica

Testing Practices

Costa Rica has been an exemplar in the food fortification realm given its decades-old history and collaboration among stakeholders – academia, industry, and government. The Ministry of Health (MoH) in Costa Rica included food fortification as a strategy in 1973 under the National Health Law. Since this legislation mandatory fortification has been enacted for the following basket of staple food products.

While large industries do not always conduct in-house highly precise quantitative testing, they consistently perform in-house qualitative testing for the internal QA/QC process. Our KII from MASECA mentioned using iron spot testing to monitor flour fortification. Large industries also consistently send samples for testing to external laboratories – either government or private laboratories. Smaller producers opt for government or local laboratories whereas bigger industry players usually send their samples to private laboratories. For instance, MASECA routinely sends its samples to a US-based laboratory for testing to comply with fortification regulations. The industry also supports compliance by performing more frequent testing than recommended by the government as corroborated by our KII.

> *"In many cases, our companies are running more testing than the government (recommends) is because of resources (in the) country. We don't have as many resources as you may think. So, in many cases, (the) industry is running way more testing than what they need (to comply with regulations)."*
>
> –Jessie Usaga, UCR, CR

The government, on the other hand, supports compliance by placing laws and regulations to assist the industry with streamlining its testing processes as described in detail in Phase I of this project. Strict penalties and corrective actions are also placed against failure to comply with fortification and labeling laws. We previously noted in the Phase I report that, "the incentives for fortification dictated by the law include tax exemption of micronutrient premixes. Sanctions included in legislation outline that if regulation is not followed the producer or importer must retrieve or forfeit the production batch from distribution centers and sanctions, not specified, enforced by the MoH. Finally, all fortified products must follow labeling regulations; the nutrition label must include fortification levels and marketing is controlled by the MoH."

Our KIIs also mentioned the monitoring of fortified products at sale sites by the government as well as blind testing done by sending the samples to the University of Costa Rica (UCR) for testing. Previously, in Phase I, we reported the role of INCIENSA (Costa Rican Institute of Research and Teaching in Nutrition) in supporting the Ministry of Health in enforcing and supervising compliance with fortification regulations. This was largely facilitated by sending professionals from INCIENSA to visit food production sites and sale sites (markets) for auditing/inspection for sample collection and further analyses at INCIENSA's laboratories (1).

The UCR was the main academic stakeholder in Costa Rica with its provision of high-quality testing services to all producers. While its technical capabilities were not as advanced as the foreign-based and private laboratories, it served numerous clients nationally – with most clients being from the industry. Given the client-provider relationship, UCR maintains the confidentiality of the testing results, reports, and other documents unless there is a genuine concern for public health and safety.

> *"For example, if you are a company (or) you are the owner of the company, and you bring a product, and I have to check something (fortification levels or other testing). (If) I know that (they are) not under compliance (then) you are gonna (be the) one who knows. (However), if it is a different topic that might change. For example, if we have a biological hazard, we have to tell the government because there are people (and) their health is of concern."*
>
> –Jessie Usaga, UCR, CR

Flour Testing Process

As a result of our conversation with our KIIs from MASECA, we were able to dissect the flour fortification and testing process, as shown in Figure 1. The process begins with the receipt of raw

materials – flour and premixes – to the final distribution. After which, the quality of the process is further reinforced by a feedback loop system.

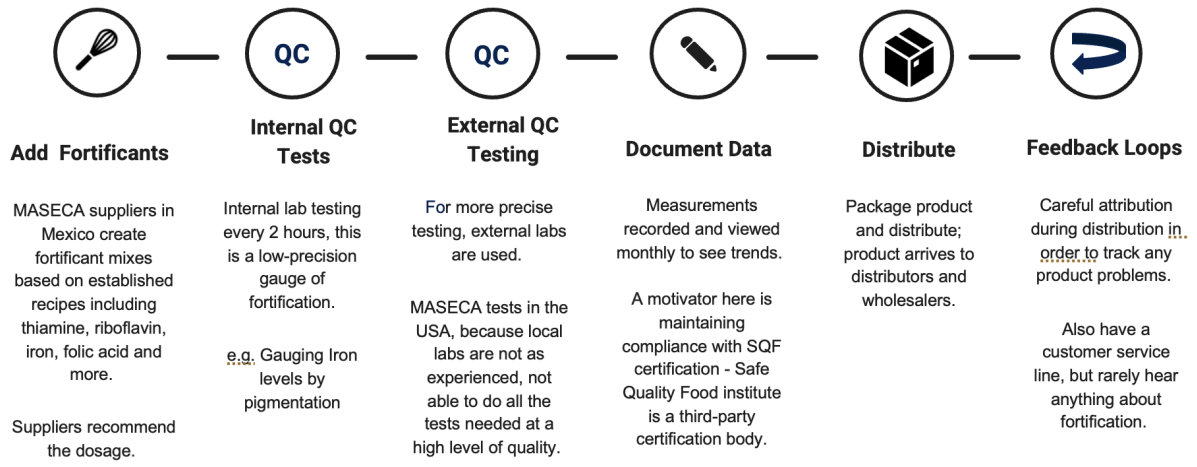

Figure 1: Fortified flour production process at MASECA in Costa Rica.

- **Add fortificants:** Raw/unfortified flour is added with premixes supplied by pre-mix suppliers. MASECA's premix suppliers supply nutrients such as thiamine, riboflavin, iron, folic acid, and others for flour fortification. Premix suppliers act as technical assistance providers as they provide bespoke guidance on the fortification process as well as QA/QC processes.
- **Internal QC testing:** After the addition of premixes based on supplier recommendations, the fortified flour is tested for QC. This internal testing is performed every two hours by iron spot-testing or "pigmentation."
- **External QC testing:** Given the lower precision of the iron spot-checking method, the samples are sent to external laboratories for precise quality control. In the case of MASECA, the samples are sent to a US-based laboratory for consistency, rapid testing, and to comply with strict fortification requirements as mentioned previously.
- **Document Data:** All the internal and external testing measurements are documented to observe trends and rapid problem resolution. These documents are however confidential and aid in compliance with the Safe Quality Food (SQF) certification. SQF is a food safety standard recognized by GFSI (Global Food Safety Initiative) as one of the benchmarked schemes that meet their stringent requirements for food safety management systems which enhances the producer's credibility and market access (2).
- **Distribute:** After all quality checks and certification compliance are satisfied, the fortified food products are finally packaged with appropriate labels and distributed to wholesalers and retailers.

- **Feedback Loops:** Notably, MASECA applied a closed-loop feedback system to ensure customer satisfaction and food quality. The feedback loop system enables them to resolve problems in food quality promptly. Although this system is largely customer-service-centric, its utility in rapid problem resolution is essential for quality-checking purposes.

Technical Assistance

The documents and regional recommendations from INCAP serve as the main resource and guidelines for food fortification in the Latin American region. The key informants from Phase I described INCAP as "the hands of PAHO"' in terms of overseeing the food fortification and micronutrient aspect of PAHO. Additionally, other international stakeholders identified in Phase I including the UN, WHO, UNICEF, GAIN, and USAID, among many others, were stated as key stakeholders. Meanwhile, the key stakeholders for technical assistance for the industry are premix suppliers. Given the reliance on their guidance and recommendations for the addition and handling of premixes, suppliers are the key source of support. From guiding the dosage of premixes, safe handling of premixes, proper mixing techniques, and packaging requirements, premix suppliers act as the main technical assistance providers for the industry. While similar training opportunities are provided by the MoH for all producers, they are not as consistent as the ones provided by the suppliers. As a result, smaller producers bear the brunt of sporadic MoH-supported training and the lack of training opportunities from large suppliers.

> *"Sometimes, the Ministry of Health gives talks, but they are actually very sporadic. When you want strong support in this fortification topic, we often turn to the same suppliers because they have quite significant technical expertise. So, we also rely on the same supplier for support."*
>
> -Maria Alexandra Sancho, MASECA

The availability of fortification certification also assists all producers in producing quality products that are compliant with the fortification requirements. As mentioned in Phase I, "A separate legislation, Decree N 39741 stipulates that all fortified foods must obtain a fortification guarantee seal. To obtain this seal, the brands must present and describe how they plan to use the guarantee seal (packaging and marketing), the MoH will inspect compliance with the law referencing national guidelines, the certification that the industry is conducting internal monitoring, and sworn declaration that the produces will maintain fortification level and comply with legislation." Additionally, the SQF certification also provides guidelines and protocols for international standard food quality management systems.

Guatemala

Testing Practices

Guatemala has a long history of large-scale food fortification. The Institute of Nutrition of Central America and Panama (INCAP) is based in this country and has been a key stakeholder in food fortification in the region. They have developed the spectrophotometric method for Vitamin A, widely used in the sugar industry. This institution has a laboratory that provides analyses to private clients and the government but not at the individual level. Carolina Martinez, our key informant from INCAP, highlighted that the INCAP laboratory processes samples from other institutions and countries.

> *" We function as a reference laboratory for some analyses…we receive samples from all the countries in the region and beyond South America… from Asia, from Africa."*
>
> - Carolina Martinez, INCAP, GT

The industry also performs testing on-site, this will be better explained in page 15. Moreover, companies usually perform more frequent analyses than the government. Oliver Tello, our key informant from Maquinas Exactas, mentioned that they perform more than 100 analyses per day using the INCAP method. All the information registered by the companies is reported to CONAFOR (which is the National Committee for Food Fortification).

> *"We have a quality analysis laboratory...specifically for vitamin A, we carry out more or less on average 144 daily analyses through the spectrophotometric method."*
>
> - Oliver Tello, ME, GT

The MoH of Guatemala, through the Department of Food Regulation and Control, has manuals of operating procedures for the four mandatory fortified foods, which describe the sampling schemes at production sites and sales points. As stated in Phase I, the *"Ministry of the Economy undertakes thorough verification assessments encompassing fortified foods net content, labeling accuracy, and advertising precision at various Points of Sale (POS). The Ministry of Public Health and Social Assistance and the National Health Laboratory work together in sampling and analyzing micronutrient content at POS. This collective effort guarantees precise information and distribution of fortified sugar to consumers."* This reflects the collaboration between two government entities. Natalia Espinal, from the MoH, further elaborated that the tests are performed by the National Health Laboratory and the MoH has established an alliance with academia to expand its monitoring efforts.

Students who take part in the supervised professional practice of a university in Guatemala collect samples in the community and send them to the laboratory.

> *"Through the students of the supervised professional practice…they contribute to commercial monitoring, so it is the way in which we measure or have an indicator of how these fortified foods are reaching these communities and help us expand coverage."*
>
> - Natalia Espinal, MoH, GT

Additional information about the student's involvement provided under the Innovation section in this report. Potential challenges in collaborating with external staff for monitoring include concerns about the conditions for collecting and transporting samples, as well as ensuring their proper storage until they reach the laboratory.

Sugar Testing Process

We gathered information about the sugar fortification process during our KIIs in Guatemala. Maquinas Exactas is the primary company responsible for adding Vitamin A and receives sugar from various regions across the country. Throughout this process, QA methodologies are employed to guarantee the appropriate levels of Vitamin A in the final product.

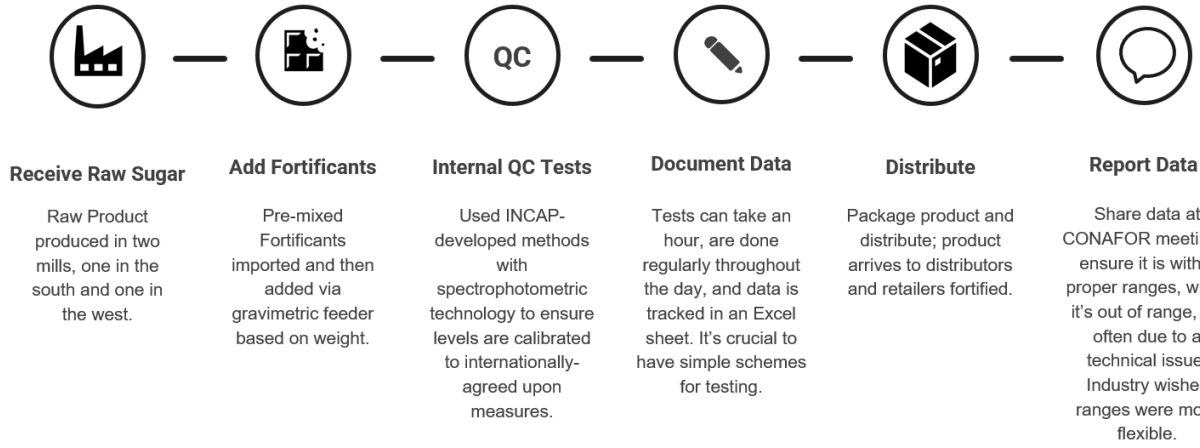

Figure 2: Sugar Testing Process at Maquinas Exactas in Guatemala

Figure 2, provides a comprehensive summary of the sugar industry processes, and the following steps were identified based on information obtained from Key Informants (KIs):

- **Raw Sugar Arrival:** Batches of raw sugar are sent to Maquinas Exactas for processing. This stage marks the point where fortificants are introduced.
- **Fortificant Addition:** Vitamin A is incorporated following the guidelines provided by the premix provider. The quantity is precisely measured based on the weight of the sugar batch, utilizing a gravimetric feeder to directly gauge the proportions of sugar and premix required.
- **Internal Quality Control (QC) Tests:** Continuous monitoring occurs throughout the processing, with approximately 144 tests conducted daily using the spectrophotometric method developed by INCAP. Process adjustments are made in response to test results. While alternative testing methods have been considered, their higher cost compared to the current method has led to the latter's continued preference.
- **Documentation:** Measurements are recorded in an Excel document and subsequently analyzed using statistical software. The collected data serves for internal assessments and the creation of reports.
- **Distribution:** Once fortification reaches the desired level, the sugar is packed and distributed to warehouses and retailers.
- **Data Reporting:** Summarized information from reports is shared with CONAFOR during regular meetings. All documents are readily accessible for review by regulatory institutions.

These steps collectively ensure the final product maintains adequate fortification levels. While the government conducts on-site testing as part of monitoring procedures, this is done less frequently than the company's internal assessments.

Technical Assistance

In terms of technical assistance in Guatemala, it is usually provided by non-governmental institutions, like INCAP. They provide training and technical assistance to the industry. They are also working on a fortification certification which should be available next year. The industry stakeholders highlighted the support of the premix suppliers, who offer technical advice if needed. Finally, the government offers sporadic training, and they have a certification related to food safety.

CONAFOR, the National Commission for Food Fortification in the country, has successfully established a collaborative platform involving consumers, the government, the private sector, and agencies to discuss and advance food fortification programs. This integration has garnered positive responses from the involved sectors, leading to the revitalization and consolidation of fortification efforts, transforming them into a national policy irrespective of changes in government. CONAFOR serves as a pivotal advocate for sustainability and enhancement of food fortification programs, ensuring regular dissemination of program results. Operating under an annual work program,

CONAFOR conducts bi-monthly sessions, with meeting minutes managed by a Permanent Secretary. The organization plays a crucial role during political transitions, emphasizing the importance and improvement of National Food Fortification Programs through engagement with national authorities.

KII Findings: Risk-Based Monitoring

INTRODUCTION

Risk-based monitoring (RBM) aims to identify potential issues early in the food fortification process. This strategy assists producers and regulators in ensuring that high-quality products reach the population. High-risk industries need more frequent testing compared to those that have demonstrated stability and success in fortification over weeks, months, or years. We delved into the risk-based monitoring practices of both the government (external monitoring) and the industry (internal monitoring). Information was obtained from our Key Informants in each country, and our findings are summarized in the sections below.

RBM Practices by Producers

Large producers have well-developed monitoring and quality assurance processes. All the information is collected in registries that allow them to keep track of the fortificants' concentrations, as Maria Sancho from MASECA mentioned. They are constantly monitoring the fortification levels to ensure the quality of the product.

> *"If we are going up in concentrations, if we are pushing the lower limits, if something is happening with the quality of the product we have to adjust."*
>
> - Maria Sancho, MASECA, CR

These QA processes are sustained by the adequate resources of these companies. Nevertheless, many factors influence the variability of the fortification procedure; for example, Carolina Cortes from the University of Costa Rica explained that changing premix providers could result in inadequate fortification, and recommended that if the provider is changed, the whole process should be observed to prevent changes in fortification levels.

> *"If the producers change premix providers the fortification levels need to be reassessed."*
>
> - Carolina Cortes, UCR, CR

Additionally, INCAP promotes that the monitoring is compatible with the variability of the process and the magnitude of the production. Carolina Martinez from INCAP stated that now there is a minimum number of samples per batch that have to be taken to determine if a product complies with food fortification. In the past, the monitoring was not aligned with the daily amount of production.

"It is a sampling scheme based in the variability of the process…in the past 100 samples were taken and for a bad result they were given the same fine if they took 5 samples, so now to make a decision there is a minimum number of samples that have to be taken…to say it complies or does not comply."

- Carolina Martinez, INCAP, GT

Overall, our inquiries to these large producers revealed well-established internal monitoring practices. The Academia in Costa Rica and INCAP in Guatemala are the main allies assisting the companies in maintaining the quality of fortified foods.

RBM Practices by the Guatemalan Government

The monitoring practices in Guatemala are grounded in the current Guatemalan regulations, with a special focus on the process for imported food products. This emphasis arises from the substantial quantity of imported food products brought into the country to meet the population's needs, necessitating an efficient and streamlined monitoring process. The authorities have sought to find a balance in releasing products promptly while concurrently promoting unhindered commerce. For imported products, there is a process called deliberation. To be released to the market, a product should comply with fortification. If a company has a one-year history of adequate compliance, they are eligible for exoneration of monitoring for the next year.

The Ministry of Health, responsible for regular monitoring of commercial sites, faces challenges such as staff shortages and resource limitations. Resource constraints sometimes compel the prioritization of large producers, who play a pivotal role in supplying the majority of the population.

"The supermarket chains are organized and agree to give us the 12 sugar samples that we normally take, the 5 salt samples, the 5 wheat flour samples, the 5 corn flour samples per batch."

- Natalia Espinal, MoH, GT

On the other hand, small retailers are sometimes reluctant to give samples to the government, which constitutes a challenge to reach the coverage of monitoring in the community. Despite the existence of a sanctions structure, primarily financial, the monitoring process can be time-consuming due to the involvement of legal departments in each company. While best practices are recommended, ongoing monitoring remains essential. Large producers, being key contributors to the market,

engage in negotiations with CONAFOR to access accurate information and maintain a comprehensive record of monitoring practices.

Since monitoring can be restricted by the available resources. Natalia Espinal pointed out that there is room for improvement in terms of staff and equipment, and that they are still trying to increase their coverage in the community.

> *"There is room for improvement in terms of personnel capacity, more equipment in the laboratory…an attempt has been made to increase the number of weekly analyses carried out on fortified foods."*
>
> - Natalia Espinal, MoH, GT

Guatemalan Data Monitoring is a Model of Strong Collaboration

In Guatemala, CONAFOR brings together all stakeholders involved in food fortification efforts. The CONAFOR involves stakeholders such as the government, the producers, Liga del Consumidor (LIDECON), the INCAP, and other international agencies like UNICEF, USAID, GAIN, and the WFP among others. Every three months, all members submit reports to share their results, reinforcing both internal and external monitoring.

> *"[Our ministry of health has] information for sugar, for example, data from internal monitoring, we have data because…[industry] presents reports [to CONAFOR] every 3 months on the results of monitoring."*
>
> *- Carolina Martinez, INCAP, GT*

As mentioned before, Eugenia Ruiz from the Sugar Producers Association highlighted that all the information registered by the industry is readily available for the regulatory institutions. The registry of the fortification measures is useful for calibration.

> *"Currently, we have our databases basically in Excel, but we do use statistical software for interpretation to adjust our process…it is fully available as required by the Government."*
>
> - Eugenia Ruiz, SPA, GT

The representative from MASECA, who also has factories in Guatemala, explained that to avoid discrepancies, they decided to send their samples to the National Health Laboratory as a strategy to reach consensus.

> *"We conduct (the analyses) in the same laboratory as the MoH because sometimes discrepancies were arising. (...)To address this, we decided to take a straightforward approach and conduct the analysis in the same place. (...) At least we know that we are using the same methodology."*
>
> *- Maria Sancho, MASECA, CR*

Costa Rican Industry Data Sharing is More Ad Hoc

The primary focus of governmental initiatives in Costa Rica, as outlined by key informants, centers around verification activities. Jessie Usaga, representing the University of Costa Rica, mentioned that the university's laboratory functions as an independent third party. Their role is strictly limited to communicating test results to the client; hence, they do not participate in reporting non-compliance unless a public health threat is identified.

> *"There's no communication...between the specific industries and the government. If there is noncompliance…detected, it just stays within the company."*
>
> - Jessie Usaga, UCR, CR

Maria Sancho, the representative of MASECA in Costa Rica explained that although they do not conduct testing of its products at the community level, it actively monitors any issues that may arise during product distribution, creating a closed-loop feedback system. This proactive approach aims to detect potential problems that could be attributed to their production processes. A call center is also available for distributors or clients to report any concerns. However, it's important to note that these problems are not necessarily related to fortification levels.

> *"We sell to distributors and also directly to supermarket chains. However, when it comes to ensuring quality, there may be some issues (….). We analyze whether it's a situation attributable or not attributable to our process, or if it's a matter of storage."*
>
> -Maria Sancho, MASECA, GT

Maria Sancho also highlighted the limited government support regarding technical advice and described the current relationship between the industry and government regarding food fortification monitoring.

> *"Years ago, the relationship [between industry and government] was very close...because that issue of fortification was being defined. Now, the relationship that exists is mostly one of verification...they verify annually if we are complying. As for advice or technical support...It's very little."*
>
> - Maria Sancho, MASECA, CR

In the event of non-compliance with food fortification regulations, as indicated by our KI, regulatory authorities initiate an observation process, wherein corrective measures are recommended. Should the identified issues persist, the company may face economic sanctions, with the most severe consequence being the potential removal of the non-compliant product from the market. Notably, stakeholders from the government of Costa Rica were not reached during our inquiry, leaving an opportunity for further exploration of this perspective.

KII Findings: Enablement

We sought to understand how food fortification compliance is enabled and sustained in Costa Rica and Guatemala to glean best practices and highlight lessons learned from these countries with exemplary food fortification programs. Our focus was on better understanding barriers and facilitators to sustainable food fortification, comparing and contrasting innovative food fortification strategies between both countries and considerations for supporting and evolving food fortification.

Barriers and Facilitators to Sustainable Food Fortification

Barriers:

1. **Requiring food fortificant levels to be exact**. Food fortification processes have variability, and thus, requiring the levels of food fortificants in the food to be exact was noted as a barrier to compliance. Having an allowable range for the levels of fortificants instead of discrete values might be one way to reduce this barrier.
2. **Costs of testing.** These costs can be a barrier, especially as more sophisticated and efficient testing is often more expensive.
3. **A dearth of timely scientific studies on population-level micronutrient needs.** KIIs noted the lack of studies needed to drive evidence-based changes in food fortification standards. National surveys are conducted in both countries, but are infrequent, occurring every 10-15 years in Costa Rica and every 5-6 years in Guatemala (3).

Facilitators:

1. **Central America has a common regulation for LSFF** that is adapted by INCAP and CONAFOR to meet country-specific needs.
2. **Large producers are self-reliant,** having developed their standardized testing and QA/QC processes. Given constrained resources, this model of internal self-monitoring seemed to facilitate efficient food fortification compliance.
3. **Pre-mix/fortificant suppliers in Latin America provide technical assistance to industries** which is an additional QA/QC measure that the industry takes.

Innovative Fortification Strategies

Our KIIs also provided insight into what was working well and facilitating sustainable food fortification in Costa Rica and Guatemala. In Costa Rica, the University of Costa Rica is continually exploring the costs and benefits of adding new fortificants to the food supply. Costa Rica stakeholders also described how their food fortificant suppliers lead innovation in the food fortification space, developing new fortification techniques and equipment.

In Guatemala, students are involved in the collection of food samples monitored for compliance which is an innovative strategy they have leveraged to build capacity for testing since 1995 (4). This has largely been done to monitor the fortification of salt with iodine and vitamin A in sugar in homes through the Micronutrient Sentinel School System. The Guatemalan government also discussed how they host regional workshops for food fortification stakeholders to align their priorities and recenter the topic of food fortification. In both Costa Rica and Guatemala, the development of new and faster testing methods was a top priority. Both countries described how they were constantly innovating in the food fortification testing space.

Conclusions

We had rich discussions with ten key informants (see Table 1) who shared lessons learned from their strong and well-established food fortification monitoring programs. These insights can be leveraged by BMGF to support countries working to establish robust food fortification processes. We discuss considerations for supporting and evolving food fortification and recommendations for further research.

Considerations for Supporting and Evolving Fortification

1. **Facilitate cross-border information sharing.** As best practices for food fortification were developed in one country, they were shared with other countries. Supporting this transference of knowledge can support the evolution and improvement of food fortification programs.
2. **Balance trust in voluntary compliance with government enforcement.** We spoke with large industry players about their voluntary compliance with food fortification standards. While this was ultimately a successful model for these larger, well-resourced producers, this might not be generalizable to smaller producers where government enforcement and technical assistance might be necessary.
3. **Fund studies to proactively iterate on the types and levels of fortificants.** Studying population-level micronutrient needs can inform effective food fortification to improve the health of populations. Without these studies, it is difficult to justify changes made to the food fortification standards to reflect population health needs.
4. **Consider food fortificant suppliers as key stakeholders and innovators.** Suppliers played a surprisingly important role in supporting food fortification technical assistance.
5. **Enable academic institutions that provide local testing services.** The University of Costa Rica provided local testing services which was a very successful model that could be replicated elsewhere.
6. **Model successful collaboration between industry, government, academia, and international agencies after CONAFOR**. CONAFOR can be viewed as a “gold standard” for cross-sector collaboration to support sustainable food fortification.

Recommended Further Research

This phase of the project focused on Costa Rica and Guatemala and took a deep dive into better understanding the perspective of the industry. Further research might aim to include:

- The perspective of Chilean stakeholders as we were not able to speak with individuals from this country, but they also have an exemplary food fortification program.
- Interviews with small or medium-sized producers, as we spoke with large producers whose experiences may not represent all producers' experiences.
- Insights from the fortificant/premix producers as they are key players in the practice of fortification as well as its technological advancement and could be key upstream influencers to improve fortification programs.
- The perspective of Government stakeholders from Costa Rica, and thus, their experiences might provide additional insights.
- How data recording and sharing enables risk-based monitoring. While some details were found in this study, it's unclear whether data can be tracked for many producers and regulators over longer periods to enable the creation of risk tiers or categories.

Ultimately there is a lingering question around the intensity at which industry should be policed and the timing of that policing. Future studies might delve deeper into the costs versus benefits of trusting the industry to comply versus investing higher quantities of resources into monitoring. There is also an opportunity to further understand where in the supply chain monitoring is best and most efficiently executed: catching issues as upstream as possible may be least resource intensive and could limit cascading effects, but non-compliance might be introduced lower downstream such that upstream monitoring is not sufficient. Further research and development in risk-based monitoring may want to focus on building up technical resources for smaller industry players and on influencing compliance through upstream stakeholders such as suppliers.

References

1. Martorell R, Ascencio M, Tacsan L, Alfaro T, Young MF, Addo OY, et al. Effectiveness evaluation of the food fortification program of Costa Rica: impact on anemia prevalence and hemoglobin concentrations in women and children. Am J Clin Nutr. 2015 Jan;101(1):210–7.

2. SQF Institute. SQFI. [cited 2024 Feb 9]. What is SQF. Available from: https://www.sqfi.com/our-program/what-is-sqf

3. Ministerio de Salud. National Nutrition Survey. San José, Costa Rica; 1996.

4. DURE Technology. Overview of the Nutrition Information System in Guatemala [Internet]. Montpellier, France: Agropolis International, Global Support Facility for the National Information Platforms for Nutrition initiative; 2019. Available from: https://www.nipn-nutrition-platforms.org/IMG/pdf/nutrition-info-system-guatemala.pdf

Appendix

Key Informant Interview Guide

The START Center is a research consulting group at the University of Washington, Seattle, USA which leverages content expertise from across the University to provide high-quality research and analytic support to the Bill & Melinda Gates Foundation, Washington State Department of Health, Abbott Labs, as well as to other public health decision-makers, both globally and in the United States. The START Center also provides structured mentorship and training to University of Washington graduate research assistants.

Goal: To delve deeper into understanding the status of large-scale food fortification in Latin America. Specifically, QA/AC within the industry, external markets, technical assistance provided to industry, and how these systems are enabled and sustained by government, industry, and policymakers.
All responses will be kept confidential and used for study purposes only.
Before we begin, are there parts of that broad research question that you can speak to more than others? We want to ensure we use our time with you to speak on matters you're familiar with versus those that are not in your scope.

Interview Questions:

Introduction:

- Could you introduce yourself and tell us about your role in food fortification?
- What is the role of your industry/agency in food fortification?
- Does your institution/industry collaborate with other entities (industry/government agencies/international agencies) in the field of food fortification?
    - Can you describe how they collaborate?

General:

- How is food fortification compliance being monitored at the food production level? At the market level?
    - What are the methods for QA (Quality Assurance: monitoring at the production site)? QC (Quality Control: monitoring of the finished product at the production site or marketplace)?

        - Are these methods documented anywhere?
        - Are these methods site-specific or industry-wide?
    - What is working well? What are the challenges?
- What kind of legislation underpins food fortification in [country]?
    - How is this legislation enforced?

Testing Practices:

- What are the methods for testing fortified foods (and premixes) at the food production level? At the market level?
    - What devices and/or equipment are being used?
        - How accurate are these devices and/or equipment?
        - How difficult or easy are these devices and/or equipment to use?
- What quantitative or qualitative metrics are being captured?
- How are the data being recorded (e.g., digitally, on paper)?
- Is data entered into a database?
    - If yes, please describe it.
    - If not, what are the barriers to recording these data?
- How is data being tracked over time?
- How is the data being used to inform decision/making?
- How are testing activities funded – by the government or by individual companies?
    - Is this funding model sustainable, or has it been successfully sustained over time?

Technical Assistance:

- What kind of training do(es) [whoever conducts FF monitoring at the food production level in this country/ whoever conducts FF monitoring at the marketplace level in this country] receive to conduct food fortification monitoring?
    - Who offers this training?
    - Is this training industry-specific?
    - Is there documentation of this training?
- What additional technical assistance resources/supports (e.g., additional training, conferences, workshops) are available? Especially if compliance standards are not met, is there additional support available?
    - Who offers these resources/supports?

How has this changed/developed:

- Have there been any significant changes in the regulatory monitoring systems in the past 50 years or more?
- Can you describe the major changes or amendments in food fortification legislation over the past few decades?
    - What promoted those changes?
- What was the fortification regulatory monitoring landscape like before the creation of those legislations?
- What legislation or specific changes do you think had a positive impact on the regulatory monitoring system?
    - What legislations or specific changes do you think had no impact or negative impact on the desultory monitoring system?
- Are there specific examples of successful outcomes resulting from recent legislative changes in food fortification policies?

  (Note to interviewer: Probe KII's to provide specific data, i.e. we changed this aspect of our policy, and compliance has increased from X% to 2X%. But if they cannot share the data, don't be too pushy.)
- Who are the main stakeholders responsible for implementing those changes?
    - Are the same stakeholders responsible for implementing changes now?

Enablement and sustainability:

- Given the changes in recommendations and legislation, how did the operational practices of industries/agencies involved in food fortification evolve to comply with these new regulations?
- Have successful strategies or approaches been employed by industries/agencies to implement the legislative changes for food fortification?
    - If yes, what are they, and how?

Innovation

- Are there successful monitoring models from other countries in LATAM or other regions that could be considered?
- Have you recently implemented new testing techniques?
    - Can you describe your organization's experience with these innovations?

- (If academia/industry) What are the barriers/facilitators to implementing these new techniques on a bigger scale?

Risk-based monitoring

- What are the criteria used to define compliance?
- How do you keep track of the monitoring practices and how do you organize that information?
- Are food safety monitoring and fortification monitoring ever conducted at the same time/with the same format to better utilize systems/resources?
- Do you always test everyone, or do you have a systematic approach?
    - How do you get a sample set?
    - How do you prioritize where to test?
- Do you group industry players by historical performance?
- Are there any sanctions/corrective measures related to the lack of compliance?

Strategies for improving compliance

- How does your organization articulate efforts with food safety monitoring programs?
- Are there certifications for producers or retailers that distribute these products?
- (Industry) Is the certification process accessible to your institution? Do you receive any assistance from other institutions for the certification process?
- (Industry) Has your institution implemented self-assessment tools?
    - Could you describe how those tools or methods work?