Large Scale Food Fortification: Monitoring and Compliance Case Studies in LATAM

Ana Pereda, Jessie Seiler, Lasata Shrestha, Rezaul Hossain and Brandon Guthrie

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STRATEGIC ANALYSIS, RESEARCH & TRAINING CENTER

AGENDA

- Team & START Overview
- Project Overview
- Methodology
- Background
- Findings
    - Regional Landscape
    - Narrative Case Studies
- Comparative Analysis
- Conclusion
- Questions and Discussion

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TEAM OVERVIEW

Ana Pereda, MS

MS Student, Health Metrics Sciences

Project Manager

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MS Student, Epidemiology

Research Assistant

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Research Assistant

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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

PROJECT OVERVIEW

PROJECT OBJECTIVES

Review regional fortification efforts:

- Understand regional support of fortification and how it impacts national projects

Review and analyze existing national food fortification programs in Chile, Costa Rica and Guatemala:

- Review national regulatory systems of food fortification
- Identify successful archetypes in monitoring and sustaining adequate levels of fortification

Comparative analysis of narrative case studies:

- Identify key success criteria on the compliance monitoring systems in fortification programs
- Assess best practices in implementation of food fortification policy
- Document common challenges in fortification compliance

METHODOLOGY

METHODS: EXTENSIVE LANDSCAPE REVIEW

- Reviewed published and gray literature
- Publicly available data sources:
  - Food Fortification Initiative — Enhancing Grains for Healthier Lives
  - Global Fortification DATA EXCHANGE
- Interviewed 2 Key Informants:
  - Dr. Hannia Leon, Executive director of ILSI Mesoamerica
  - Thelma Alfaro, INCIENSA

UN Agencies	International Agencies	Bilateral Agencies	Regional Agencies	Philanthropic Agencies
• World Health Organization (WHO) • United Nations Children's Emergency Fund (UNICEF) • Food and Agriculture Organization (FAO) • World Food Programme (WFP)	• Nutrition International • Micronutrient Forum • International Food Policy Research Institute (IFPRI) • GAIN • PATH	• United States Agency for International Development (USAID) • Center for Disease Control and Prevention (US-CDC) • Japan International Cooperation Agency (JICA)	• PAHO • INCAP • Inter-American Development Bank • ILSI Latinoamerica • SICA	• Bill and Melinda Gates Foundation • Rockefeller Foundation

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BACKGROUND

BACKGROUND

WHAT IS LSFF?

World Health Organization

"Food fortification is defined as the practice of deliberately increasing the content of essential micronutrients in a food so as to improve the nutritional quality of the food supply and to provide a public health benefit with minimal risk to health."

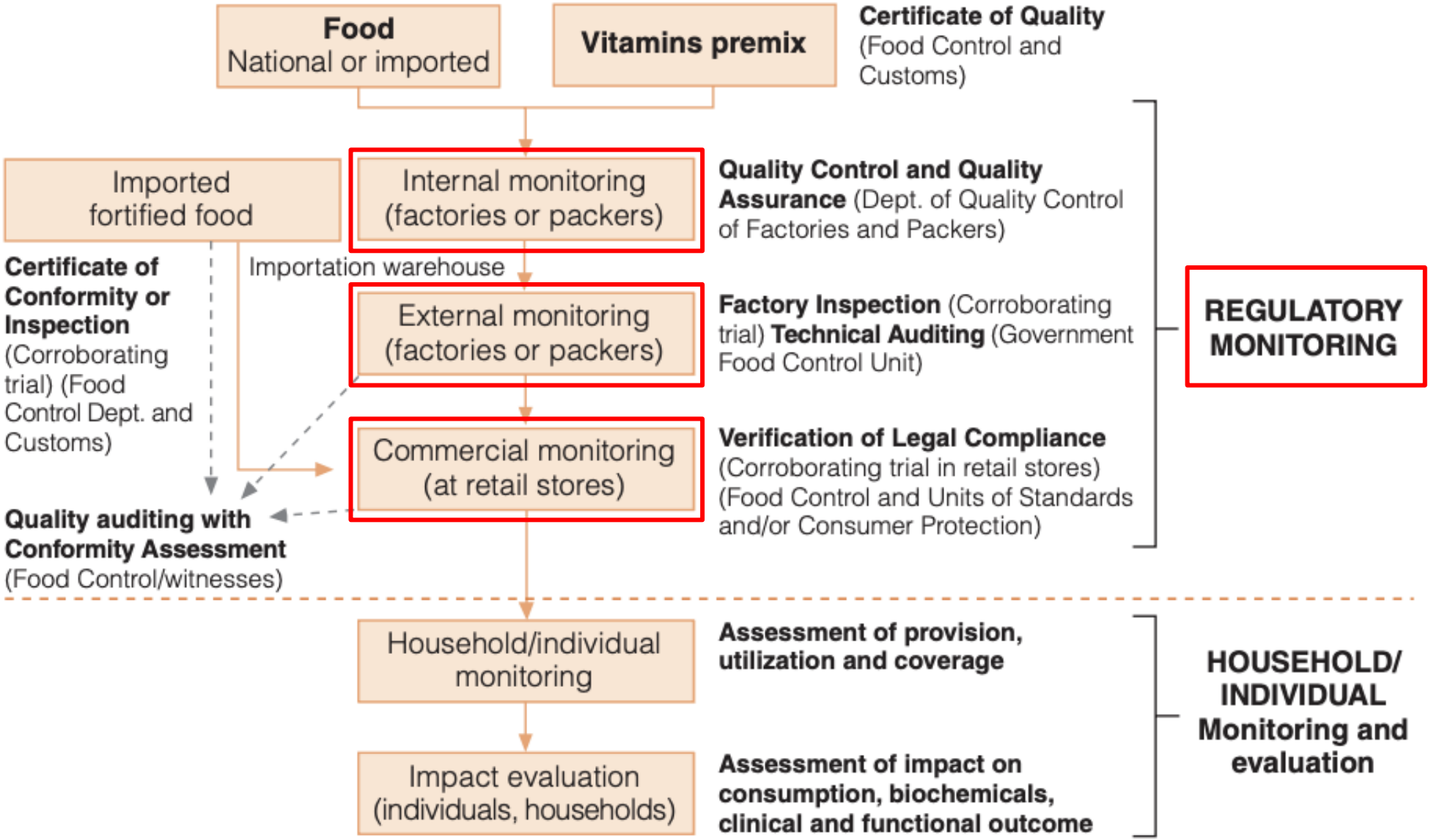
-WHO, Guidelines on Food Fortification with Micronutrients

"Large-scale food fortification (LSFF) is a key part of the response to the crisis of malnutrition, adding one or more essential nutrients to widely and regularly consumed foods during processing."

-Global Alliance for Improved Nutrition (GAIN)

gain Global Alliance for Improved Nutrition

A monitoring and evaluation system for food fortification programs



FINDINGS

Regional Landscape

FOOD FORTIFICATION REGULATORY STAKEHOLDERS

REGIONAL STAKEHOLDERS

PAHO | INCAP | Research Agencies | International Agencies

Capacities:

- Regional strategy and plan of action
- Facilitation of regional cooperation
- Guidelines
- Funding
- Technical assistance in QA and M&E
- Oversee INCAP

Exemplary Activities:

- Guidelines for food fortification in Latin America and the Caribbean (1971)
- Code of practice for food premix operations (2005)
- Improvement of salt fortification programs in selected Latin American countries through multi-sectoral dialogue and technical assistance in quality assurance and monitoring (2001)

REGIONAL STAKEHOLDERS

PAHO | INCAP | Research Agencies | International Agencies

Capacities:

- Coordinating entity for member countries
- Design, implementation, monitoring, and evaluation of public nutrition programs and projects
- Translated and adjusted 13 quality control manuals
- Technical assistance to the network of national laboratories and regional reference laboratories
- Conduct national nutrition surveys
- Training/capacity building
- Progress monitoring toward achievement of agreed nutrition targets by Member States
- Funding evaluation efforts
- Assessment of technologies and vehicles for iron fortification and supplementation

Exemplary Activities:

- Manual for inspection at Point of Sale (2009)
- Situation of Fortified Foods in Guatemala in the Year 2002 (2002)
- Evaluation of the national program of Sugar Fortification with vitamin A in Guatemala (2009)
- Manual para el monitoreo externo de la fortificacion de sal con yodo (Auditoría técnica e Inspección) (2011)

REGIONAL STAKEHOLDERS

PAHO | INCAP | Research Agencies | Regional Agencies

ACTORS	CAPACITIES	EXEMPLARY ACTIVITIES
Instituto de Salud Pública (The Public Health Institute) (ISP)	• Reference laboratories (regional) • Monitoring for the MoH • Impact evaluation	
Instituto Costarricense de Investigación y Enseñanza en Nutrición y Salud (INCIENSA)	• Reference laboratories (regional) • Monitoring and Evaluation: part of the auditing/inspection, take samples of the fortified foods and market.	
Instituto Conmemorativo Gorgas de Estudios de la Salud	• Reference laboratories (regional)	
Center for Studies of Sensory Impairment, Aging and Metabolism (CeSSIAM)	• Surveillance of the Vitamin A status in Guatemala to check for adequacy and to avoid overdosing	• Vitamin A status of Guatemalan population after introduction of fortified sugar (2012) • Nutrition in Vulnerable Populations in Guatemala (2015)

REGIONAL STAKEHOLDERS

PAHO | INCAP | Research Agencies | Regional Agencies

ACTORS	CAPACITIES	EXEMPLARY ACTIVITIES
International Life Sciences Institute (ILSI)	• Dissemination of information • Capacity building (training, webinars) • Liaison between academia, public & private sectors	• Food fortification for Central America and the Caribbean (2016) • III ILSI Latin America Food Fortification Symposium (2016)
Inter-American Development Bank (IDB)	• Fund regional initiatives: provide loans and grants • Support regional coalition • Technical assistance/cooperation • Conduct extensive research	• Public Goods Program: "Regional public goods for food fortification with micronutrients in Central America" (2007) • Food Fortification with Folic Acid and other Micro-Nutrients (2006)
Central American Integration System (SICA)	• Harmonization of Food Fortification Regulations • Regional Cooperation	• Harmonization of Food Fortification Regulations
TechnoServe	• Policy Guidance Document	• Regulatory Monitoring of National Food Fortification Programs: A Policy Guidance Document (2018)
Inter-American Institute for Cooperation on Agriculture (IICA)	• Forum of Rice Fortification participant • Coordination and development of the Assembly of the Inter-American Network of Food Analysis Laboratories	• Agriculture for Nutrition in Latin America and the Caribbean: From Quantity to Quality (2014)

FINDINGS

Narrative Case Studies

CASE STUDIES: OVERVIEW

CHILE: BACKGROUND

VEHICLE	MICRONUTRIENT
Wheat flour	Thiamin Riboflavin Niacin Iron Vitamin D Folic acid
Salt	Iodine

CHILE: STAKEHOLDERS

MINISTRY OF HEALTH	• Enacting and enforcing legislation • Reviews potential changes to fortification program
MINISTRY OF HEALTH REGIONAL OFFICES	• Inspects mills in each region • Collects and sends in wheat samples
NATIONAL REFERENCE LABORATORY	• Conducts analysis of wheat samples • Compiles and disseminates reports
NATIONAL INSTITUTION OF NUTRITION AND FOOD TECHNOLOGY	• Interdisciplinary institution within the University of Chile • Participated in monitoring and evaluation workshop to monitor folic acid in wheat flour samples

CHILE: LEGAL FRAMEWORK

- Article 350 of the Sanitary Regulation for Food Products
- Strong review process triggered in 1965, 2000, 2010, and 2023

1. **Level of fortification**
2. **Labelling**
3. **Monitoring frequency and procedures**

CHILE: QUALITY CONTROL AND COMPLIANCE

Internal Monitoring

- Producers and importers are responsible for proper fortification
- No standard operating procedure for internal monitoring

External Monitoring

- Coordinated between MoH and MoH regional offices
- Samples are taken 4 times a year at each mill
- National Laboratory at ISP conducts laboratory analysis and reports to MoH
- Reports include statistics of samples measured, % of compliance and recommendations by state and micronutrient.

COSTA RICA: BACKGROUND

Since *1973* legislation has been enacted to make fortification mandatory for the following basket of staples

VEHICLE	MICRONUTRIENT
Wheat Flour	Thimine, Riboflavin, Niacine, Folic Acid and Iron
Rice	Thiamine, Niacine, Folic Acid, Vitamin B12, Vitamin , Selenium and Zinc
Sugar	Vitamin A
Salt	Iodine and Fluorine
Milk	Iron, Vitamin A and Folic Acid
Corn Flour	Thiamine, Riboflavin, Niacine, Folic Acid and Iron

COSTA RICA: STAKEHOLDERS

MINISTRY OF HEALTH	• Enacting and enforcing legislation • External monitoring and inspection
INCIENSA	• Technical arm of the MoH aimed to improve food fortification systems and strategies. • Analysis of samples, production of technical reports and publications of teaching materials around nutrition
NATIONAL MICRONUTRIENT COMMISION	• Ensure nutritional food intake • Responsibilities include: promote coordination among public, private and NGOs and create networks for technical cooperation
PRODUCERS AND IMPORTERS	• Fortify according to national legislation • Producers are responsible for internal monitoring and importers must present a certificate of fortification

COSTA RICA: LEGAL FRAMEWORK

- Food fortification included in National Health Law in 1973
- Nutritional problems were set as a priority in national agenda in 1994
- Mandatory legislation for each fortified vehicle includes 14 articles with the following information

1. **Definitions**
2. **Stakeholders**
3. **Import tax exemptions and labelling**
4. **Compliance timeline**

COSTA RICA: QUALITY CONTROL AND COMPLIANCE

Internal Monitoring

- Producers and importers must ensure proper fortification
- Each factory may establish qualitative and quantitative
- To acquire fortification seal for a product the factory must present required documentation. The MoH will conduct an inspection to verify compliance

External Monitoring

- Coordinated between MoH and INCIENSA
- MoH is responsible for sampling at *Point Of Sale* (POS) for all brands in different locations
- INCIENSA conducts sample testing and reports to MoH
- Reports include statistics of samples measured, % of compliance and recommendations if applicable to correct fortification

GUATEMALA: BACKGROUND

Since *1974* legislation has been enacted to make fortification mandatory for the following basket of staples

VEHICLE	MICRONUTRIENT
Wheat Flour	Thiamine, Riboflavin, Niacine, Folic Acid, Iron
Maize flour	Iron (NaFe-EDTA), Folic Acid, Vitamin A, Zinc
Sugar	Vitamin A
Salt	Iodine
Milk	Iron, Vitamin A, Folic Acid

GUATEMALA: STAKEHOLDERS

GOVERNMENT ORGS (MSPAS, MOH, MOE)	• Enacting and enforcing legislation • External monitoring and inspection
INCAP	• Oversees monitoring and quality assurance for fortification • Dispute Resolution: Conducts quality assurance audits for producers in disagreement with Ministry of Health inspections. • Program Integrity: Maintains accountability among sugar producers, ensuring compliance and effectiveness.
NATIONAL HEALTH LAB	• Monitors sugar distribution accuracy with the Ministry of Health. • Compliance Assurance: Analyzes and verifies content, labeling at sales sites.
EPIDEMIOLOGICAL SURVEILLANCE	• Gather vital data through national surveys and initiatives like Micronutrient Sentinel School, CeSSIAM CORMAF*, and SIVESNU**. • Assess program effectiveness and M&E at the household level.

*CORMAF: Regional Commission for Micronutrients and Fortified Foods of Central America
**SIVESNU: Micronutrient Sentinel School and the Health and Nutrition Epidemiological Surveillance System

GUATEMALA: LEGAL FRAMEWORK

- National Strategy Incorporation: Integrated into National Health Law in 1973 as large-scale food fortification strategy
- Specific Vehicle Legislation: Each mandatory fortified product governed by constitution-based legislation overseen by the INCAP and Ministry of Health

1 **Legislation**

2 **Stakeholders**

3 **Monitoring and compliance**

GUATEMALA: QUALITY CONTROL AND COMPLIANCE

Internal Monitoring

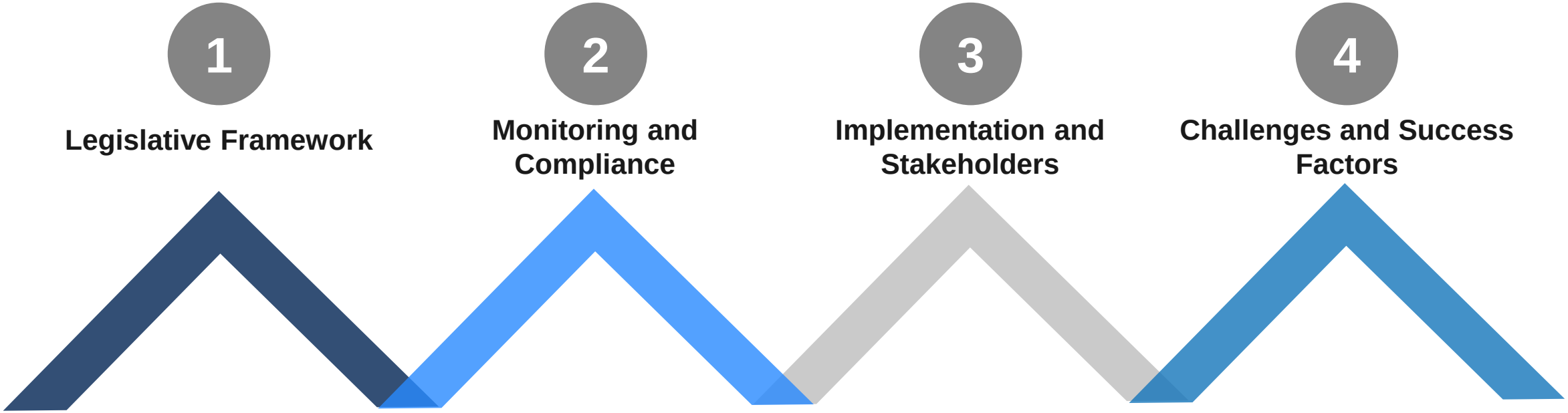
- Producers must ensure proper fortification
- Each factory may establish qualitative and quantitative

External Monitoring

- Regular Content Verification by MoE: Ensures fortified content, labeling, and sales site advertising accuracy *(frequency could not find in public reports)*
- Annual Vitamin A Analysis: Conducts yearly household sugar sample analysis for Vitamin A content

COMPARATIVE ANALYSIS

COMPARATIVE ANALYSIS: OVERVIEW



- Law and Regulation
- Mandatory vs. Voluntary Fortification

- Monitoring mechanisms
- Laboratory Infrastructure
- Enforcement and Penalties
- Sampling Strategies
- Budget
- Data Transparency

- Government Agencies
- Private Sector Involvement

- Barriers
- Success Factors

COMPARATIVE ANALYSIS: LEGISLATIVE FRAMEWORK

	SIMILARITIES	DIFFERENCES
Laws and Regulation	● Costa Rica and Guatemala have a parent legislation placing LSFF as a national strategy ● Costa Rica and Guatemala have specific legislation for basket of fortified staples	● Chile only includes wheat flour legislation under article 350 of the Sanitary Regulation for Food Products
Mandatory vs. Voluntary Fortification	● Fortification of specific vehicles is mandatory for all human consumption	

COMPARATIVE ANALYSIS: MONITORING AND COMPLIANCE

	SIMILARITIES	DIFFERENCES
Monitoring Mechanisms		• Costa Rica only samples at POS (2 times a year) • Guatemala samples at industry, POS and household level (annual) • Chile only samples at industry level (4 times a year
Laboratory Infrastructure	• Centralized laboratory usually working with MoH as a technical branch	
Enforcement and Penalties	• Penalties take the form of official advisory letters and fines all enforced by the MoH	• In Costa Rica, production batches must be retrieved and INCIENSA may initiate feedback loops for systematic errors that may suggest inconsistencies at the production level
Budget	• It is built between MoH and national laboratory	
Data Transparency	• Costa Rica and Guatemala have confidential technical reports	• In Chile, INTA and ISP have public technical reports

COMPARATIVE ANALYSIS: STAKEHOLDERS

	SIMILARITIES	DIFFERENCES
Government Agencies	• Fortification legislation is enacted and enforced by the Ministry of Health • Monitoring, Testing and compliance is done by a national laboratory usually managed by the Ministry of Health usually centralized	• Chile assigns sampling procedure and enforcement to regional offices to the Ministry of Health
Private Sector Involvement	• Industry is responsible of fortification and internal monitoring • There are no guidelines for internal monitoring	

COMPARATIVE ANALYSIS: BARRIERS & SUCCESS FACTORS

	SIMILARITIES	DIFFERENCES
Barriers	• For Costa Rica and Guatemala there are no reports published for compliance levels	• Chile has published information about inconsistencies in sampling
Success	• Strong political will from the central government to fortify and monitor	

LESSONS LEARNED AND LIMITATIONS

LESSONS LEARNED AND LIMITATIONS

1. Legislation mandates fortification for *all human consumption* products and is *comprehensive*
2. Monitoring and compliance is centralized at MoH; and they serve as a coordinating agency for sampling and reporting
3. Monitoring and compliance funding is national and consistent
4. Sampling is occurring at different levels which makes us think that coordination and reporting is more important than procedures

Regional Landscape

The role of INCAP and PAHO was influential especially in Central America to install programs, but it has waned in the past decade. There are no coordinating agencies for South America.

Limitations

- Limited information about specific procedures and challenges from Chile and Guatemala
- Reports and legislation accessed are more than a decade old
- Programs are considered to be successful; it is difficult to point to differentiating success factors

THANK YOU!

Questions and Discussion