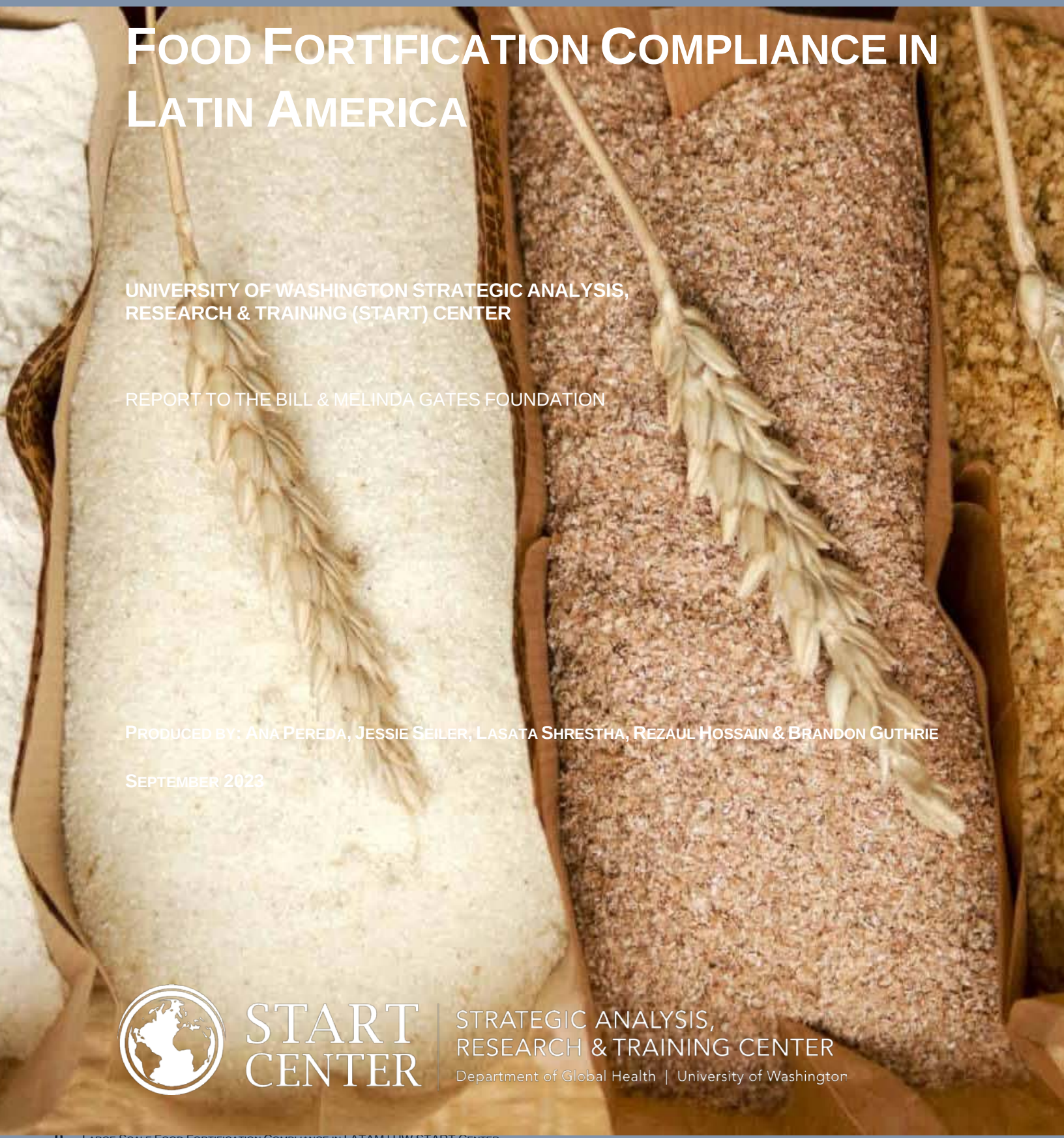

Food Fortification Compliance in Latin America

UNIVERSITY OF WASHINGTON STRATEGIC ANALYSIS, RESEARCH & TRAINING (START) CENTER

REPORT TO THE BILL & MELINDA GATES FOUNDATION

Produced by: Ana Pereda, Jessie Seiler, Lasata Shrestha, Rezaul Hossain & Brandon Guthrie

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START CENTER
STRATEGIC ANALYSIS, RESEARCH & TRAINING CENTER
Department of Global Health | University of Washington

List of Acronyms

Abbreviation	Definition
LSFF	Large scale food fortification
WHO	World Health Organization
WFP	World Food Programme
USAID	United States Agency for International Development
UNICEF	United Nations Children's Emergency Funds
FAO	Food and Agriculture Organization of the UN
PAHO	Pan American Health Organization
INCAP	Institute of Nutrition of Central America and Panama
IDB	Inter-American Development Bank
ILSI	International Life Sciences Institute
MoH	Ministry of Health
INTA	National Institution of Nutrition and food technology
SICA	Central American Integration System
FFI	Food Fortification Initiative
IICA	Inter-American Institute for Cooperation on Agriculture
ISP	Chilean National Institute of Public Health
CIAT	International Center for Tropical Agricultural Research
INCIENSA	Instituto Costarricense de Investigación y Enseñanza en Nutrición y Salud

Executive Summary

In the summer of 2023, the Bill & Melinda Gates Foundation (the foundation) engaged the University of Washington's Strategic Analysis, Research & Training (START) Center to conduct a regional landscape stakeholder analysis and create three narrative case studies about large Scale Food Fortification monitoring and compliance in Latin America. To this end, the START team conducted a literature review of published gray and peer-reviewed academic literature and conducted a series of key informant interviews to complete the research request.

This report summarizes work conducted by the team, providing a review of regional efforts in harmonizing food fortification monitoring practices and identification of key stakeholders with their exemplary efforts or activities. Additionally, the report reviews and analyzes existing national food fortification programs pertaining to select food vehicles and micronutrients in Chile (wheat with folic acid), Costa Rica (multiple food vehicles and micronutrients), and Guatemala (sugar with Vitamin A) to identify successful archetypes in quality assurance and sustaining adequate levels of fortification. Furthermore, a comparative analysis of these successful food fortification programs is also included in the report to identify key success criteria of the compliance monitoring systems in the fortification program.

Key findings from our research:

This research aims to support the BMGF Nutrition team's strategy and focus areas for improving compliance monitoring in national and/or regional fortification in other countries of interest. Some of the exemplar practices and key success factors identified are:

- The role of INCAP and PAHO was influential especially in Central America to install programs but it has waned in the past decade. In South America, there is less presence of bilateral agencies, like the PAHO, and no regional coordinating agencies.
- Mandatory legislation on fortification of food for all human consumption staples are present in Chile, Costa Rica and Guatemala. The legislation specifies the levels of fortification, stakeholders' responsibilities, and sanctions for noncompliance.
- Monitoring and compliance activities are centralized at the Ministry of Health in all exemplar countries. They serve as a coordinating agency that delegates technical analysis to a national laboratory and participates in compliance enforcement.

Content

Introduction

Project Overview

This report summarizes work conducted by the University of Washington's Global Health Strategic Analysis and Research Training Program (START) team in response to the Bill and Melinda Gates Foundation's (the foundation) work order *"Case Study Analysis of Food Fortification Compliance Systems in Latin America.*" This report provides a review of regional efforts in Latin America to harmonize food fortification, an outline of the landscape of regulatory monitoring, and identification of key stakeholders with their exemplary efforts or activities. In the context of food fortification, "monitoring" refers to the continuous collection and review on programme implementation activities, to identify problems, such as noncompliance, and inform corrective actions. The term "evaluation" on the other hand refers to the assessment of the effectiveness and the impact of food fortification programs on the target population.

Additionally, this report reviews and analyzes existing national food fortification programs pertaining to select food vehicles and micronutrients in Chile (wheat with folic acid), Costa Rica (multiple food vehicles and micronutrients), and Guatemala (sugar with Vitamin A) to identify successful archetypes in monitoring and sustaining adequate levels of fortification. Furthermore, a comparative analysis of these successful food fortification programs is also included in the report to identify key success criteria of the compliance monitoring systems in the fortification program.

This work specifically aims to review the large-scale food fortification (LSFF) efforts in Latin America to create narrative case studies and to identify the regional stakeholders. These exemplar practices and key success factors identified through this research aims to support the BMGF Nutrition team's strategy and focus areas for improving compliance monitoring in national and/or regional fortification in other countries of interest.

Methodology

Review of published and gray literature

To understand the regional landscape of LSFF regulatory monitoring in Latin America and country specific case reports, we conducted a rapid literature review of published and peer-reviewed publications. For the impact section of the case studies, academic research including information on regional and country specific micronutrient deficiency, and population level impact evaluation post-fortification was cited. Targeted searches were done as per the needs of the case studies.

Most of the literature review was conducted via gray literature review given the nature of the literature and evidence we aimed to review. The sources included national legislation that was available in government official websites, guidelines and reports, regional case studies, digital media outputs (news, articles, and reports), policy and operation recommendations and manuals issued by bilateral organizations. Appropriate Medical Subject Headings (MeSH) terms and subject headings were used for the search on different databases, including PubMed and the websites for the identified stakeholders. The terms included “large scale food fortification”, “food fortification”, “fortification”, “regulatory monitoring”, “guidelines”, “policies”, and “laws”. To complete case studies, targeted searches were conducted using Google search engines in English and Spanish to access legislation and reports on government official websites and bilateral organizations’ collaborative projects.

Review of publicly available data sources

Publicly available data sources on global progress on food fortification, country-specific nutrition profile, and food fortification status were reviewed for the project. The data sources included the Food Fortification Initiative (FFI)’s Global Progress (1) and Country Profile*s (2)* and the Global Fortification Data Index (GFDx) (3).

Key informant interviews

We conducted key informant interviews to collect information about the regional initiatives taken to harmonize food fortification regulatory monitoring in Latin America, regional stakeholders, country-specific key players, and to identify key data sources. The key informants enabled us to understand the current situation and roles of key regional agencies and enabled us to identify other regional key informants. The interviews were conducted in English and Spanish.

Table 1: Key informant interviews

NAME	DESIGNATION	ORGANIZATION	KEY THEMES
Dr. Hannia Leon	Executive Director	International Life Sciences Institute (ILSI) Mesoamerica, Costa Rica	• Role of ILSI in LSFF • Current situation of the regional landscape • Identification of key stakeholders
Thelma Alfaro	Coordinator	INCIENSA's National Bromatology Reference Center	• Internal and external monitoring and compliance in Costa Rica • Challenges and Success of the LSSF monitoring in Costa Rica

Background

The *Guidelines on Food Fortification with Micronutrients* (4) published by the WHO defines food fortification 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.” Fortified foods have existed for over 100 years and currently over 160 nations worldwide fortify at least one food product or vehicle to supply necessary micronutrients. In order to ensure the provision of fortified food products at a population level, large scale food fortification (LSFF) is crucial. It is an essential tool in the fight against malnutrition as it supports the immune system and can help eliminate micronutrient deficiencies that cause many health problems, including rickets, birth defects, goiter, blindness, brain damage, and weakening the immune system.

LSFF is an evidence-based, and cost-effective system-level intervention that has the potential to improve diets and nutrition. Global Alliance for Improved Nutrition (GAIN) defines LSFF as 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” (5). This enables equitable access to micronutrients through consumption of staple fortified foods which requires effective monitoring and evaluation efforts.

In the context of food fortification, “monitoring” refers to the continuous collection and review on program implementation activities, to identify problems, such as noncompliance, and inform corrective actions. The term “evaluation” on the other hand refers to the assessment of the effectiveness and the impact of food fortification programs on the target population which could be an increase in the intake of a fortified food or of specific nutrients, or an improvement in the nutritional status, health or functional outcomes of the target population.

Guatemala, Chile, and Costa Rica have been recognized as exemplar nutrition programs that include mandatory fortification laws, coordinated monitoring and evaluation systems, and collaboration between the public, private, and academic stakeholders. This report presents a case study for each of these nations and highlights their success factors and facilitators of their nutrition program.

Stakeholder Analysis

The stakeholder analysis aims to provide a snapshot of all the organizations that have played a role in LSFF in Latin America. To understand the regional landscape there is a deeper dive into the local stakeholders and its impact in national programs. Figure 1 summarizes global stakeholders in LSFF

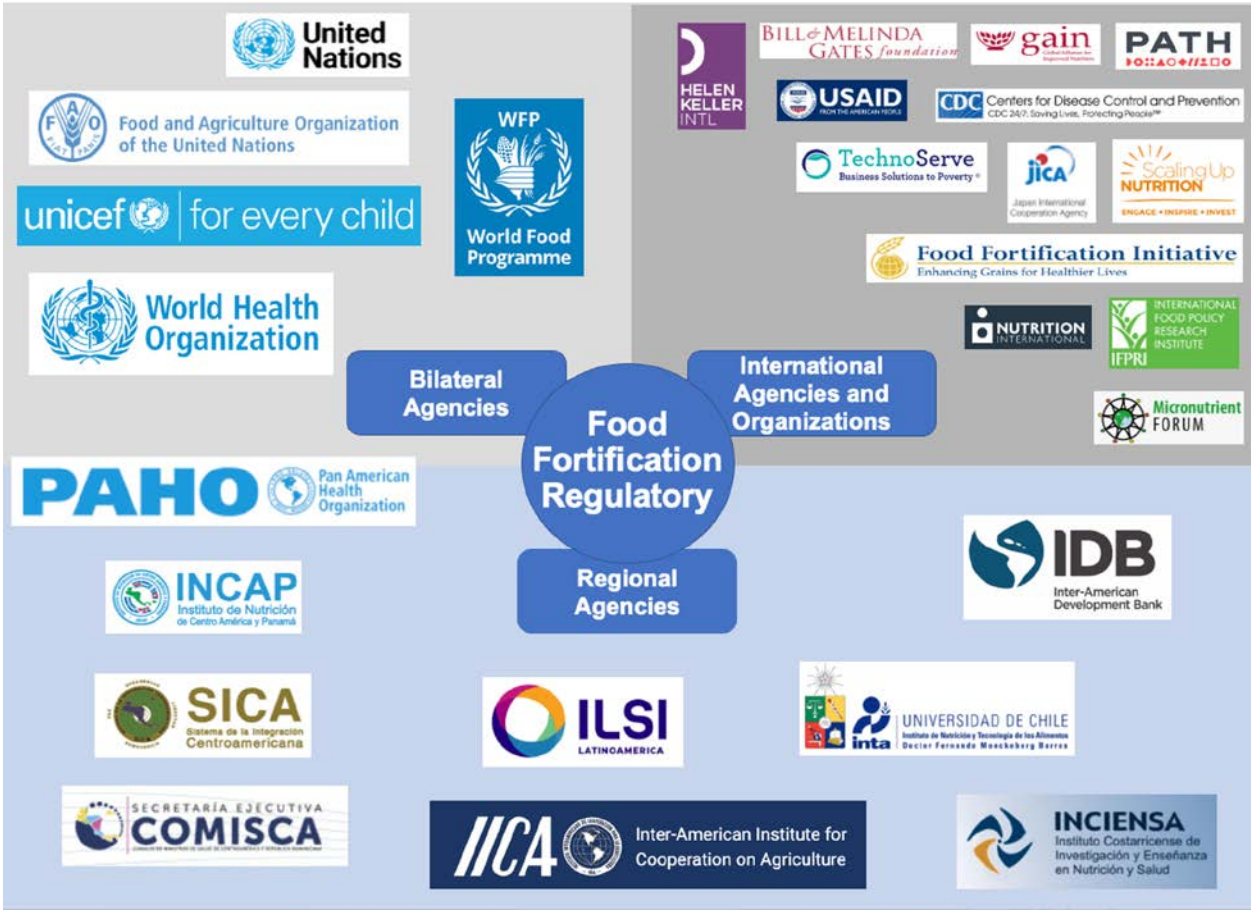

Figure 1: Large Scale Food Fortification Stakeholder Snapshot

The stakeholders are divided into three main groups: bilateral organization, international agencies and organizations, and regional agencies. This section describes each of the identified stakeholders, including exemplary activities in regulatory and compliance initiatives.

Bilateral Agencies: United Nations (**UN**) agencies including the World Health Organization (**WHO**), Food and Agriculture Organization of the UN (**FAO**), United Nations Children's Emergency Funds (**UNICEF**), and World Food Programme (**WFP**) play leadership roles in monitoring food fortification programs by extending their technical expertise as well as formation of guidelines and making policy recommendations. Some of their exemplary activities include: the *Guidelines for Food Fortification with Micronutrients (4)* to assist countries in the design and implementation of appropriate food

fortification programs as part of a comprehensive food-based strategy for combating micronutrient deficiencies. WHO has further established guidelines for specific food vehicles and micronutrients, for instance, the *WHO Guideline: Fortification of Maize Flour and Corn Meal with Vitamins and Minerals (7)*. These guidelines include a compilation of available evidence, recommendations for levels of fortification, monitoring and evaluation approaches, and suggested regulatory monitoring activities for launching food fortification programs.

International Organizations and Agencies: Key global agencies participate mainly in the implementation and funding of fortification efforts. Organizations contributing to regulatory monitoring practices include Global Alliance for Improved Nutrition (**GAIN**), Nutrition International (**NI**), and United States Agency for International Development (**USAID**), and Food Fortification Initiative (**FFI**) among many. Some of their exemplary activities include: GAIN has published policy guideline documents (8) for monitoring of food fortification programs as well as aided in identification of barriers and good practices of regulatory monitoring of fortified food. NI has created an assessment of country-by-country opportunities for food fortification improvements and regional food industry (9), and has conducted a situation assessment of wheat flour fortification in Latin America and Caribbean (10). FFI has been instrumental in monitoring flour fortification in Chile (11) and wheat flour fortification in the Dominican Republic (12).

Regional Organizations: Latin American stakeholders played a critical role in installing and maintaining fortification programs in the region through funding, coordination and technical assistance. Some of its main stakeholders are PAHO, INCAP and Inter-American Development Bank (IDB). Other stakeholders include International Life Sciences Institute (ILSI) Latinoamerica and Mesoamerica, International Center for Tropical Agricultural Research (CIAT), and Inter-American Institute for Cooperation on Agriculture (IICA) among many.

- **PAHO:** It is the regional office for the Americas within the WHO. PAHO's fundamental role in addressing the nutrition problems of the Region is to strengthen the institutional capacity of member states to implement intersectoral policies and programs that promote micronutrient interventions, and healthy diets and physical activity (14). This is achieved by funding and supporting studies assessing nutritional state of its member nations through its collaborating centers, policy observatories (15).

  PAHO also has a unique role to set norms and standards and promote evidence-based programs to address regional nutrition needs and to provide technical cooperation to ensure their implementation and evaluation. For instance, the creation of "*Guidelines for food fortification in Latin America and the Caribbean (1971)*" and "*Code of practice for food premix operations (2005)*"(16). It also aids in fostering regional networks, partnerships, and alliances,

disseminating information on cost-effective interventions, monitoring nutritional trends, documenting best practices, forming policy documents and case studies (15), mobilizing resources, and generating exchange of experiences among countries. To support all these efforts PAHO created INCAP which provides technical cooperation to achieve and maintain the food and nutrition security of their populations, through research, information and communication, technical assistance, training and development of human resources, and mobilization of financial and non-financial resources (17).

- **Institute of Nutrition for Central America and Panama (INCAP):** The Institute of Nutrition for Central America and Panama (INCAP), in the words of one of our key informant interviews, is "the hand of PAHO" in terms of overseeing the food fortification and micronutrient aspect of PAHO, its headquarters are located in Guatemala City and created in 1946 by PAHO. Its role has evolved from conducting regional nutrition evaluation, nutritional surveys, publication of findings (generating evidence for fortification), and policy recommendations to now acting as coordinating entity providing technical assistance regarding fortification initiatives to member countries as needed (17)(18). Given these roles, it has been able to conduct assessments of technologies and vehicles for food fortification and supplementation (19). Primarily, it provides technical and financial assistance in the design, implementation, monitoring, and evaluation of public nutrition programs and projects of its member states. It also monitors the progress toward achievement of agreed nutrition targets and promotes training and capacity building initiatives (13).

  Exemplary activities include translating and adjusting 13 quality control manuals – to adapt it to the Latin American context – that apply to the three monitoring stages for large scale fortified foods (20). They authored manuals for quality assurance and control of micronutrient premixes used in different foods to standardize fortification programs across Latin America. Additionally, initially funded by the IDB in 2010, INCAP was appointed as the coordinating entity to provide technical assistance to the Regional **Network of Laboratories for Central America and the Dominican Republic** to ensure that there are laboratories that can carry out analyzes to monitor the levels of fortification in foods for mass consumption. It provides technical assistance to the network of national laboratories and regional reference laboratories for continuous monitoring of fortification levels in food vehicles, which include Instituto de Salud Pública (The Public Health Institute) (**ISP**) in Chile, Instituto Costarricense de Investigación y Enseñanza en Nutrición y Salud (**INCIENSA**) in Costa Rica, **Instituto Conmemorativo Gorgas de Estudios de la Salud** in Panama, and other national laboratories of its 13 member states (20).

The role of INCAP has been limited to technical advising currently, and according to one KII participant, “INCAP is like an empty building with no one in it.” This has empowered other regional stakeholders to fill the gaps left by INCAP like Inter-American Development Bank (IDB), International Life Sciences Institute (ILSI) Latinoamerica and Mesoamerica, International Center for Tropical Agricultural Research (CIAT), and Inter-American Institute for Cooperation on Agriculture (IICA) among many.

- **Inter-American Development Bank (IDB):** It is the main source of financing for sustainable, social and economic development in Latin America and the Caribbean. Regarding LSFF, it funded the "Regional public goods for food fortification with micronutrients in Central America" (20). This initiative was part of the Promotion of Regional Public Goods created in 2004 by the Inter-American Development Bank (**IDB**). It was designed to harmonize the regional fortification regulatory monitoring efforts by facilitating cooperation of seven countries of the Central American (Guatemala, Honduras, El Salvador, Nicaragua, Costa Rica, Panama, and Belize) from 2007-2012. The project enabled standardization of LSSF production and monitoring for specific food vehicles and micronutrients with support from regional entities like Central American Integration System (**SICA**) including its micronutrient entity the Comisión Regional de Micronutrientes y Alimentos Fortificados de Centroamérica y República Dominicana (**COMISCA**) as well as the nation-specific entities like the Regional Commission for Micronutrients and Fortified Foods of Central America (**CORMAF**) in Guatemala.

- **Other regional stakeholders:** This group is composed of smaller organizations that fill gaps in research and technical expertise coordination.
    - **International Life Sciences Institute (ILSI) International**, has played an instrumental role in acting as a liaison between academia, public, and private sector in LSFF. This is done primarily by assisting dissemination of evidence of nutrient deficiency in the population from academic institutions, supporting capacity building (training, webinars, symposiums, etc.) opportunities, and publication of reports/briefs and policy guidelines/recommendations.
    - **Inter-American Institute for Cooperation on Agriculture (IICA)** is a specialized agency for agriculture of the Inter-American System that supports the efforts of member states to achieve agricultural development and rural well-being. IICA was part of the Forum of Rice Fortification, where the advances in the field and regulations implemented were presented with participation of the industrial sector, consumers, government and international organizations, among other interest groups. Additionally, IICA participated in the coordination and development of the Ninth Assembly of the

Inter-American Network of Food Analysis Laboratories (RILAA) to support regional food safety needs.

- **Alliance of Bioversity International and CIAT** delivers research-based solutions that harness agricultural biodiversity and sustainably transform food systems. It works with local, national, and multinational partners across Latin America and the Caribbean, Asia, and Africa, and with the public and private sector partners including IFPRI, CGIAR members, and HarvestPlus, among many. It has been involved in randomized feeding trials of bio-fortified food products, understanding the consumer acceptance of fortified food products, which has led to selection of appropriate food vehicles, and assessment of nutritional value of fortified products (21).

Narrative Case Studies

This section includes a review of existing national food fortification programs in Chile, Costa Rica, and Guatemala. We offer a brief analysis of the impact of each program, main stakeholders and their roles, the legal frameworks that are in place to support food fortification programs, quality control and compliance practices, and imported product legislation. These elements all illuminate critical archetypal components of successful food fortification programs.

Chile

Background

Chile began mandatory fortification of flour in 1951 by implementing a law that, in the year 2000, was modified to add folic acid to the list of required micronutrients. **Article 350 of the Sanitary Regulation for Food Products in Chile**, the law in question, requires folic acid to be present in the range of 1.0 to 2.6 mg/kg. Other micronutrient requirements are listed below (22)(3).

Table 2- Chile Fortified Vehicle List

VEHICLE	MICRONUTRIENT	DOSE OF MICRONUTRIENT
Wheat Flour	Thiamin	6.3 (mg/kg)
	Riboflavin	1.3 (mg/kg)
	Niacin	13 (mg/kg)
	Iron	30 (mg/kg)
	Vitamin D	0.027 (mg/kg)
	Folic acid	1.8 [1.0 to 2.6] (mg/kg)
Salt	Iodine	40 (mg/kg)

Impact

Neural tube defects in newborns, including spina bifida, anencephaly, and encephalocele, are often preventable with folic acid fortification programs implemented with women of child-bearing age in mind.

In Chile, the folic acid fortification program has been associated with significant decreases in neural tube defect (23)(23)(24). A 2004 evaluation conducted by academics sampled bread from 50 randomly selected bakeries in Santiago in addition to analyzing blood samples from volunteers and reported bread consumption (23). The evaluation, which was conducted in the months following the new requirement for folic acid and which involved shipping samples to the University of Florida for testing, found improved folate status in women of childbearing age, which was the population of interest. The researchers also identified a 40% decrease in neural tube disorders from the pre-fortification period to post-fortification, from 17.2 to 10.1 per 10,000 births (RR 0.60, 95% CI 0.46–0.77).

Main Stakeholders and Roles

Stakeholders in monitoring and compliance in Chile are:

Ministry of Health: Responsible for enacting and enforcing legislation in large scale food fortification. The Ministry of Health reviews requests to change micronutrient levels in fortified vehicles, examines evidence, confers with experts to determine success of the fortification process, and coordinates monitoring efforts.

Ministry of Health regional offices*:* Responsible for inspecting mills within their own regions four times a year and collecting flour samples for analysis, as described below..

National Reference Laboratory, Chilean National Institute of Public Health (ISP): Responsible for analyzing samples of wheat flour sent in by Ministry of Health regional offices and compiles and disseminates reports related to the fortification program.

National Institution of Nutrition and food technology (INTA): An interdisciplinary institution within the University of Chile that conducts nutrition research projects and has participated in a monitoring and evaluation workshop for folic acid in wheat flour samples (6)(11).

Legal Framework

Mandatory fortification of wheat flour is included under a single article, article 350 of the Sanitary Regulation for Food Products (11)(25). It has been updated several times since its inception, including in 1965, 2000, 2010 and 2023. There is a standardized review process in place: any individual or organization can request changes to article 350 and associated regulations. That triggers a technical evaluation to assess whether changes to the law are indicated by the science, after which the Ministry of Health considers the changes with the help of a multi-sectoral committee and stakeholders spanning nutrition science and the milling industry. This process typically takes one to two years before technical

consensus is reached. In fact, this is how folic acid was initially added to the list of nutrients required for flour fortification under Article 350.

Article 350 includes information about the level of fortification for all the micronutrients and the chemical compound that is supposed to be used. Fortified products of all varieties are indicated with a label on the packaging; labels also are required to provide consumer-facing guidance about the benefits of fortified foods.

Quality Control and Compliance(9)(25)

Although the Ministry of Health requires certain levels of fortification in flour and other food, the vitamin premix is not subject to Ministry of Health oversight. In fact, premix levels – which are the vitamin and micronutrient status indicators for the food additive that goes into flour products to ensure their compliance with nutritional standards – are not stipulated clearly in article 350. For that reason, the ministry of health does not oversee premix composition. Suppliers are left to conduct quality assurance checks themselves. Granotec, which is one of the major sources for vitamin premix in Chile, appears to have a rigorous internal quality system, with checks related to the intake of raw materials, verification of the premix's chemical characteristics, and contaminants levels. They also regularly check and verify manufacturing plant hygiene, equipment status, calibration of equipment that weighs product, waste disposal, and finished product analysis. Some wheat flour mills assure the quality of the vitamin premix based on certificates of analysis from premix suppliers and some send samples away for independent analysis.

Quality control and compliance with fortification practices is assured through processes both internal to industrial milling companies and external to them, through the activities of the Ministry of Health, as described below.

Internal monitoring: Chile's national fortification regulations do not prescribe a standard operating procedure for internal monitoring of folic acid at the level of wheat flour production, and there is no national standard for such internal monitoring. The milling sector has strong quality control and assurance systems in place, and mills and milling groups independently developed their own standards of product production procedures; however they are not publicly available.

External monitoring: Quality assurance checks rely on what can be learned from analysis of flour samples post-production rather than inspection at the production stage. Ministry of Health regional offices are required to inspect each mill four times a year, with inspectors taking flour samples for analysis. These samples are sent to a central laboratory, the National Reference Laboratory, which analyzes each sample for required micronutrients. Results of these monitoring activities are published every year, disaggregated by region and micronutrient. A review of Ministry of Health records in 2011 indicated significant improvements in food fortification quality over the previous three years, but not all

regions were found to be observing the requirement to take samples four times a year from each mill. At that time, 9 of Chile's 16 administrative regions had been sending fewer than four wheat flour samples a year for analysis.

The 2011 report also suggests relatively low compliance with required folic acid levels in acquired samples. Although other micronutrients had higher levels of compliance, including 87% of samples with adequate thiamine levels and 90% with adequate riboflavin levels, just 10% of samples were in the required range for folic acid. Furthermore, fortification compliance varied within each given mill during that time, suggesting issues with consistency. However, this report dates to 2011 and conditions may have changed subsequently.

There are no downstream inspections conducted by the Ministry of Health at, for example, the distribution or further processing or retail levels of the supply chain of wheat flour and wheat flour products.

Imported products

Because almost no wheat flour products are imported into Chile, there is no legal framework in place to support standard operating procedures for inspecting imported products for folic acid levels. However, as climate change shifts what Chile (among other countries) are capable of producing for themselves and potentially forces more imported products onto the domestic market, this topic may be worth revisiting.

Costa Rica

Background

Costa Rica has been a global model in its fight to improve public health through campaigns on large-scale food fortification, strengthening the primary healthcare system, sanitation, deworming and immunization since the 1930s (6). The country is recognized globally as an exemplar in health for its tremendous results in indicators like under 5 mortality, maternal mortality, and life expectancy.

The ministry of health in Costa Rica included food fortification as a strategy in 1973 under the National Health Law (26). Since this legislation mandatory fortification has been enacted for the following basket of staples (27):

Table 3- Costa Rica Fortified Vehicle List

VEHICLE	MICRONUTRIENT	DOSAGE
Wheat Flour	Thimine Riboflavin Niacine Folic Acid Iron	6.2 (mg/kg) 47.2 (mg/kg) 55.0 (mg/kg) 1.8 (mg/kg) 55.0 (mg/kg)
Rice	Thiamine Niacine Folic Acid Vitamin B12 Vitamin E Selenium Zinc	6.0 (mg/kg) 50.0 (mg/kg) 1.8 (mg/kg) 10 (µ/kg) 5.0 UI 105.0 (µ/kg) 19.0 (mg/kg)
Sugar	Vitamin A	6.0 - 20.0 (mg/kg)
Salt	Iodine Fluorine	30.0 - 60.0 (mg/kg)
Milk	Iron Vitamin A Folic Acid	1.4 (mg/kg) 600 UI 4.0 (µ/kg)
Corn Flour	Thiamine Riboflavin Niacine Folic Acid Iron	4.0 (mg/kg) 2.5 (mg/kg) 45.0 (mg/kg) 1.3 (mg/kg) 22.0 (mg/kg)

Impact

There are many studies that have looked at the impact of staple fortification of foods in Costa Rica. Through national nutrition evaluation surveys and scientific evaluations, prevalence of many micronutrient deficiencies in Costa Rica have been greatly reduced.

Regional health organizations like PAHO and ILSI report the reduction in micronutrient deficiency diseases. The prevalence of goiter due to iodine deficiency was reduced from 18% in 1969 to 4% in 1979; retinol deficiency, which was mostly affecting preschool children, went from 33% in 1966 to 2% in 1981 (15). A study looking at the effect of folic acid fortification found a 51% decrease in prevalence of neural tube defects from the pre-fortification period to the post-fortification period (28). Finally, a study looking at the effectiveness of the iron fortification program resulted in a reduction of anemia in children from 19% to 4% and in women from 18% to 10% (29).

Main Stakeholders and Roles

Stakeholders in monitoring and compliance in Costa Rica are:

Ministry of Health: Responsible for enacting and enforcing legislation in large scale food fortification in which they define vehicle, micronutrients and level of fortification responding to national health and nutrition surveys, as well as the technology to be used. It is also responsible for external monitoring and inspection.

INCIENSA: The Costa Rican Institute of Research and Teaching in Nutrition is a technical arm of the Ministry of Health aimed to improve food fortification systems and strategies. INCIENSA's main responsibility is to work together with the ministry of health for the analysis of samples, production of technical reports and publications of teaching materials around food and nutrition.

National Micronutrient Committee: Created by the Costa Rican government in 1998 with the goal to ensure nutritional food intake for the population. Responsibilities listed under its legal framework include: to promote coordination among public, private and non-governmental sector, to implement prevention and control of nutritional deficiencies, to create a national network of technical cooperation for food fortification, to recommend procedures for quality assurance and control and promote and build awareness in industry and consumers about the importance of food deficiency and food fortification as a solution for prevention and control.

Producers and Importers: They hold responsibility to fortify foods according to national legislation. Food producers are responsible for internal monitoring practices to ensure

compliance with fortification level, while importers and distributors must present a certificate of fortification to the Ministry of Health before entering distribution channels.

Legal Framework

The first vehicle fortified in Costa Rica was salt with iodine in the late 1960s as a response to regional endemic goiter disease; although it was not until 1973 when that it was included as a strategy in the National Health Law. The two main articles that refer to this process are **article 196 and article 198**, which recognize nutrition as essential for health and designates food producers as responsible to comply with fortification mandate levels, defines fortified food and dosage to improve nutritional value (26).

In 1994 three fundamental policy instruments placed nutritional problems in the national agenda; a declaration to create and execute an agri-food and nutritional plan, a national anti-poverty plan and a national health. This led to the introduction of specific legislation under the Constitution enacted by the Ministry of Health for each of the fortified vehicles and public private alliances that ensure the correct level of fortification (30).

All the food fortification legislation in Costa Rica follows the same format. It includes 14 articles that provide a list of definitions that include: definition for food fortification, specify fortification premix, along with others. It designates producers and importers as the responsible of fortification and internal monitoring, and the ministry of health as the central regulatory body to define the level of fortification and coordinating center for a monitoring system (30),(31),(32).

Incentives for fortification dictates by the law include tax exemption of micronutrient premixes, there was no information found on whether there is special taxationof 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 ministry of health(30),(31),(32).

Finally, all fortified products must follow labeling regulations; the nutrition label must include fortification levels and marketing is controlled by the Ministry of Health. 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 ministry of health will inspect compliance of law referencing national guidelines, certification that the industry is conducting internal monitoring, and sworn declaration that the produces will maintain fortification level and comply to legislation (33).

Quality Control and Compliance

Costa Rica has produced several national plans to prevent micronutrient deficiencies in which they specify highly detailed objectives and goals for the specific vehicle-nutrient pairs (34), (35). The 2011-2020 plan includes sampling twice a year at the industry, point of sale (POS), and household levels (34). The following description of quality control came from an interview with Dr. Thelma Alfaro, who works at INCIENSA and manages food fortification program monitoring.

Internal Monitoring: Producers and importers are responsible by law to ensure proper fortification of their product. Each factory may establish qualitative and quantitative monitoring strategies. INCIENSA provides technical support to industry at the beginning of each fortification program around sampling and analysis and has done specific auditing visits to verify the correct storage of some fortification premixes.

External Monitoring: Ministry of Health and INCIENSA coordinate annual plans to monitor the national fortification program. The Ministry of Health is responsible for the purchase of reagents, equipment, and supplies, while INCIENSA provides the infrastructure, personnel, and basic services.
The plan contemplates the number of samples and frequency and every year two samples are taken of all foods that are fortified by law. The Ministry of Health is responsible for scheduling visits in different regions and sampling at the same location occurs approximately every two years. Samples are taken at different shops (supermarket, grocery store, convenience stores and other small stores) and are intended to include all the brands available. At the borders, they include brands that are not brought through custom. The Ministry of Health and INCIENSA are more interested in POS sampling because product rotation and incorrect storage may cause vitamins and mineral degradation even when correct micronutrients levels are registered in the industry.

INCIENSA produces real time sample reports that are immediately shared with the ministry of health. The MoH enforces fortification by sending sanitary sanctions to brands that are not complying with fortification levels, they must retrieve the production batch from all POS, and communicate strategies to correct fortification. At the end of the year, a technical report is made for each of the fortified vehicles in which they include a complete analysis of all the samples, behavior of the brands over time, and recommendations. Through these analyzes INCIENSA have initiated feedback loops to improve fortification programs; for example, in a given year all samples of nonfat milk did not comply with fortification levels and the analysis revealed that the premix was not stable in lipid free environment and by engaging with the Ministry of Health and industry the error was corrected.

Imported Products

In Costa Rica, importers must present a quality certificate with a quantitative analysis from a certified laboratory of micronutrient composition before custom clearance and distribution of the product, all costs must be covered by the importer (30),(31).

Guatemala

Introduction

Guatemala's commitment to enhancing public health through food fortification dates back to 1974 when the government passed a crucial legislation mandating the fortification of all table sugar intended for domestic consumption with 15 retinol equivalents (RE) per gram of sugar (36). This fortification program has played a pivotal role in significantly reducing the prevalence of vitamin A deficiency in the country.

Beyond sugar, Guatemala has extended the scope of mandatory fortification to other staple foods, with micronutrient dosages based on Recommended Dietary Allowances (RDAs) specifically tailored for Guatemalans (36). In addition to sugar, the following foods are also subject to mandatory fortification in Guatemala (27):

Table 4- Guatemala Fortified Vehicle List

VEHICLE	MICRONUTRIENT	DOSES OF MICRONUTRIENT
Wheat Flour	Thiamine Riboflavin Niacin Folic Acid Iron	6.2 (mg/kg) 47.2 (mg/kg) 55.0 (mg/kg) 1.8 (mg/kg) 55.0 (mg/kg)
Sugar	Vitamin A	15 (mg/kg)
Salt	Iodine Fluorine	20.0 - 60.0 (mg/kg) 175.0 - 225.0 (mg/kg)
Corn Flour	Thiamine Riboflavin Niacin Folic Acid Iron Vitamin B12 Zinc Malic Acid	4.7 (mg/kg) 3.7 (mg/kg) 26 (mg/kg) 1.64 (mg/kg) 38.2 (mg/kg) 5.1 (microgram/kg) 33.0 (mg/kg) 475.0 (mg/kg)

Impact

The assessment of Guatemala's vitamin A fortification program showed encouraging outcomes. Within six months of consuming fortified sugar, a substantial reduction in the prevalence of low plasma retinol levels was observed. After 12 months, the mean prevalence of low plasma retinol values in the

population was less than 5%. The fortification initiative also resulted in a noteworthy 50% decrease in the prevalence of human milk samples with inadequate retinol levels (37).

Advancements in technology enabling the double fortification of sugar with vitamin A and highly absorbable iron tris-glycine chelate present an opportunity to effectively address iron deficiency and iron-deficiency anemia. Remarkably positive outcomes have been witnessed through iron bis-glycine chelate fortification in milk in Brazil, significantly reducing the prevalence of iron-deficiency anemia from 70%-80% to 10%-15% (38)(39).

Overall, the vitamin A fortification of sugar in Guatemala has demonstrated its potential to significantly improve the population's vitamin A status, and the development of double fortification with iron chelate provides a promising solution to address iron deficiency and anemia in the region using the same fortification vehicle.

Main Stakeholders and Roles

Stakeholders in monitoring and compliance in Guatemala are:

Institute of Nutrition of Central America and Panama (INCAP): Plays a central role in overseeing the monitoring and quality assurance processes. In addition to its monitoring responsibilities, INCAP facilitates quality assurance auditing for producers who may have disagreements with the Ministry of Health inspection and monitoring. This auditing process serves as a mechanism to resolve disputes and maintain the program's integrity while promoting accountability among sugar producers. INCAP's involvement ensures the program's effectiveness and compliance with fortification standards, contributing to the overall improvement of the population's nutritional status (40).

United States Agency for International Development (USAID): As an international agency, USAID provided funding for the program’s evaluation and played an important role in supporting nutrition research in the region (6).

***Ministry of Health and Social Assistance (MSPAS)*:** Responsible for enacting and enforcing legislation and for coordination of monitoring and compliance to ensure quality standards (6)

National Health Laboratory: The National Health Laboratory is involved in point-of-sale monitoring, along with the Ministry of Public Health and Social Assistance, to ensure accurate distribution of fortified sugar to consumers. They conduct analysis and verification of net content, labeling, and advertising on sales sites to add an extra layer of compliance assurance (6).

Ministry of the Economy: Responsible for verifying compliance, labeling, and advertising on sales sites, further ensuring that the fortified sugar meets the necessary requirements (6).

Epidemiological Surveillance Authorities: Responsible for national surveys and initiatives like the Micronutrient Sentinel School and the Health and Nutrition Epidemiological Surveillance System (SIVESNU) and, Regional Commission for Micronutrients and Fortified Foods of Central America (CORMAF) in Guatemala. Collecting and analyzing samples at household level (40)

Comisión Guatemalteca de Normas (COGUANOR): Play a crucial role in overseeing the labeling process, which must include weight, registration number, producer information, and a color component to indicate fortification. This comprehensive approach ensures that the program meets quality standards and maintains its impact on improving the population's nutritional status.

National Commission on Food Fortification (CONAFOR): Independent entity that coordinates and supervises sugar fortification in Guatemala. They closely monitor producers' adherence to fortification guidelines and ensure quality control, including proper packaging and labeling.

Consumers and Consumer League Association (LIDECON): Consumers play a crucial role as end-users of fortified sugar, benefiting from the transparency and awareness enhanced by product labeling indicating Vitamin A fortification. The Consumer League Association further supports quality control and compliance by conducting external monitoring and surveillance, obtaining samples from areas with limited official inspections (42).

Legal Framework

The legal framework for sugar fortification with vitamin A in Guatemala began with the introduction of the program in 1976-1977. At this time, sugar producers in the country implemented the fortification process under the direction of Dr. Guillermo Arroyave from INCAP. However, fortification was suspended during the 1977-1978 harvest due to resistance from sugar producers who questioned the program's value (6).

In 1987, Dr. Oscar Pineda revived the fortification program with sugar producers and support from USAID and UNICEF. It improved technical standards, regulations, and technology, while strengthening monitoring and involving various stakeholders in national commissions (37)(38)(6).

In 1992 the Guatemalan government introduced a **General Law for Food Fortification** in which they designate the state as responsible to promote health with special attention to micronutrient

deficiencies. This legislation established the National Commission on Food Fortification (CONAFOR), an independent entity responsible for coordinating and supervising food fortification programs. CONAFOR played a critical role in facilitating discussions and resolving issues during this period. This law holds importers and producers accountable for fortification, as well as internal monitoring. The Ministry of Health and Social Security, specifically the Food Registrar Department, is responsible for external monitoring and ensuring compliance. All premixes, fortification, and monitoring equipment are exempt from import taxes. The law also specifies a five-phase sanction system, starting with a written warning and escalating to financial penalties proportional to the producer's facility. It may also lead to the suspension of activities related to commerce or production for a period ranging from one to six months, or even the ultimate consequence of register and sanitary license cancellation (13)(41).

Guatemala took a pioneering step in sugar fortification, making it mandatory through **Decree 44-92** introduced under the Ministry of Health and Social Security in 2000. This comprehensive law, comprising five sections and 21 articles and covers various aspects of fortification. The initial section defines terms related to sugar, fortification, and the roles of producers and importers in the fortification process. The subsequent section mandates that all sugar consumed in Guatemala must be fortified, specifying the requirements for fortification premixes and levels of fortification. It also emphasizes the responsibility of producers and importers to obtain a sanitary license and register their products with the appropriate institution.

The legal framework for sugar fortification with vitamin A in Guatemala encompasses several crucial aspects to ensure the program's effectiveness and longevity. Packaging and transportation guidelines are included to prevent nutrient degradation during handling and distribution. Moreover, COGUANOR oversees the labeling process, which must include weight, registration number, producer information, and a color component to indicate fortification (43).

The regulation also emphasizes sanctions for producers who fail to comply with fortification levels, aligning with the general law of food fortification. However, to address any disagreements with the Ministry of Health inspection and monitoring, producers have the option to request quality assurance auditing facilitated by INCAP.

Quality Control and Compliance

The quality control and compliance process encompass a series of components meticulously designed to guarantee the effectiveness and success of the fortification program.

Internal Monitoring: Producers and importers are responsible by law to ensure proper fortification of their product. There is no information available about specific procedures.

External monitoring: External monitoring begins with rigorous government inspections to ensure sugar producers adhere to the fortification guidelines outlined in the decree at the industrial level. However, there is no available information regarding the frequency of these inspections. The primary goal of these inspections is to verify that the fortified products meet the required quality standards and deliver the intended nutritional benefits. This transparency and consumer awareness are further enhanced through mandatory product labeling, clearly indicating the Vitamin A fortification.

As part of the vigilance strategy, 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 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. Regular analysis of Vitamin A content in household sugar samples is a cornerstone of the quality control process. This involves collecting samples during multipurpose annual surveys, allowing authorities to assess the actual fortification levels and determine the extent of population coverage. The household surveillance aspect is carried out through essential programs like the Micronutrient Sentinel School and the Health and Nutrition Epidemiological Surveillance System (SIVESNU). These initiatives provide valuable insights into the actual consumption patterns of fortified sugar among the population, particularly in distant regions not covered by routine regulatory monitoring (42).

Publicly available reports are scarce, mainly co-authored by bilateral organizations such as UNICEF and USAID. A 2016 report includes information about all fortified vehicles and micronutrients; it reports the percentage of compliance at POS and household levels (42). Finally a 2021 report from LIDECON offers suggestions to regulatory officers, primarily focused on rectifying labeling issues—by brand and at the point of sale, as well as by region at the household level (44).

Imported Products

Decree 44-92 establishes that all imported sugar must be authorized and cleared by The Department of Food Regulation and Control under the Ministry of Health and Social Assistance (MSPAS); it also specifies that importers and distributors are responsible for fortification and obtaining the health registration (43).

Comparative Analysis

The final objective of this research project was to identify the key success criteria of the compliance monitoring systems in the fortification program. This comparative analysis looks at each country's practices and policies across several areas, including the legislative framework, monitoring mechanisms, enforcement practices and penalties, sampling strategies for micronutrient assays, data issues, and stakeholder roles. It does not intend to be a full analysis of the successes or failures of each program, because each country's needs and characteristics are different, in particular, differences in local availability of certain crops and import/export practices.

Food Fortification in Latin America has been implemented since the 1960s (29)(45). Although Chile introduced wheat flour fortification earlier than Costa Rica and Guatemala, it has the least number of fortified vehicles, significantly fewer than the other countries profiled in this report.

Chile, Costa Rica and Guatemala count with specific legislation that makes fortification mandatory for all human consumption specific vehicles. These are enacted and enforced by the Ministry of Health. Some of the similarities across these laws include standard definitions for fortification, micronutrient, level of fortification, stakeholders and sanctions. Legislation in Costa Rica and Guatemala is under the constitution, while Chilean legislation is under the Sanitary Regulation for Food Products. The Central American legislative framework also includes mandatory explicit procedures for imported products. In contrast, the Chilean system is also notable for lack of regulation regarding imported wheat products, which is justified based on the very low proportion of wheat products that are imported into the country.

The three countries profiled in this report are consistent in their legislation's lack of standard operating procedures for internal monitoring of food fortification at the production level. Their external monitoring practices vary significantly, however, with Costa Rica conducting testing of profiled products at the point of sale twice a year, Chile relying on mill inspections rather than point of sale assays, and Guatemala sampling at industry locations, points of sale, and households. Costa Rica's real-time reporting to the Ministry of Health may also be unique among these programs. Of the three countries, Chile alone has strong data transparency practices. All three countries use official advisory letters and fines to address lack of compliance, an effort coordinated by the Ministry of Health in each country.

In terms of partnerships, food fortification monitoring and compliance is centralized by the Ministry of Health. However, Chileinvolves regional ministry of health offices for sampling and enforcement of compliance, this is likely due to the large geographical size of the country and unique government structure. All three countries depend on a national laboratory site for testing, relying on strong partnerships between various components of the national public health infrastructures. It is important

to highlight that Guatemala and Costa Rica feature more extensive involvement of a large number of organizations compared to Chile, and have created national micronutrition commissions whose sole responsibility is to support LSFF programs.

Despite these differences, all three countries have seen improved public health outcomes as a result of their fortification programs and are considered exemplars in the field. Common strengths that may contribute to these successes include strong political will to keep these policies in place; barriers include non-existent public reporting in Guatemala and Costa Rica, as well as irregular sampling practices in Chile. However, given significant variation in each country's ability to produce critical crops and their need to import basic foods to supplement what they can produce domestically, the comparison of programs suggests that a single set of criteria for judging all the various food fortification programs across the globe is unlikely to be helpful; instead, the contrasts in these highlighted programs and their histories of success suggest that rigorous monitoring and evaluation, including examinations of inputs, activities, outputs, and short-, middle-, and long-term goals, will be critical, due to each country's specific context.

Conclusion and Limitations

The experiences of Chile, Costa Rica, and Guatemala in implementing food fortification programs and their strategy for monitoring and evaluation programs offer valuable insights for global public health efforts.

In conclusion, the success of compliance mechanisms for large scale food fortification hinges on the following characteristics: collaborative efforts, robust legislation and consistent funding, and centralized quality control and monitoring. A strong similarity between the three case studies was the existence of collaborative efforts between government bodies, international entities, research institutions and industry, which was as vital to initiate programs and ensure success. Chile, Costa Rica and Guatemala have robust legislation that underpins effective fortification efforts; they include clear roles, standards and penalties that lay the groundwork for accountability and compliance. In the three case studies included in this report, the Ministry of Health is the central agency responsible for enacting and enforcing legislation, moreover they are the coordinating agency for external monitoring, usually involving a national lab that conducts testing. Guatemala, Costa Rica, and Chile follow different procedures for testing in terms of frequency and level in the supply chain; however, since these three programs are considered successful, this suggests that testing design can vary and adapt to a countries needs and expertise. Finally, funding for quality assurance and compliance in Costa Rica and Chile is national and consistent; Guatemala still receives funding from bilateral organizations, especially when fortification is targeted to vulnerable populations. National and consistent funding is a characteristic that makes these programs more likely to succeed.

Large scale food fortification has been present in Latin America for the last fifty years; the role of PAHO and inception of INCAP was influential to initiate programs, especially in Central America; however, their presence has waned in the past decades and countries have successfully sustained and expanded efforts. There is much stronger coordination and cooperation occurring in Central America, with organizations like SICA, when compared to South America. Finally, international organizations fill the gap around coordination of cross-country cooperation, capacity building and impact evaluation.

Acknowledging the limitations inherent in this study is crucial for a comprehensive understanding of its scope and implications. Firstly, the focus of our key informant interviews was primarily on Costa Rica, which allowed for an in-depth exploration of sampling procedures, implementation nuances, barriers, and successful strategies from the perspective of implementers. While this approach provided rich insights, future research should expand informant perspectives from the other case study countries. Secondly, a notable constraint pertains to the majority of technical reports being classified as confidential national documents. Consequently, this research draws upon academic literature,

policy analyses, and national reports that, in some cases, date back over a decade. Despite this limitation, the enduring positive impact of micronutrient evaluation on population-level nutrition underscores the significance of promoting data transparency. The need to analyze trends over time to facilitate comparisons of implementation strategies remains imperative. Finally, the three case studies investigated represent successful large-scale food fortification programs. The comparative analysis undertaken in this study underscores both commonalities and distinctions among these cases. However, discerning precise differentiating success factors within monitoring and compliance mechanisms was beyond the scope of this assessment.

Future work can involve actively engaging experts in the field to deliberately seek insights to enhance depth of understanding in quality assurance and compliance. This collaborative approach can extend beyond the limitations of existing data sources. Furthermore, another direction can be to identify strategies within the case studies that hold replicable potential for other geographies of interest.

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