Food Fortification: Part

Lasata Shrestha, Hanna Shephard, Andrea Rivas, Liza Sankar-Gorton, Akhtar Badshah



START CENTER STRATEGIC ANALYSIS, RESEARCH & TRAINING CENTER

TEAM OVERVIEW



Lasata Shrestha MPH Student, Epidemiology Research Assistant



Andrea Rivas, MD MPH Student, Epidemiology Research Assistant



Hanna Shephard, MPH PhD Student, Epidemiology Research Assistant



Liza Sankar-Gorton MBA Student Project Manager



Akhtar Badshah, PhD, MS Professor, Public Policy, Business Faculty Lead



START OVERVIEW



Leverages leading content expertise from across the University of Washington



Provides high quality research and analytic support to the Bill & Melinda Gates Foundation and global and public health decision-makers



Provides structured mentorship and training to University of Washington graduate research assistants



AGENDA

- Background
- Project Overview
- Overall KII Themes
- Country-Specific KII Findings
 - Costa Rica
 - Guatemala
- Risk-Based Monitoring
- Enablers
- Questions and Discussion





BACKGROUND

PHASE 1 RECAP

Key Findings

01

Legislation mandates fortification for *all human consumption* products and is *comprehensive*



Monitoring and compliance is centralized at MoH; and they serve as a coordinating agency for sampling and reporting

03

Monitoring and compliance funding is national and consistent



Sampling is occurring at different levels which makes us think that coordination and reporting is more important than procedures



PROJECT OVERVIEW

PHASE 2: UNDERSTAND INDUSTRY THROUGH KIIS

	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 CR Academia	Costa Rica		
3	Elba Cubero-Castillo Karolina Sanchez Alan Carolina Cortes	Professor Researcher, Chemist Professor	University of CR, UCIMED Academia	Costa Rica		
4	Carolina Martinez	Laboratory Lead	Institute of Nutrition Central America, 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		



LEARNING TO ENABLE STRONG QA/QC AT THE FOOD PRODUCER LEVEL



Describe current QA/QC practices through KIIs with a focus on industry and regulatory stakeholders



Understand coordination and cooperation between stakeholders; How industry, academia, and government work together to enable fortification



Help **inform what can be done to improve compliance** in the Latin American market



OVERALL KII THEMES

KII THEME 1

Large established industry players say their compliance is voluntary, intrinsically motivated, and sanctions are not strictly enforced

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

"We don't have that level of control (over industries) and because of that, in many cases, what we do in industry, it depends on ethics. Just what the company knows that they have to do (in good faith)." -Jessie Usaga, University of Costa Rica (UCR), CR



KII THEME 2

The industry takes a proactive approach to monitor food fortification compliance, and engaging in collaboration with suppliers & other non-government stakeholders

"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

"(The supplier) gives me the recommendation for the...doses that I have to make per kilo of flour, per ton of flour to comply with the fortification regulation...Monthly we look at the records to see the trends we are having and if any preventive or corrective action needs to be taken" -Maria Sancho, MASECA, CR



KII THEME 3

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

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

"The problem we have is time...in 1 hour our production quantity is very high, so we are currently testing other methodologies that are a little faster, but the cost is very high." -Oliver Tello, ME, GT



COUNTRY-SPECIFIC KII FINDINGS

KII QUESTIONS AIMED TO UNCOVER INDUSTRY PRACTICES

In hour-long interviews, we inquired about:

- Fortification **Testing Methods** and Procedures
- Technical Assistance Provided to Industry
- Risk-Based Monitoring Practices
- Innovations in Fortification
- The Enablement and Sustainability of Fortification



KII FINDINGS: COSTA RICA

Testing Practices, Technical Assistance

COSTA RICAN TESTING PRACTICES



Industry	 Does not always perform in-house quantitative testing Sends samples to government or private laboratories (e.g. Maseca sends samples to the US) Performs more frequent tests than recommended by government 	"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, industry is running way, more testing, than
Government	 Regulations in place to assist industry with streamlining testing processes Sends samples to UCR for blind testing Monitors at sale sites 	what they need (to comply with regulations)." –Jessie Usaga, UCR, CR
	 Penalties and corrective actions against failure to comply with fortification and labeling laws 	
Academia	 UCR provides testing services to industries Industry serves as a client and all data/reports are confidential 	UNIVERSIDAD DE COSTA RICA



COSTA RICAN FLOUR INDUSTRY



AIDED BY FOREIGN LABS AND CERTIFICATIONS



Add Fortificants

Maseca suppliers in Mexico create fortificant mixes based on established recipes including thiamine, riboflavin, iron, folic acid and more.

Suppliers recommend the dosage.



QC

Internal lab testing every 2 hours, by iron sport test, a low-precision gauge of fortification.



QC

For more precise testing, external labs are used.

MASECA tests in the USA, because local labs are not as experienced, not able to do all the tests needed at a high level of quality.

Document Data

Measurements recorded and viewed monthly to see trends.

A motivator here is maintaining compliance with SQF certification - Safe Quality Food institute is a third-party certification body.



Package product and distribute; product arrives to distributors and wholesalers.

Feedback Loops

Careful attribution during distribution in order to track any product problems.

Also have a customer service line, but rarely hear anything about fortification.



SUPPLIERS ARE KEY STAKEHOLDERS PROVIDING TECHNICAL ASSISTANCE

Stakeholders	 Suppliers play a main role in providing technical assistance for industry INCAP provides training and guidance in the Central American region Other institutions: UNICEF, USAID, GAIN, etc.
Training	 Suppliers provide training to their clients Training is offered sporadically by the MoH Smaller producers have limited access to training
Certifications	 Costa Rica has fortification certifications for different products. The process is accessible for producers Producers who receive the seal are subject to supervision
Technology	Use Safe Quality Food (SQF) Protocol



KII FINDINGS: GUATEMALA

Testing Practices, Technical Assistance

GUATEMALAN TESTING PRACTICES

 $\langle \rangle \rangle$

	 Developed innovative and cost-effective methods: e.g., spectrophotometric method with UV detection for Vit A Analyzes samples sent by the industry, government, and other institutions (but not individuals) 	"We function as a reference laboratory for some analyseswe receive samples from all the countries the region and beyond South America from Asia, from Africa." - Carolina Martinez, INCAP, GT
INCAP		
Industry	 Sugar fortification levels done on site, with INCAP method Performs more frequent analyzes than by the government Reports to CONAFOR every 3 months 	"We have a quality analysis laboratoryspecifically for vitamin A, we carry out more or less on average 144 daily analyzes through the spectrophotometric method." - Oliver Tello, ME, GT
	 Their manuals of operating procedures encompass 	
Government	 sampling schemes for the four mandatory fortified foods Testing at production sites and sales points Samples are sent to National Health Laboratory (NHL) 	"Through the students of the supervised professional practicethey contribute to commercial monitoring, so it is the way in which we
Academia	 Students collect samples in the community and bring them to the NHL, expanding monitoring efforts 	measure or have an indicator of how these fortified foods are reaching these communities and help us expand coverage." - Natalia Espinal, MoH, GT



GUATEMALAN SUGAR INDUSTRY:

AIDED BY SUPPLIERS, INCAP, AND CONAFOR

Receive Raw Sugar

Raw Product produced in two mills, one in the south and one in the west. **Add Fortificants**

Pre-mixed Fortificants imported and then added via gravimetric feeder based on weight. **Internal QC Tests**

Used INCAPdeveloped methods with spectrophotometric technology to ensure levels are calibrated to internationallyagreed upon measures.

Document Data

Tests can take an hour, are done regularly throughout the day, and data is tracked in an Excel sheet. It's crucial to have simple schemes for testing.

Distribute

Package product and distribute; product arrives to distributors and retailers fortified.

Report Data

Share data at CONAFOR meetings, ensure it is within proper ranges, when it's out of range, it's often due to a technical issue. Industry wishes ranges were more flexible.



THE MAIN SOURCES OF TECHNICALASSISTANCE FOR THE INDUSTRY ARE NON-
GOVERNMENT INSTITUTIONS

INCAP	 Provides training and technical assistance to the industry Spectrophotometric method is the most common and cost-effective method for internal QA Is working in a fortification certification for the upcoming year 	Sugar producers association
Premix suppliers	 Pre-mix suppliers provide technical advice to the industry 	Máquinas Exactas
Government (MoH)	 Training is offered sporadically Provides safety certifications 	MAXA [®] azúcar para todos



KII FINDINGS: RISK-BASED MONITORING

Data Tracking, Data Sharing, Collaboration for Compliance

RISK BASED MONITORING PRACTICES BY PRODUCERS

- In large companies, monitoring is incorporated in the producers' QA processes. The collected information is used to report to regulatory institutions
- Testing needs to be continuous and adapted to the required regulations. Changes in premix providers or other productions methods are a motivating factor for reassessment
- INCAP promotes that monitoring should be compatible with the variability and magnitude of the fortification process

"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

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

"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

RISK BASED MONITORING BY THE GUATEMALAN GOVERNMMENT

- Each import of fortified food that enters, by law, must go through a release process that depends on the results of the NHL, noncompliance is subject to sanctions
- If an imported good has a history of one year of compliance, it is eligible for exoneration of the process of monitoring
- Risk-based monitoring is restricted by the available resources

"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, and the 5 corn flour samples per batch." - Natalia Espinal, MoH, GT

"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 STRONG MODEL FOR COLLABORATION

"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 "[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



COSTA RICAN INDUSTRY DATA SHARING WITH GOVERNMENT IS MORE AD HOC

"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 "Years ago, the relationship [between industry and government] was very close...because that issue of fortification was being defined. Now, basically 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



KII FINDINGS: ENABLEMENT

Fortification Barriers, Facilitators, Innovation & Evolution

BARRIERS AND FACILITATORS TO SUSTAINABLE FOOD FORTIFICATION

	 Fortification processes have variability 	
BARRIERS	 Scientific studies on nutritional needs lag behind 	
	 Testing methods are costly 	"We need ranges, which they have in Guatemala, but not here in Costa Rica "
		- Maria Sancho, MASECA, CR
	 Central America has a common regulation for LSFF 	
FACILITATORS		

- Large producers are self-reliant for QA/QC
- Pre-mix suppliers are incentivized to innovate



INNOVATIVE FORTIFICATION STRATEGIES



- Academic partners are exploring the addition of new fortificants to the food supply and the associated costs and benefits
- Fortificant suppliers and food producers are developing new techniques in fortification equipment

HPLC (High performance Liquid Chromatography) is a **faster testing method**, but is expensive and requires training. Research into cheap, fast testing is ongoing

 $\langle \rangle$

Guatemala

- Students are involved in the collection of samples monitored for compliance, providing more testing bandwidth
- Government stakeholders are participating in a regional workshop to return to the issue of food fortification monitoring



<u>CONSIDERATIONS FOR</u> SUPPORTING AND EVOLVING FORTIFICATION

Facilitate cross-border information sharing

Balance trust in voluntary compliance with government enforcement

Fund studies to proactively iterate fortificants and their levels

Consider fortificant suppliers as key stakeholders and innovators

Enable academic institutions that provide local testing services

Model successful collaboration between industry, government, academia and international agencies after CONAFOR



RECOMMENDED FURTHER RESEARCH

RECOMMENDED FURTHER RESEARCH





THANK YOU!

Questions and Discussion