FEED THE FUTURE
The U.S. Government's Global Hunger & Food Security Initiative

Assessment of the Policy Enabling Environment for Large-Scale Food Fortification (LSFF) —With an Application to Kenya—

Research Paper #13
December 2022

Authors: Veronique Theriault, Lilian Kirimi, Ayala Wineman, Ephiphania Kinyumu, and David Tschirley

USAID FROM THE AMERICAN PEOPLE
INNOVATION LAB FOR FOOD SECURITY POLICY RESEARCH, CAPACITY, AND INFLUENCE (PRCI)
EGERTON UNIVERSITY
TEGEMEO INSTITUTE OF AGRICULTURAL POLICY AND DEVELOPMENT
MICHIGAN STATE UNIVERSITY

Statement of Support

This report was prepared for the Center for Nutrition of the Bureau for Resilience and Food Security (RFS), United States Agency for International Development by the Feed the Future Innovation Lab for Food Security Policy, Research, Capacity, and Influence (PRCI) with funding from the United States Agency for International Development under Grant No. 7200AA19LE00001.

 Published by the Department of Agricultural, Food, and Resource Economics, Michigan State University, Justin S. Morrill Hall of Agriculture, 446 West Circle Dr., Room 202, East Lansing, Michigan 48824

Authors

Veronique Theriault is an Associate Professor in the Department of Agricultural, Food, and Resource Economics at Michigan State University, East Lansing, Michigan.

Lilian Kirimi is a Senior Research Fellow at Tegemeo Institute of Agricultural Policy and Development, Egerton University, Nairobi, Kenya.

Ayala Wineman is a Research Associate in the Department of Agricultural, Food, and Resource Economics at Michigan State University, East Lansing, Michigan.

Ephiphania Kinyumu is a Senior Research Assistant at Tegemeo Institute of Agricultural Policy and Development, Egerton University, Nairobi, Kenya.

David Tschirley is a Professor in the Department of Agricultural, Food, and Resource Economics at Michigan State University, East Lansing, Michigan.

Authors' Acknowledgment:

The authors wish to thank key stakeholders who were willing to participate in the interviews, survey, and validation event on the policy enabling environment for large scale food fortification in Kenya. Without their participation, this study would not have been possible. The authors are also grateful to Melissa Hill, who assisted with graphical design. Financial support for this study came from the Center for Nutrition of the Bureau for Resilience and Food Security (RFS), United States Agency for International Development under the Feed the Future Innovation Lab for Food Security Policy, Research, Capacity, and Influence (PRCI) (Grant No. 7200AA19LE00001).

Contents

Executive Summary

Food insecurity, including micronutrient malnutrition, remains a challenge in many settings worldwide. As micronutrient deficiencies are primarily driven by poor diets, large-scale food fortification (LSFF) programs that improve the nutritional quality of commonly consumed foods have the potential to improve a population's nutritional status. The success of LSFF programs depends heavily on the "policy enabling environment", understood here to encompass all aspects of the policy landscape that influence and either enable or disable fortification activities.

In this study, we present a novel framework to assess the policy enabling environment for large-scale food fortification. It can be applied either at one point in time or over time (i.e., to monitor and evaluate changes in the policy enabling environment). We conceptualize the policy enabling environment as having three domains: (1) policy agenda setting; (2) policy implementation; and (3) policy monitoring and evaluation. Policy agenda setting encompasses policy prioritization (placing LSFF on the formal policy agenda) and policy formulation. Policy implementation spans all activities through which laws and regulations are put into effect. Policy monitoring and evaluation refers to overseeing and enforcing the implementation of the laws and regulations, evaluating the policy to understand whether it is achieving the desired outcomes and impacts, and reforming if necessary.

Each domain of the policy enabling environment is captured through a set of indicators that can be measured or evaluated through expert judgment. For example, under policy agenda setting, one indicator captures whether there was consultation among stakeholders in the design of the food fortification legislation. Under policy implementation, one indicator captures the extent to which there is adequate financial, human, and physical capacity among the food industries to comply with the fortification policy. Under policy monitoring and evaluation, one indicator captures the extent to which there is enforcement of standards and regulations in a manner that is consistent, fair, and transparent. In total, 18 indicators comprise the policy enabling environment framework.

To apply this framework in the assessment of the policy enabling environment for large-scale food fortification in a country, information on these 18 indicators can be gleaned from existing documentation, key informant interviews, and/or a survey of stakeholder perceptions. Individual key informant interviews can be conducted with a broad set of stakeholders from across the value chain for food fortification, i.e., those involved in food procurement, processing, and trade, as well as in support services. To carry out the key informant interviews, this report includes a semi-structured interview guide with questions about each domain, element, and indicator of the framework. A stakeholder perception survey regarding the policy enabling environment for food fortification can likewise be administered to a broad set of stakeholders from across the value chain. Toward this end, this report includes a questionnaire that can be used to gain insight on the various indicators in the policy enabling environment framework.

Information gathered through the literature review, key informant interviews, and/or a survey can be triangulated to arrive at an understanding of each indicator. To construct an index of the policy enabling environment, a four-point Likert scale is used to score each indicator. The values for each indicator are then summed to arrive at the overall score or index value. There are six indicators under each domain, resulting in equal weighting of each domain in the overall score. This score conveys whether the policy enabling environment is "highly", "moderately", or "marginally" favorable for LSFF activities.

To validate this framework and demonstrate how it can be operationalized, we applied it in Kenya, where a mandatory LSFF program for maize and wheat flours and vegetable oils was introduced in 2012. The fortification requirements apply only to packaged products, though smaller-scale processors of unpackaged products can also participate in the program on a voluntary basis. We carried out a literature review of the LSFF program and conducted interviews with 21 key informants, including representatives of government at national and county levels and representatives of industry, research/academia, development partners, and civil society organizations. We also administered an online survey of stakeholder perceptions to a separate set of respondents that similarly spanned all stakeholder groups. Data collection took place in mid-2022, one decade after the program was rolled out. A validation event was held with stakeholders in Nairobi, Kenya in October 2022 to ensure an accurate interpretation of the qualitative data.

The information gathered was synthesized to assign a value to each indicator of the policy enabling environment framework. Per our assessment, Kenya has achieved the greatest success within the domain of policy agenda setting, moderate success in policy implementation, and has the weakest record in policy monitoring and evaluation. Summing the values across the 18 indicators, we conclude that Kenya has a "moderately favorable" policy enabling environment for LSFF.

This report contains a detailed discussion of each indicator. Multiple perspectives are presented and synthesized whenever we heard diverging accounts or contradictory experiences across different stakeholder groups. Informants generally felt quite positive about the extent of consultation in the initial design of legislation for Kenya's LSFF program, as well as the clarity of the legislation. The interviews also revealed general satisfaction with the extent of consultation and communication in the program's implementation, particularly through the Kenya National Food Fortification Alliance (KNFFA). However, stakeholders were somewhat less enthusiastic about the effectiveness of coordination in the program, especially among different levels of government.

The capacity of processors to comply with the fortification mandate varies with the food product and the size of the firm. Large-scale firms show greater capacity, while small- and medium-scale processors are more likely to struggle with finances, personnel, and access to size-appropriate equipment. Because the maize flour industry includes numerous medium- and small-scale mills, industry capacity is lower for maize flour than for the other products. Regulatory agencies in Kenya also lack human, physical, and financial capacity to surveil and enforce the LSFF program, with limited laboratory capacity (though this is improving over time) and budgets that are sustained by development partners rather than government. Furthermore, Kenya seems to have fallen short when it comes to the collection and dissemination of data on LSFF activities (e.g., volumes, compliance rates) and impacts (micronutrient deficiencies in the population). It is important to acknowledge that the LSFF program in Kenya is just 10 years old and has been on a positive trajectory for many indicators in the policy enabling environment framework.

This assessment yields several policy implications for the LSFF program in Kenya, especially around financial sustainability; ways to improve the processes and reliability of surveillance and enforcement; a need to clarify definitions when measuring compliance and to improve the data landscape; and opportunities for learning that emerge from Kenya's 47 counties and the diversity within its maize flour industry. We conclude that our novel framework of the policy enabling environment for LSFF is a promising tool that is accessible and useful.

List of Tables

List of Figures

List of Acronyms

BEE	Business Enabling Environment
CIN	Consumer Information Network
CMA	Cereal Millers Association
CoG	Council of Governors
Cofek	Consumers Federation of Kenya
DHS	Demographic Health Survey
EAC	East African Community
ECSA-HC	East, Centra, and South Africa Health Community
FSU	Food Safety Unity
GoK	Government of Kenya
IDD	Iodine Deficiency Disorder
JKUAT	Jomo Kenyatta University of Agriculture and Technology
KCO	Kenya Consumers Organization
KEBS	Kenya Bureau of Standards
KEMRI	Kenya Medical Research Institute
KM	Kaleidoscope Model
KNFFA	Kenya National Food Fortification Alliance
LSFF	Large-Scale Food Fortification
MFI	Micronutrient Fortification Index
MoH	Ministry of Health
MoH-NDU	Ministry of Heath–Nutrition and Dietetics Unit
MoU	Memorandum of Understanding
NPHL	National Public Health Laboratory
PHO	Public Health Officer
SAPFF	Strengthening African Processors of Fortified Foods
TAAP	Technical Assistance Accelerator Prelude Project
UGMA	United Grain Millers Association
WEAI	Women's Empowerment in Agriculture Index

1. Introduction

Achieving food security is a continuing challenge worldwide. The combination of climate change, violent conflicts, and other crises (e.g., Covid-19 pandemic and high inflation) has exacerbated food insecurity by disrupting food production and access to food. According to the most recent estimates, about 3.1 billion people cannot afford a healthy diet (FAO et al. 2022). This implies that two-fifths of the population is food insecure, with a concentration in the low-income countries of Asia and Africa. Furthermore, about 10% of the population suffers from hunger, with the highest prevalence in Africa (20%) (Ibid). Meeting the sustainable development goals of ending hunger, food insecurity, and malnutrition (UN/ESC 2022) requires—more than ever—implementing concrete actions to expand access to nutritious and safe foods.

Food insecurity can be linked to undernutrition, overweight/obesity, and micronutrient deficiencies, three types of malnutrition that often co-exist. Undernutrition refers to an insufficient intake of calories and nutrients and can result in underweight, wasting (low weight for height), and stunting (low height for age). Excessive intake of calories, particularly from low-cost ultra-processed foods with little nutritional value can lead to overweight and obesity (high weight for height) and related non-communicable diseases such as diabetes, hypertension, and heart diseases. Micronutrient deficiencies, which refer to inadequate intake of essential vitamins and minerals, can have long-lasting adverse effects on mental and physical health. Globally, vitamin A, iron, iodine, folate, and zinc are the most common micronutrient deficiencies, with iron deficiency being the most prevalent (Bailey et al. 2015). According to the World Health Organization, 42% of children under five and 40% of pregnant women are anemic (WHO 2022a).

Various policies and programs have been implemented to address food insecurity, including price incentives (e.g., trade measures) and fiscal support (e.g., farm input subsidies, cash transfers) (FAO et al. 2022). A key criticism of these programs is that they frequently focus on agricultural productivity, trade, and macro-economic factors rather than on nutrition and, therefore, fail to address the multifaceted nature of malnutrition (Spring 2018). Addressing food insecurity requires a mix of interventions, including some that focus wholly on nutrition.

Given that micronutrient deficiencies are primarily driven by poor diets, they can in principle be ameliorated through large-scale food fortification programs that focus on foods that are commonly consumed. However, the success of LSFF programs in tackling these deficiencies depends heavily on the policy enabling environment, which creates incentives and disincentives to which different stakeholders respond. In the absence of a supportive policy environment for food processors, LSFF in many countries has not been able to reach its full potential (UNICEF 2021).

In this study, we develop a novel framework to assess the policy enabling environment for large-scale food fortification. The framework is comprehensive—spanning the realms of policy agenda setting, implementation, and monitoring and evaluation—and the proposed method is straightforward and low-cost to implement. We apply the method to Kenya, which introduced a new LSFF program 10 years ago. We demonstrate how the method can be used to understand the strengths and weaknesses of the policy enabling environment and to glean policy recommendations to help the LSFF program be more successful. The framework can be applied either at one point in time or periodically (i.e., to monitor and evaluate changes in the policy enabling environment for LSFF following an intervention/policy reform).

The study is organized as follows. First, we define large-scale food fortification and review the literature on enabling environments and relevant assessment methods. Next, we present our novel framework and method to assess the policy enabling environment for large-scale food fortification. Then, we apply the method in Kenya, present results, and discuss policy implications that emerged from this exercise.

2. Key Concepts

2.1 Large-Scale Food Fortification (LSFF)

Food fortification is used to address micronutrient deficiencies in a population. Deficiencies can vary across countries and population groups. Food fortification consists of "deliberately increasing the content of one or more micronutrients (i.e., vitamins and minerals) in a food or condiment to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health" (WHO 2022b:1). Vitamin A, vitamin B_2, vitamin B_6, vitamin D, folic acid, iodine, iron, and zinc are among the micronutrients that have been added to food to address dietary inadequacies (Nutrition International 2022; Olson et al. 2021; Meija 1994). In large-scale food fortification programs, the food vehicles should be widely and regularly consumed foods by the population. Wheat flour, maize flour, salt, sugar, rice, and edible oils and fats are common food vehicles used in such programs. Other criteria to be considered for an appropriate food vehicle are that the added nutrient: 1) is already present in the food; 2) remains stable under typical conditions of storage and use; and 3) will not cause an imbalance of essential nutrients and will not be consumed in amounts sufficient to be toxic (NRC/AMA, 1968 as cited in NAS 2003). Examples of fortified foods include iodized salt, vitamin A fortified oil and sugar, and flour fortified with iron, zinc, and other vitamins.

Food vehicles are not all equal for the purpose of addressing malnutrition through LSFF. Sugar was among the first foods to be fortified in low-income countries, starting in the 1970s in Central America (WHO 2018). Back then, the population consumed sugar regularly but in small quantities. Nowadays, sugar may be viewed as an inappropriate food vehicle as its consumption is substantial and can increase the risk of overweight/obesity and non-communicable diseases such as diabetes. Other food vehicles may also have ambiguous impacts on malnutrition, especially when targeted by contradictory policies. For example, within the same country, the iodization of salt may be mandatory to address iodine deficiency, and at the same time, a tax may be introduced to reduce salt intake (Spring 2018).

Many governments and development partners focus their LSFF initiatives on large-scale firms, which are "food processors that are of sufficient size and sophistication to cover their costs of fortification (equipment, fortificant, operations) within the market price of the fortified foods (typically <5 percent)" (USAID 2002:6). Though the definition of large-scale varies across settings and products, large firms in low-income countries are sometimes delineated as those with a processing capacity of more than 50 metric tons per day (Osendarp et al. 2018; Enzama et al. 2017 as cited in Khamila et al. 2019; USAID 2022).

LSFF programs can be voluntary or mandatory (optional or required by government). The motivation for firms to comply in a voluntary fortification program is likely a combination of promoting public health and increasing profits through product differentiation in an appeal to health-conscious consumers. Under mandatory fortification legislation, governments outline the standards for selecting nutrients and nutrient levels in specific foods and regulate all fortification activities. In the absence of

mandatory fortification legislation, it remains crucial for governments to provide guidelines and oversight to processing firms that voluntarily fortify to ensure product safety for consumers.

The World Health Organization recommends universal salt iodization and the fortification of maize and wheat flours, corn meal, and rice with micronutrients (WHO 2022b). The number of countries with mandatory or voluntary fortification programs for different food vehicles is presented in Table 1. Salt is the most commonly fortified food: worldwide, 126 countries have mandatory requirements for the iodization of salt, while 21 countries set regulations for voluntary fortification.

Table 1. Number of countries with mandatory and voluntary fortification programs

Food vehicle	Mandatory fortification	Voluntary fortification
Salt	126	21
Wheat flour	90	14
Vegetable oil	33	11
Maize flour	19	2
Rice	8	8

Source: Global fortification data exchange (GFDx) 2022

Several recent studies offer lessons for improving LSFF program effectiveness. First, mandatory programs are more successful at consistently providing safe fortified food to the population, leading to greater public health benefits (WHO 2022b). Their success is mainly attributable to better monitoring and regulation. Second, food fortification programs work better when the targeted food sector is concentrated (i.e., just a small number of large formal food processing firms are involved in food fortification) (Lalani et al. 2019). This is because large and mature firms have a greater capacity to absorb the costs associated with fortification and can thus scale their operations more rapidly and keep costs down for consumers. Enforcement costs for regulators are also likely to be lower when fewer firms are involved. Third, LSFF programs that rely more heavily on imported inputs, such as premix, equipment, and agricultural commodities/food products, are more likely to fail (Lalani et al. 2019). Import duties and taxes increase costs and, therefore, can dissuade firms from fortifying. Fourth, LSFF programs that rely not only on the public and private sectors but also on partnerships with other parties and organizations tend to be more successful since they are more effective in promoting mutual accountability (Olson et al. 2021). Finally, food fortification programs are more successful in a policy environment that is enabling to improvements in nutrition (Olson et al. 2021; Lalani et al. 2019). Yet, there is no explicit discussion on which policy elements matter.

2.2 Policy Enabling Environment

The literature review indicates that a policy enabling environment is a key factor in determining the success of LSFF programs. But what, exactly, is a "policy enabling environment" for large-scale food fortification? In the Food Fortification Global Mapping Study (Hoogendoorn et al. 2016), the enabling environment characteristics for different fortified foods, such as salt and vegetable oils and fats, are analyzed without a policy focus and without a clear list or description of those characteristics. Although the role of the enabling environments for agricultural innovation (Batsue et al. 2020; Roseboom 2012; Tripp 2003) and business (WB 2022; ILO 2014) have been widely studied, we are not aware of a study that has defined or assessed the "policy enabling environment" of any activity, including food fortification.

Several analytical frameworks have been used to understand the policy and business enabling environment, policy change, and policy process. Below we describe four analytical frameworks that

have influenced our thinking around a method to assess the policy enabling environment for food fortification. The first framework of relevance is the Business Enabling Environment (BEE), which is used to assess the competitiveness of a value chain to understand how actors behave and make predictions about how they will respond to different interventions (Marketlinks 2021). The second framework is the Kaleidoscope Model (KM), which examines the drivers of policy change and discusses what factors shape the effectiveness of policy implementation (Resnick et al. 2018). The third framework is the PMCA[1] approach, which is used to analyze the policy system around agriculture, including a mapping of stakeholders, along with their interests and influence on policy outcomes; identification of key constraints to policy reforms; and proposal of actions to remove these constraints (Sitko et al. 2017). The fourth framework of relevance is the women's empowerment in agriculture index (WEAI), which measures women's empowerment at the project level to discern whether project interventions are effective in empowering women (IFPRI 2022).

Among these four frameworks, several common elements emerge. First, most frameworks, including BEE and KM, contain a feedback loop to capture the dynamic nature of a policy/business environment. For instance, major events, such as the Global Summit on Food Fortification in 2015, may have a lasting effect on policy design and/or may affect the position of different actors toward food fortification, necessitating the inclusion of a feedback loop to capture the effect of these events. Second, the policy process can be divided into three major domains: the identification of a value chain/policy priority, the intervention/policy implementation, and finally, policy or program monitoring and evaluation. Third, the empirical application of these frameworks often entails a stakeholder mapping exercise. Fourth, most frameworks include a set of indicators to characterize the environment or measure the policy/intervention outcomes. Toward this end, information is drawn from secondary data, key informant interviews, focus groups, and/or surveys. For instance, the World Bank uses 41 indicators spanning ten topics to assess the ease of doing business in 190 countries. The WEAI uses 12 indicators to measure different aspects of empowerment; a person is considered to be empowered if they meet certain criteria for 9 of the 12 indicators.

In this study, we understand the policy enabling environment for large-scale food fortification to be the whole policy landscape that influences and enables or disables fortification activities. This landscape encompasses formal elements (such as laws and regulations, trade agreements, and public infrastructure), as well as informal elements (such as cultural and social norms) that can either facilitate or hinder food fortification.

3. Framework of the Policy Enabling Environment for LSFF

3.1 Domains and Elements of the Policy Enabling Environment

USAID's Feed the Future initiative broadly defines policy as a three-legged stool (Gomes 2018). The first leg represents the laws or regulations that comprise the policy agenda in a country and influence how value chain actors participate in, and benefit from, the formulated policies. The second leg represents the institutions that define and implement those policies. The third leg represents the process through which countries define and implement those policies—referred to as mutual accountability—and the process through which mutual accountability is built and reinforced to ensure

[1] PMCA stands for Policy inventory, Mapping of stakeholders, Constraint identification, and Actions.

that all stakeholders respect their commitment. Each leg is critical to supporting the whole policy environment.

The policy cycle is also relevant to our task of establishing a framework for a policy enabling environment. The policy cycle is commonly conceptualized as having five stages: 1) identification of the issue as a policy priority; 2) placement on the policy agenda; 3) formulation of policy options; 4) implementation of the policy; and 5) evaluation of the policy. One limitation of the policy cycle framework for understanding policy is that it does not explain why an issue gained the attention of policy makers or how decisions were made (Cairney 2019).

Building on this work, we conceptualize the policy enabling environment as having three domains: 1) policy agenda setting; 2) policy implementation; and 3) policy monitoring and evaluation. In an enabling environment, each domain must be strong and closely aligned such that they reinforce one another. In Figure 1, the outer circle represents these three domains. Under each domain, there are two elements (shown in the middle circle). These elements are, in turn, captured through two or more indicators (shown in the inner circle). The framework is circular in order to convey the interconnection in the system, with arrows in the center that show the influence each domain has on the others through a mutually reinforcing and iterative process. The framework can be applied to assess the policy enabling environment for the whole food fortification program or for a specific fortified food in a given country.

We rely on a multi-indicator approach to assess the policy enabling environment for large-scale food fortification. Using multiple indicators allows for measures that are precise and differentiating (Maggino 2014). The set of indicators has been carefully selected after reviewing the relevant literature in order to minimize the risks of omission of relevant indicators, overrepresentation of some elements, and inclusion of irrelevant indicators (Schang et al. 2021).[2] There are six indicators under each domain for a total of 18 indicators.

[2] The set of indicators was further reviewed and validated in the course of applying this framework to the case of Kenya, as discussed in section 4. Only the validated set of indicators is presented.

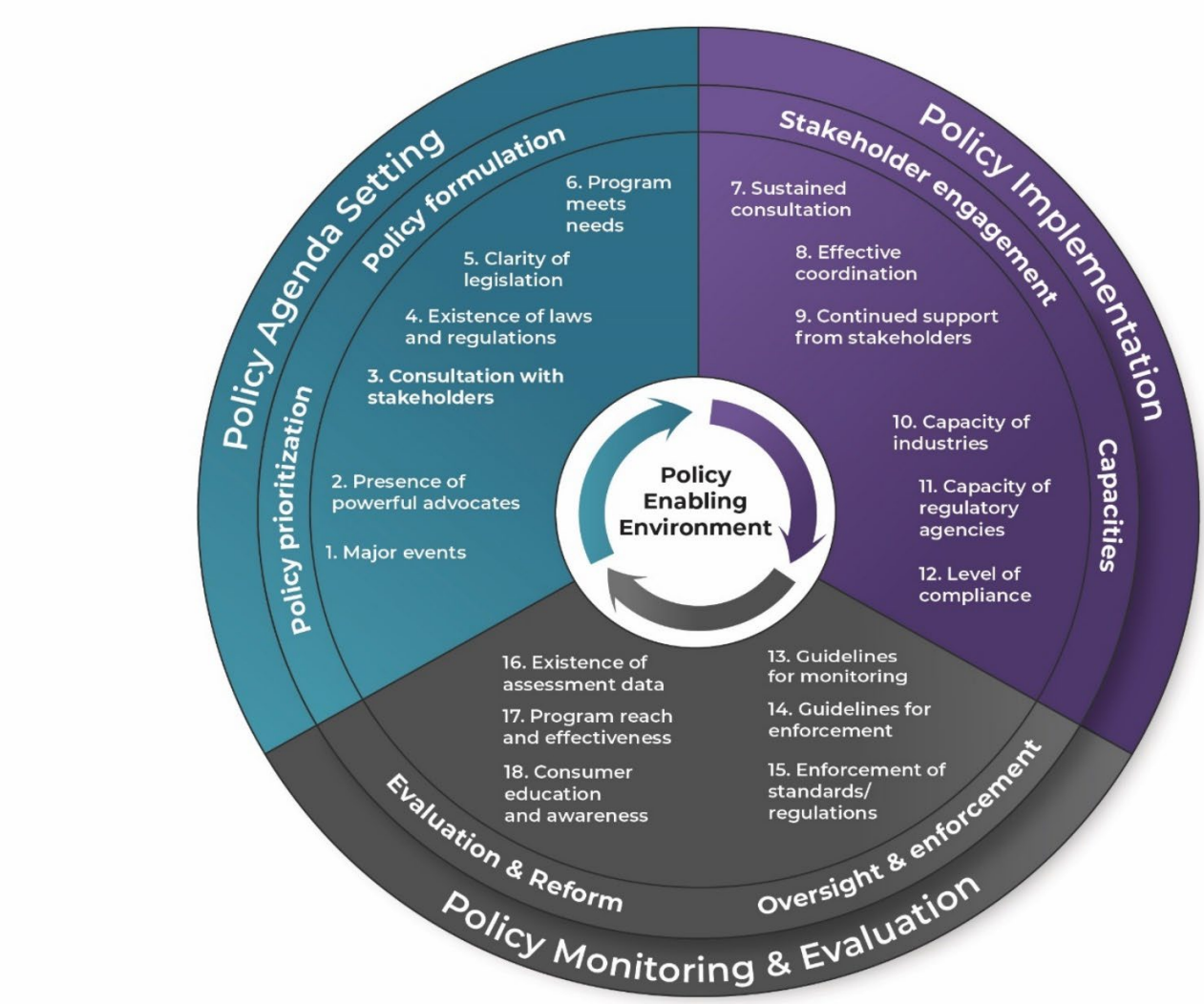

Figure 1. Framework of the policy enabling environment for large-scale food fortification
Source: Authors

The first domain, policy agenda setting, encompasses identifying the issue of micronutrient deficiencies as a priority, placing LSFF on the formal policy agenda (policy prioritization), and policy formulation. Within a country, unlimited issues could be addressed, but only a few make it to the political agenda. Previous work indicates that a problem is more likely to gain the attention of policy makers if it is the focus of a high-level international event and if it has strong advocates (Resnick et al. 2018). The prioritization of food fortification is assessed through the country's participation in a major event, such as the first and second Global Summits on Food Fortification, held in 2015 and 2020, which can attract the attention of the public, food industries, and/or policy makers (indicator 1). The prioritization of food fortification is also assessed through the presence of powerful advocates pushing for action (indicator 2).

Policy formulation refers to the selection, development, and legitimation of policy instruments/actions for LSFF, including the drafting and adoption of laws and regulations. Indicator 3 captures whether there was consultation among stakeholders in the design of the food fortification legislation. As highlighted by Cairney (2019), consultation is critical to ensure that the policy is

accepted. Indicators 4 and 5 capture whether there exist laws and/or regulations on food fortification and whether the legislation is clear and easily understood by stakeholders. As discussed previously, the existence of codified policies, such as a mandate, influences the success of a fortification program (WHO 2022b). Finally, in an enabling environment, the policy instruments must adequately address the issue. That is, the fortification program must be well-designed to meet the population's needs in terms of types and amounts of nutrients and choice of food vehicles to address micronutrient deficiencies in the population and ensure food safety and quality (indicator 6) (Hoogendoorn et al. 2016).

Identifying food fortification as a priority and adopting relevant policies are necessary but not sufficient to create an enabling policy environment. Policy implementation encompasses the activities that put laws and regulations into effect. Indicator 7 measures whether there is sustained consultation among stakeholders to ensure that the program is well communicated and understood, even after the initial design stage. This is important as successful implementation rests on having a well-understood policy (Cairney 2019). Indicator 8 captures whether there is effective coordination among stakeholders through well-defined and complementary roles and responsibilities. Indicator 9 assesses whether there is continued support in terms of enthusiasm, engagement, and assistance from stakeholders in implementing the program.

In addition, there must be adequate financial, human, and physical capacity of the food industries to comply with fortification policies (indicator 10), as well as adequate financial, human, and physical capacity of the regulatory agencies to monitor, control, and enforce product quality and safety (indicator 11). Successful implementation is also reflected in a satisfactory level of compliance with the fortification requirements by the food industries (indicator 12).

The last domain, policy monitoring and evaluation, refers to monitoring and enforcing existing laws and regulations and evaluating and reforming the policy, if necessary. Effective monitoring to track progress is needed to identify gaps in implementation. This is captured through the existence of clear guidelines for monitoring (indicator 13). Program success also requires the existence of clear guidelines for enforcement (indicator 14), along with the enforcement of standards and regulations in a manner that is consistent, fair, and transparent (indicator 15).

An enabling policy environment also includes policy evaluation to assess whether the policy is achieving the desired outcomes and impacts in order to reform the policy agenda and implementation as needed. This requires regular tracking and reporting of assessment data, such as production and sales volumes and rates of compliance with the policy (indicator 16) (Hoogendoorn et al. 2016). In addition, adequate efforts must be made to evaluate the reach and effectiveness of the program (i.e., by measuring rates of compliance, assessing the availability and affordability of fortified products in local markets, and determining the impacts on public health) (indicator 17). Finally, a strong enabling policy environment requires consumers who are aware of the importance of fortified foods, accept fortified foods, and know how to identify them in the market, especially when there is no nationwide mandate (indicator 18).[3] The indicator applies to both mandatory and voluntary fortification, since consumers who disapprove of fortified foods can opt out from purchasing and consuming them.

[3] There is no need to create consumer demand in the context of a mandatory LSFF program (UNICEF 2021).

Table 2. Description of indicators

Domains	Elements	Indicators	Description
Policy agenda setting	Policy prioritization	1. Major events	A major event has attracted the attention of the public/industry/policy makers to LSFF.
		2. Presence of powerful advocates	There are powerful advocates for LSFF in the country.
	Policy formulation	3. Consultation with stakeholders	There was consultation among stakeholders in the design of the LSFF legislation.
		4. Existence of laws and regulations	There exist laws and/or regulations on LSFF.
		5. Clarity of legislation	The legislation related to LSFF is clear/easy to understand.
		6. Program meets needs	The LSFF program is well designed to meet the population's needs in terms of types and amounts of nutrients and choice of food vehicle.
Policy implementation	Stakeholder engagement	7. Sustained consultation	There is sustained consultation among stakeholders in the implementation of the LSFF program (i.e., the program is well communicated and understood).
		8. Effective coordination	There is effective coordination among stakeholders in the implementation of the LSFF program (i.e., roles and responsibilities are well defined and complementary).
		9. Continued support from stakeholders	There is continued support in terms of enthusiasm, engagement, and assistance from stakeholders in the implementation of the LSFF program.
	Capacities	10. Capacity of industries	Industries have adequate financial/human/physical capacity to meet the fortification requirements.
		11. Capacity of regulatory agencies	Regulatory agencies have adequate financial/human/physical capacity to monitor and enforce the fortification requirements.
		12. Level of compliance	There is a satisfactory level of industry compliance with the fortification requirements.
Policy monitoring and evaluation	Oversight and enforcement	13. Guidelines for monitoring	There exist clear guidelines for monitoring LSFF.
		14. Guidelines for enforcement	There exist clear guidelines for enforcement of LSFF.
		15. Enforcement of standards/regulations	The fortification requirements are adequately enforced (i.e., they are enforced consistently, fairly, and transparently).
	Evaluation and reform	16. Existence of assessment data	Data on LSFF (e.g., volumes, compliance rates) and population micronutrient deficiencies are tracked and reported over time.
		17. Program reach and effectiveness	Program reach and effectiveness is satisfactory.
		18. Consumer education and awareness	Consumers are aware of the importance of fortified foods, accept fortified foods, and know how to identify fortified products in the market.

Source: Authors

3.2 Methods of Data Collection and Evaluation

As most of the indicators are qualitative rather than quantitative, we measure them through the lens of key stakeholders' opinions. Eliciting expert opinions is especially useful when information and data are sparse; it allows us to synthesize the limited available knowledge to inform policies (Knol et al. 2010). Different methods exist to elicit stakeholder and expert opinions, including individual interviews, expert group discussions, semi-structured questionnaires administered in person or online, or a combination thereof. The conventional Delphi approach aims at "structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem" (Turoff and Helmer 2002:3). It relies on an iterative process in which expert participants independently respond to written survey questionnaires and then have the opportunity to revise their responses according to the group responses until a consensus is reached. The nominal group technique consists of a structured discussion among a small group of stakeholders to reach a consensus on prioritized solutions or recommendations (CDC 2018).

In this study, we do not explicitly apply one of these methods of elicitation, though we apply some of their concepts by asking expert participants to independently share their views on the policy enabling environment for LSFF. To keep the process simple and low-cost, we suggest two methods for gathering experts' views: individual interviews and an online survey. Individual interviews are more time-consuming but tend to be less financially demanding than expert group elicitation sessions (Knol et al. 2010).

For the individual interviews, we developed a semi-structured interview guide with questions about each domain, element, and indicator of the framework (Figure 1). This interview guide is provided in Annex 1. The guide was built around the 18 indicators, in general eliciting direct responses to the statements in each and then asking for additional information around that indicator. For example, interview subjects are asked whether the country organized a major event on LSFF (Indicator 1), who the policy champions are for LSFF (Indicator 2), and whether there was consultation between policy makers, civil society, and private sector in the design of the LSFF legislations (Indicator 3), with follow-up questions for each to gain more insight.

There is no magic number for the number of experts to interview. In their application of the Kaleidoscope Model to the topic of vitamin A fortification in Zambia, Resnick et al. (2018) conducted semi-structured interviews on policy reform episodes with representatives of 19 institutions. Sitko et al. (2017) recommend that key informant interviews be conducted with at least one relevant public, private, and civil society stakeholder to ensure a minimum level of representativeness at each stage of the PMCA approach. Others suggest that six to 12 experts should be included in an expert panel, as less than six experts might undermine the validity of the results, and more than 12 experts might bring few benefits (Knol et al. 2010). For this assessment, we suggest that at least 20 expert interviews should be conducted, while keeping in mind that interviews should continue until there is data saturation—that is, until no new insights are obtained from an additional interview. Previous work indicates that little information is generated after interviewing 20 experts on a specific topic in most qualitative research (Green and Thorogood 2018 as cited in Vasileiou et al. 2018).

In addition, we designed a survey to elicit stakeholders' perceptions of the policy enabling environment for food fortification. This survey instrument is provided in Annex 2. The survey comprises a set of statements of relevance to the domains, elements, and indicators of the framework. Respondents indicate the extent to which they agree with each statement; they also have an opportunity to provide additional comments. The question of sample size for this survey is not straightforward. The number

of participants in surveys is usually greater than for individual interviews. Braun et al. (2021) note that the appropriate sample size for online qualitative surveys is influenced by the research question and participants' motivation, among other factors. As we aim to capture opinions on a relatively narrow topic (i.e., the policy environment for LSFF), we suggest a target of 40 stakeholders to complete the survey.

Experts interviewed or surveyed should include representatives along the entire food fortification value chain. The value chain comprises four main activities: procurement, processing, trading, and consumption (Figure 2). First, agricultural commodities/food products are produced/procured domestically or procured through imports. The imported food products may be fortified or unfortified. Then, the commodities are processed by large-, medium-, or small-scale processors. This is where fortification occurs; in many settings, it can be expected that some firms do fortify and some do not. Fortification can be mandatory or voluntary. The fortification process requires premix and specialized equipment, such that suppliers of these items are also key actors in the value chain. Finally, the processed food products are distributed through wholesalers and retailers to domestic consumers, or they are exported.

In addition to the stakeholders involved in these four activities, other key stakeholders in the food fortification value chain are those involved in support services. These include government agencies that monitor and enforce regulations to ensure compliance and quality assurance; research networks that provide technical assistance; development partners that support investments in physical and human capital; and civil society organizations that build consumer awareness of the benefits of consuming fortified foods.

To identify experts who can inform the assessment of the policy enabling environment for large-scale food fortification in a country, it is necessary to map the value chain for food fortification. This entails tracing the path of Figure 2 and identifying individuals, firms, organizations, and agencies involved in food procurement, processing, and trade, as well as those involved in support services (development partners, government agencies at all relevant levels, researchers, and civil society organizations). This generation of a stakeholder list can be done through an online search and through a snowball approach in which stakeholders are asked to provide additional contacts that can be approached. From this list, individuals can be selected for interviews and/or for an invitation to participate in the survey. Key informants and respondents for the survey should include representation from across the entire extent of the value chain depicted in Figure 2.

As a last step, a validation workshop should be organized with key stakeholders to review, discuss, and validate the results from the application of the framework.

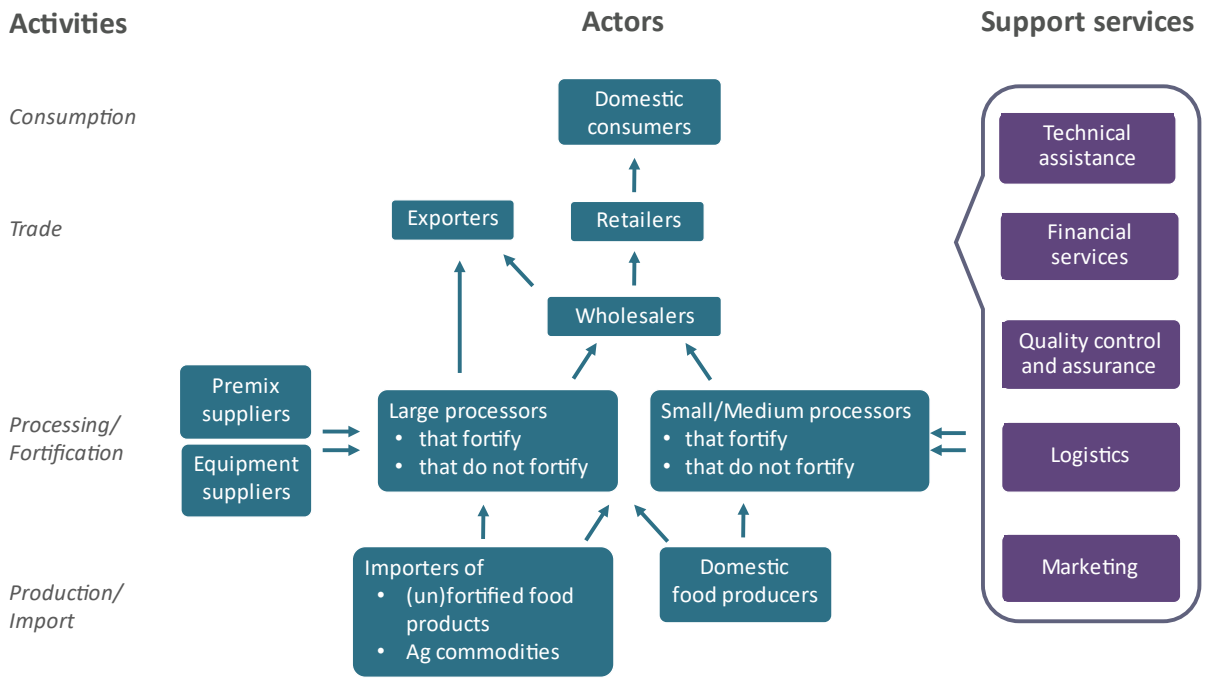

Figure 2. Food fortification value chain map

Source: Authors

3.3 Calculation of the Index

Information gleaned from the existing documentation, key informant interviews, and the stakeholder perceptions survey can be triangulated to arrive at an understanding of each indicator within the framework for the policy enabling environment for large-scale food fortification (Figure 1). To construct an index of this environment, information from all three sources is assessed by the study team and a four-point Likert scale is used to score each indicator. The Likert scale provides more granular information than a binary (0/1) scale. With reference to the descriptions of the indicators provided in Table 2, the four-point Likert scale is as follows: 1=completely disagree; 2=somewhat disagree; 3=somewhat agree; 4=completely agree with the description of the indicator (i.e., the indicator is satisfied). We purposefully omit the option "neither disagree nor agree" to 'force' a decision (Table 3).

The values for each indicator are summed to arrive at the overall score or index value, with a minimum value of 18 and a maximum value of 72. Note that each indicator is given equal weight, and there are an equal number of indicators for each of the three domains of the framework. The policy enabling environment is considered "highly favorable" to large-scale food fortification if the summed score is over 54, "moderately favorable" if it is between 36 and 54, and "marginally favorable" if it is less than 36.[4]

This index can be computed for a country's LSFF program, in its entirety. We follow this approach in Kenya in section 4. However, in countries with multiple food vehicles or sub-programs, this index can also be computed for each commodity and sub-program separately.

[4] The possible scores range from 18 to 72 points, and we divided them equally into three groups.

Table 3. Scoring of indicators

Indicators	To what extent do you agree or disagree with the description of each indicator? (1= completely disagree, 2= somewhat disagree, 3= somewhat agree, 4= completely agree)
1. Major events: A major event has attracted the attention of the public/industry/policy makers to LSFF.	
2. Presence of powerful advocates: There are powerful advocates for LSFF in the country	
3. Consultation with stakeholders: There was consultation among stakeholders in the design of the LSFF legislation.	
4. Existence of laws and regulations: There exist laws and/or regulations on LSFF.	
5. Clarity of legislation: The legislation related to LSFF is clear/easy to understand.	
6. Program meets needs: The LSFF program is well designed to meet the population's needs in terms of types and amounts of nutrients and choice of food vehicle	
7. Sustained consultation: There is sustained consultation among stakeholders in the implementation of the LSFF program (i.e., the program is well communicated and understood).	
8. Effective coordination: There is effective coordination among stakeholders in the implementation of the LSFF program (i.e., roles and responsibilities are well defined and complementary).	
9. Continued support from stakeholders: There is continued support in terms of enthusiasm, engagement, and assistance from stakeholders in the implementation of the LSFF program.	
10. Capacity of industries: Industries have adequate financial/ human/physical capacity to meet the fortification requirements.	
11. Capacity of regulatory agencies: Regulatory agencies have adequate financial/human/physical capacity to monitor and enforce the fortification requirements.	
12. Level of compliance: There is a satisfactory level of industry compliance with the fortification requirements.	
13. Guidelines for monitoring: There exist clear guidelines for monitoring LSFF.	
14. Guidelines for enforcement: There exist clear guidelines for enforcement of LSFF.	
15. Enforcement of standards/regulations: The fortification requirements are adequately enforced (i.e., they are enforced consistently, fairly, and transparently).	
16. Existence of assessment data: Data on LSFF (e.g., volumes, compliance rates) and population micronutrient deficiencies are tracked and reported over time.	
17. Program reach and effectiveness: Program reach and effectiveness is satisfactory.	
18. Consumer education and awareness: Consumers are aware of the importance of fortified foods, accept fortified foods, and know how to identify fortified products in the market.	
	TOTAL:

Source: Authors

4. An Application of the Framework to Kenya

4.1 Background on LSFF in Kenya

Micronutrient deficiencies are prevalent in Kenya, where 26% of pregnant women exhibit iron deficiency; 30.9% and 34.7% of women of reproductive age are deficient in folate and vitamin B_{12}; and 80% of the population experiences zinc deficiency (MoH 2011, cited in GoK 2018). Large-scale food fortification, as highlighted in the National Food and Nutrition Security Policy (KEBS 2012) and the Kenya National Nutrition Action Plan (2018–2022) (GoK 2020b), has been embraced as a key intervention to enhance the intake of key micronutrients.

National food fortification requirements were first introduced in Kenya in 1978 when the Iodine Deficiency Disorder (IDD) legislation made it mandatory for salt meant for human consumption to be fortified with iodine (TechnoServe 2016). Mandatory fortification of vegetables oils and maize and wheat flour was enacted in 2012 with an amendment to the Food, Drugs and Chemical Substances Act of the Laws of Kenya CAP 254, Notice No. 62. At this time, Kenya adopted the East African Community (EAC) standards for fortification, including EAS 767 for maize flour,[5] EAS 768 for wheat flour, and EAS 769 for edible fats and oils. In 2015, the standards for oils and flour were made explicit within Kenyan policy in CAP 254, Notice No. 157 (GoK 2018). As stated in the regulation, these standards apply only to packaged oil, wheat flour, and dry milled maize products, regardless of the size of the food processing firm[6] (TechnoServe 2016:16). Standards on fortification of the four mandated products in Kenya are presented in Table 4.

Table 4. Standards of fortification for salt, vegetable oils, maize flour, and wheat flour

Product	Fortificants	Year of implementation	Standards for key fortificants
Salt	Iodine	1978	Iodine: 50–84 mg/kg
Maize flour	Iron, zinc, folic acid, vitamin B_1, B_2, B_3 (niacin), B_6, B_9, and B_{12} and vitamin A	2012	Vitamin A: 0.5–1.4mg/kg Zinc: 33–65mg/kg Iron: 21–41mg/kg
Wheat flour	Iron, zinc, folic acid, vitamin B_1, B_2, B_3 (niacin), B_6, B_9, and B_{12} and vitamin A	2012	Zinc: 40–80mg/kg Iron: >20mg/kg
Vegetable oils and fats	Vitamin A (retinol)	2012	Vitamin A: ~30 mg/kg

Source: GoK 2018; Fiedler et al. 2014; Makhumula et al. 2014; Global Fortification Data Exchange 2022

In Kenya, packaged maize flour is largely equated with that produced by roller mills and not hammer (posho) mills (Fiedler et al. 2014). Hammer mills use simpler, smaller-scale, and less advanced technology than roller mills, with many of the smallest hammer mills operating as toll mills (fee-for-service mills) that process grain brought to the mill by customers who often produce the grain themselves. There are several reasons for only packaged products to be targeted: 1) It would be logistically and technically more demanding for the government to monitor compliance in the numerous hammer mills that exist[7]; 2) The incremental costs of fortification are understood to be

[5] What is commonly referred to as maize meal in Kenya is considered by the worldwide milling industry to be flour.

[6] "Packaged wheat flour shall be fortified and conform to the food requirements specified"; "Packaged dry milled maize products shall be fortified and conform to the requirements specified"; "Vegetable fats and oils shall be fortified with vitamin A in accordance with the Kenya Standard for edible fats and oil'.

[7] The Cereal Millers Association has a membership of more than 32 large grain milling companies. The Grain Mill Owners Association has about 300 members across 6 associations; one of them being UGMA. The high number of hammer mills is not currently known.

relatively higher for smaller scale millers, as there are economies of scale in fortification; and 3) Size-appropriate fortification technologies (e.g., dosers) are difficult to access (Enzama et al. 2017; Khamila et al. 2019; Makhumula et al. 2014). Nevertheless, the Government of Kenya has expressed an intent to support food fortification by small- and medium-scale industries in the Kenya National Food Fortification Strategic Plan (2018-2022) (GoK 2018).

There is no universal definition of small-, medium-, or large-scale food processors. In Kenya, food processing firms with a production capacity of less than 20 metric tons (MT) daily are usually considered small-scale, while those producing between 20 and 50 MT/day and over 50 MT/day have been referred to as medium- and large-scale, respectively (Enzama et al. 2017). Nano-scale processing firms (i.e., hammer mills/posho mills) are more informal and rarely process more than 10 MT/day.

The Government of Kenya has assessed the level of compliance with fortification standards across the salt, vegetable oil, maize flour, and wheat flour industries (Table 5). For maize flour, brands are understood to comply if they meet the requirements of at least three micronutrients (Khamila et al. 2020). Salt is by far the most concentrated industry with just three registered companies that together supply almost all salt marketed in Kenya (with some exported to other countries). Compliance in the salt industry is reported to be nearly 100% (although it was mentioned during the validation workshop that herbal salts may not be fortified as required). The vegetable oil industry is also relatively concentrated and is dominated by medium- or large-scale companies; an estimated 87% of oil in the market is fortified. Wheat flour is another fairly concentrated industry, and about 80% of wheat flour in the market is fortified. However, maize milling is far less concentrated and compliance is far lower, with just 47 out of 103 commercial mills fortifying and 37% of marketed maize flour being fortified (GoK 2018). Along these lines, a survey of maize mills that produced packaged flour found that all large-scale mills implemented the fortification program, but just 46% of the medium and 24% of small-scale mills complied (Khamila et al 2019).

Table 5. Compliance with fortification requirements by industry

Product	No. registered companies fortifying	% market share of fortified products	Annual production of fortified product in MT
Salt	3	99.9	300,000
Maize flour	47 out of 103 commercial mills/companies	37	1,052,632
Wheat flour	24 (mostly in major towns)	80	789,474
Oil	14 (7 large, 7 medium companies)	87	190,054

Source: GoK 2018

Noncompliance can stem from multiple sources. Firms can ignore the fortification requirements even when they produce packaged product. Some mills can claim to be fortifying when they are not, as was observed in about 10% of firms in a survey of maize mills in Kenya (Khamila et al. 2019). When firms do fortify their product, mismanagement at multiple nodes of the value chain, including manufacturing and distribution, can result in the degradation of the vitamins and minerals (Dunn et al. 2014). To preserve quality before it is used in fortification, premix should be stored away from sunlight, heat, and water and should be kept in polythene bags inside heavy cardboard boxes. However, many mills store premix in sacks, which are permeable to oxygen, and keep the premix at room temperature (Khamila et al 2019; Khamila et al 2020). A last source of noncompliance is the use of premix that

itself does not meet specifications.

Food fortification in Kenya is coordinated by the Ministry of Health, Nutrition and Dietetics Unit (MoH-NDU). Premix suppliers and distributors are certified by the Kenya Bureau of Standards (KEBS) and registered annually by the Ministry of Health, Nutrition and Dietetics Unit (GoK 2018). Guidelines for premix importation are laid out in Premix Requirements KS 2571. The certification process involves an application, an assessment (inclusive of inspection of the production facility and product sampling), and an evaluation (laboratory analysis of the samples) (GoK 2020a). A fortification logo, developed in 2006, is placed on food packaging (Figure 3). However, it has been noted that consumers do not generally recognize the logo or associate it with improved nutrient content (GoK 2018).

Surveillance of fortification is conducted by the Food Safety Unit (FSU), the National Public Health Laboratory (NPHL), and County Governments (GoK 2018). KEBS quality assurance officers conduct inspections of industries in accordance with Monitoring Guidelines KS 2765 (KBS 2017). This includes twice-yearly visits to mills at which point samples are taken and sent for analysis. These audits may be pre-arranged or impromptu.

Figure 3. Official fortification logo

To facilitate oversight and monitoring, the MoH-NDU initially set up a data collection and management system, the national food fortification database (GoK 2018). It was intended that industries, premix suppliers, and regulators would populate the database, and the Ministry of Health would be able to easily monitor the food fortification program. For example, industries were expected to report on their monthly production, amount of premix used, premix manufacturer's name, and dose rate of the premix. Premix suppliers would report on the amount of the premix imported and the industries they supplied. Regulators would enter test results from their surveillance activities.

Though food fortification is officially coordinated by the Ministry of Health, the Kenya National Food Fortification Alliance (KNFFA) oversees fortification activities in the country (GoK 2018). The KNFFA was established in 2005/06 and brings together various public and private sector agencies and development partner representatives. Membership includes the Ministry of Health; Kenya Bureau of Standards (KEBS); industry representatives; the Ministries of Industrialization and Trade; development partners such as WHO, USAID, Nutrition International (NI), and GAIN; and the Kenya Medical Research Institute, among others (TechnoServe 2016). The role of the KNFFA is to coordinate fortification activities and provide guidance and advisory services during development and revision of standards.

4.2 Data and Methods

To assess the policy enabling environment for LSFF in Kenya, we conducted semi-structured interviews with key informants representing various stakeholder groups. Guiding questions used in the semi-structured interviews are found in Annex 1. The interviews covered topics related to policy agenda setting, policy implementation, and policy monitoring/evaluation, and conversations were shaped around the aim of evaluating the extent to which the LSFF program in Kenya has achieved the 18 indicators within the LSFF policy environment framework introduced in section 3.1 (Figure 1). Interviews were conducted virtually from June to September 2022.

Table 6. Key informant interviews

Stakeholder group	No. of informants
Government (national)	2
Government (county)	6
Industry*	4
Civil society organization	3
Development partner*	5
Research/Academia	1
Total	21

*One informant, categorized here as a development partner, was also a representative of industry.

In total, 19 interviews were conducted with representatives of government (at the national and county levels); industry; civil society organizations; development partners; and academia. Two interviews included two informants from the same office, bringing the number of key informants to 21. There was some representation in the sample from each of the main stakeholder groups (Table 6). The affiliations and group categories of these 21 key informants are provided in Annex 3. Each interview lasted 60-120 minutes, with an estimated average of 75 minutes. The interviews were recorded and analyzed thematically to inform our assessment of the LSFF policy enabling environment.

In addition to the key informant interviews, a short stakeholder perceptions survey was conducted to capture the views of stakeholders that we were not able to interview and to more directly gauge the extent to which stakeholders perceive the LSFF program to be functioning well and achieving its goals. The survey was intended to be completed by a diverse set of stakeholders with involvement in LSFF activities. Stakeholders from research and academia were the most likely to complete the survey, so we purposively targeted other stakeholder groups to ensure that all groups have a voice. The questionnaire is provided in Annex 2.[8]

Table 7. Stakeholder perceptions survey

Stakeholder group	No. respondents
Government	13
Industry	8
Civil society organization	2
Development partner	5
Research/Academia	16
Other*	2
Total	46

*The 'other' category includes an independent consultant and the head of nutrition in a hospital.

Participants were identified through online research[9] and through a snowball method of asking key informants and other contacts to identify additional individuals who are knowledgeable about LSFF. The survey was administered online, and invitations to participate were sent between July and September 2022. In total, 46 stakeholders completed the survey, 16 of whom were representatives of research/academia (Table 7). It should be emphasized that this is not a representative sample of the

[8] Note that the questionnaire in the annex is an improved version of the initial questionnaire administered in Kenya. Readers may notice slight differences in the formulation of the questions.

[9] The online search consisted of typing keywords (e.g., maize millers in Kenya) in a search engine (e.g., Google) to collect and compile information needed for the study (e.g., the contact information of large-scale maize millers in Kenya).

universe of LSFF stakeholders in Kenya; rather, the survey can only measure sentiments among those who selected to be included in the sample.

All stakeholders who participated in the interviews were invited to a validation workshop, held in Nairobi, Kenya in October 2022, to review, discuss, and validate our preliminary results. The feedback received in this workshop has informed the results and conclusions presented below.

4.3 Results

Based on information gleaned in the key informant interviews and stakeholder perceptions survey, we assessed the extent to which the 18 indicators of the framework (Figure 1) are found in the policy environment around the LSFF program in Kenya. The values for each indicator and the aggregate policy enabling environment "score" are first presented in section 4.3.1; results of the stakeholder perceptions survey are presented in section 4.3.2; and a detailed discussion of each indicator is provided in section 4.3.3.

4.3.1 Index of the Policy Enabling Environment for LSFF in Kenya

Following the method laid out in section 3.3, each element of the policy environment was ranked on a scale from 1 to 4, with 1 indicating that we "completely disagreed" with the descriptive statement in Table 2 and 4 indicating that we "completely agreed". The values for each element of the framework are presented in Table 8. As per our assessment, Kenya has achieved the greatest success within the domain of policy agenda setting, has achieved moderate success in policy implementation, and has the weakest record in policy monitoring and evaluation. Summing the values across the 18 indicators, this translates into a score of 48—a "moderately favorable" policy enabling environment.

Table 8. Achievement of LSFF policy enabling environment indicators in Kenya

Domains	Elements	Indicators	To what extent does Kenya achieve this indicator? (1 to 4)[a]
Policy agenda setting	Policy prioritization	Major events	4
		Presence of powerful advocates	4
	Policy formulation	Consultation with stakeholders	4
		Existence of laws and regulations	4
		Clarity of legislation	4
		Program meets needs	4
Policy implementation	Stakeholder engagement	Sustained consultation	4
		Effective coordination	2
		Continued support from stakeholders	3
	Capacities	Capacity of industries	2
		Capacity of regulatory agencies	2
		Level of compliance	2
Policy monitoring and evaluation	Oversight and enforcement	Guidelines for monitoring	2
		Guidelines for enforcement	2
		Enforcement of standards/regulations	1
	Evaluation and reform	Existence of assessment data	1
		Program reach and effectiveness	2
		Consumer education and awareness	1
			TOTAL = 48

[a] Scale of 1 to 4, with reference to the descriptions/statements in Table 2: 1= completely disagree, 2= somewhat disagree, 3= somewhat agree, 4= completely agree

4.3.2 Results of the Stakeholder Perceptions Survey

The stakeholder perceptions survey asked respondents to express the extent to which they agreed with various statements that characterize a favorable policy enabling environment for LSFF in their country. Respondents could indicate that they "completely agree", "somewhat agree" "somewhat disagree", or "completely disagree" with each statement or, alternatively, that they do not have an opinion or prefer not to answer.[10]

Results for statements relating to LSFF policy agenda setting are presented in Figure 4.[11] Respondents had favorable views of the extent to which the LSFF program is designed to meet the population's needs (i.e., through the selection of food vehicles and the types and amounts of fortificants). Respondents were least confident that the legislation is facilitative, i.e., that the legislation provides support and encouragement for processors beyond just establishing parameters for noncompliance.

Results for statements relating to policy implementation are presented in Figure 5. Among these statements, respondents felt most positive (on average) about the level of consultation and coordination among stakeholders. However, there was much less agreement that industries have the capacities needed to make the program a success, and under half (46%) of respondents either "somewhat" or "completely" agreed that there is a satisfactory level of compliance with the fortification requirements.

Results for statements relating to policy monitoring and evaluation are presented in Figure 6. Respondents were least likely to feel positively about the level of consumer awareness of, and appreciation for, LSFF. Moreover, 37% of respondents "completely disagreed" with a statement that data on food fortification are tracked and reported consistently. These tabulations will be considered in a detailed discussion of the framework indicators in section 4.3.3.

[10] We cannot directly compare our overall score with a single metric from the stakeholder perceptions survey as the list of statements slightly differs. The version of the stakeholder perceptions survey that was implemented in Kenya has been refined; it is the improved version that is provided in Annex 2.

[11] The number of stakeholders in each group is too small to break down the responses per group and draw meaningful results.

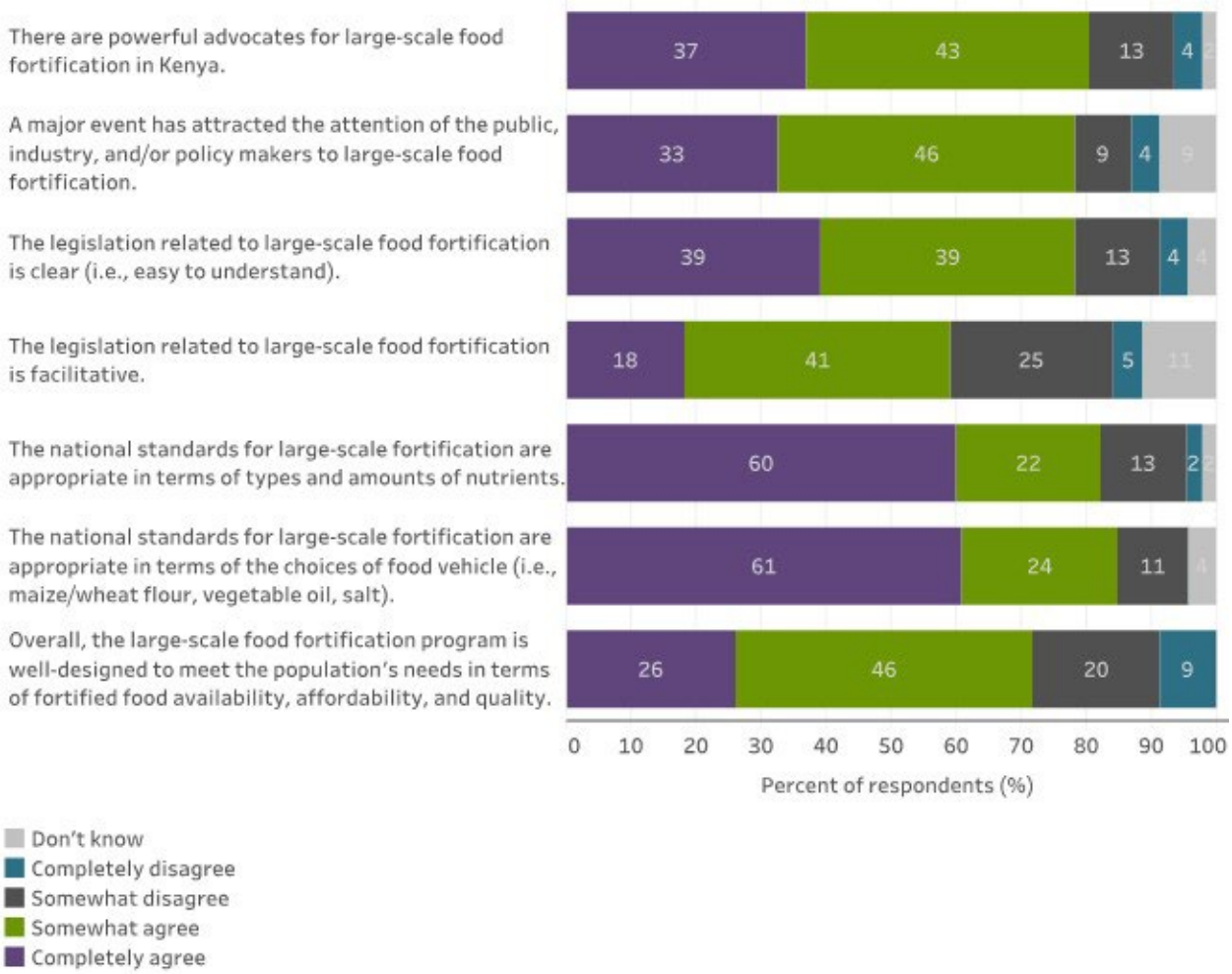

Figure 4. Perceptions of LSFF policy agenda setting

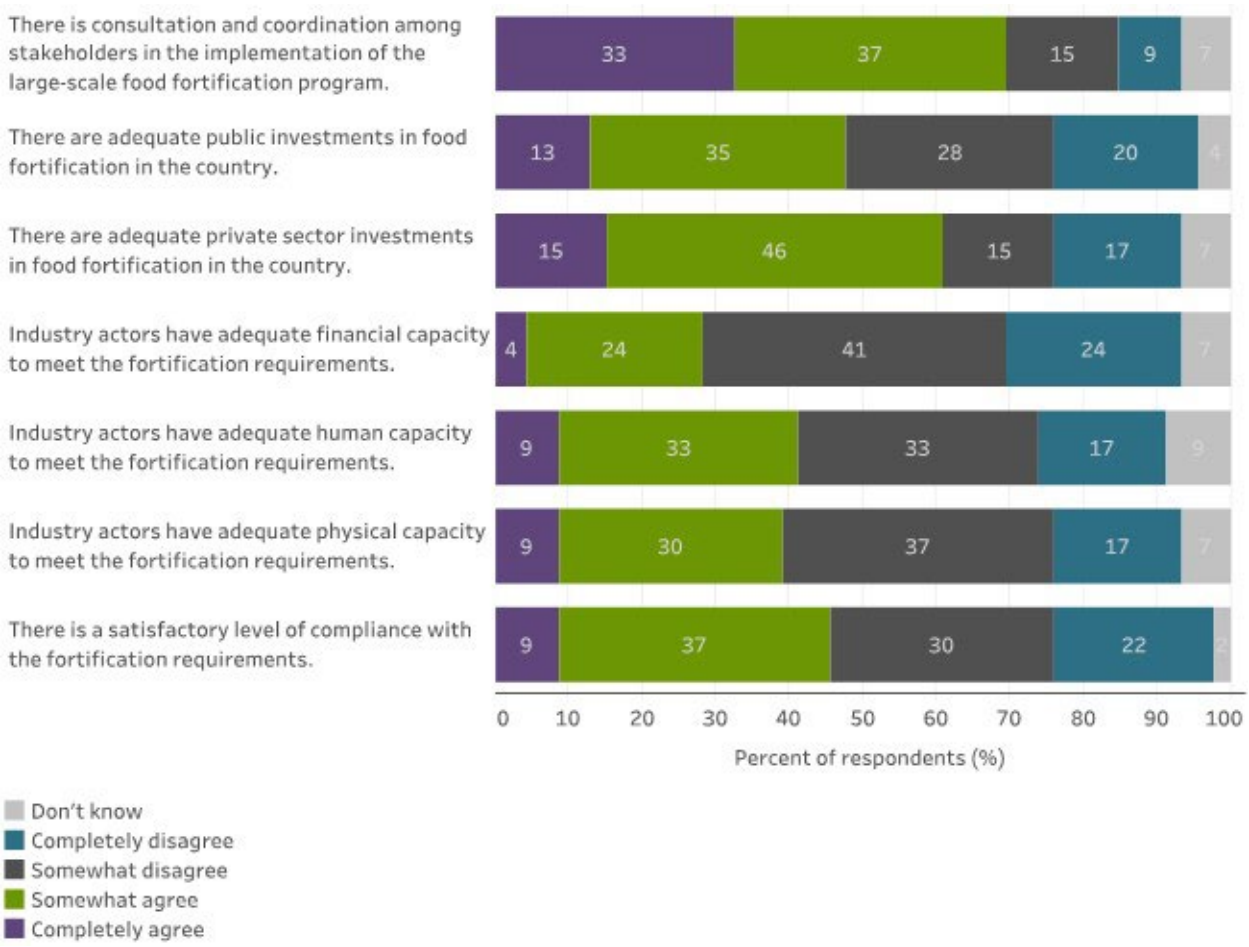

Figure 5. Perceptions of LSFF policy implementation

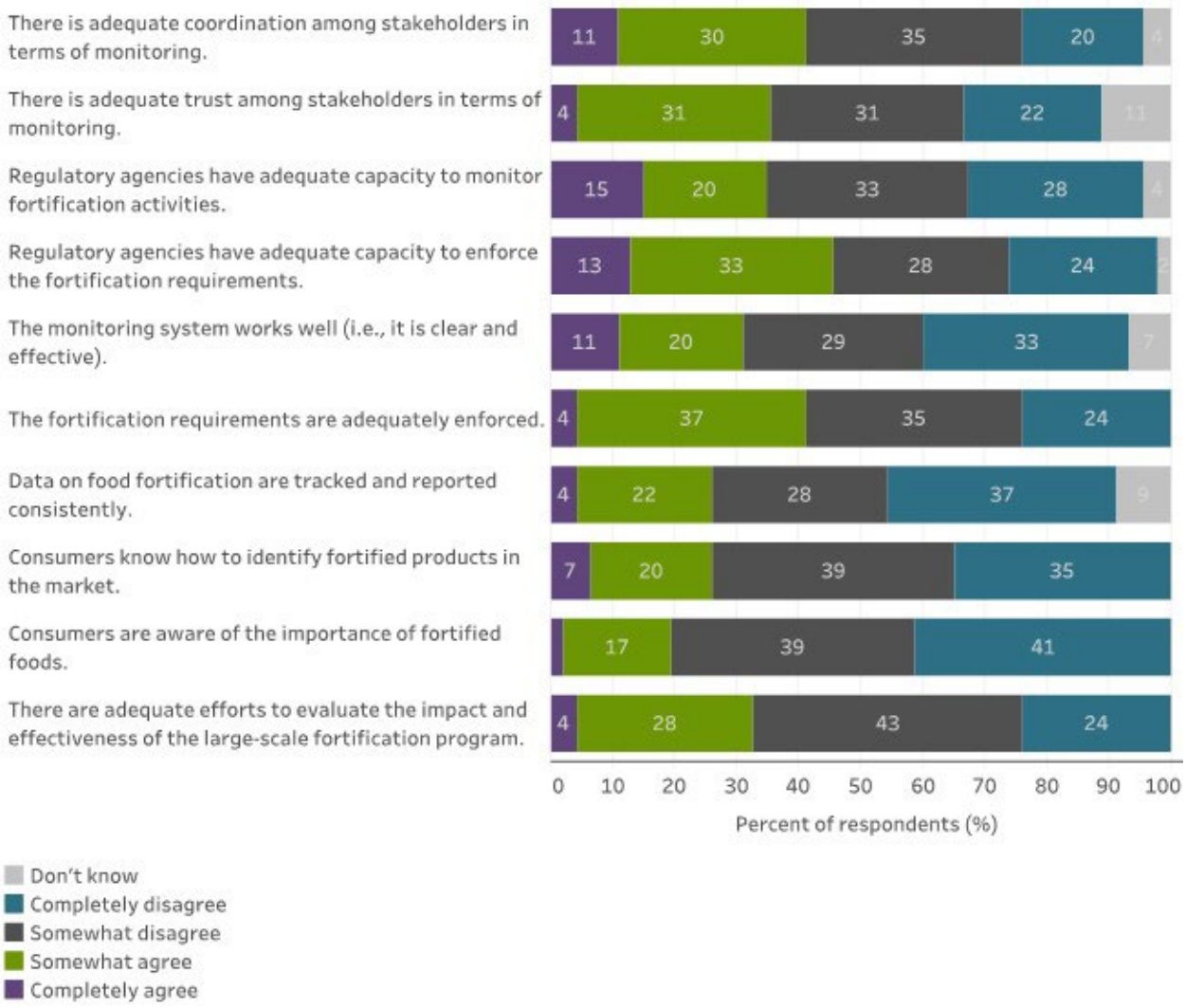

Figure 6. Perceptions of LSFF policy monitoring and evaluation

4.3.3 Evaluation of Indicators of the Policy Enabling Environment

Domain I: Policy agenda setting

Participation in major events:

Kenya has participated in or hosted multiple large events around the topic of LSFF, earning a value of 4 for this indicator of the policy enabling environment. Seventy-eight percent of respondents in the stakeholder perceptions survey "completely" or "somewhat" agreed that a major event has attracted the attention of the public, industry, and/or policy makers to LSFF, and one informant noted that they "have been seeing a fortification event every year or so." For example, a Kenya National Food Fortification Summit was held in June 2021. The fortification summits are perceived as quite successful. They serve as an opportunity for stakeholders to learn about the country's progress in terms of LSFF, share experiences, brainstorm solutions to various challenges, and build awareness of advances in LSFF in other parts of the world.

Presence of powerful advocates:

Kenya has powerful advocates for LSFF, including representatives of government, industry, and development partners, and 78% of respondents in the stakeholder perceptions survey either "completely" or "somewhat" agreed that there are powerful advocates for LSFF in the country. This earns Kenya a value of 4 for this indicator.

> "Goodwill from local leaders is paramount for the success of the food fortification program in the county."
>
> –*Representative of county government*

At the national government, the Ministry of Health, Division of Nutrition and Dietetics has been the main champion of LSFF, and it is supported in compliance and enforcement matters by KEBS (in the Ministry of Industrialization and Trade). Specific names mentioned include Robert Kilonzo, the former head of the Food Safety Division and a food fortification "pioneer" in Kenya, and Brendah Obura and Gladys Mugambi, the current heads of the Division of Food Safety and the Division of Health Promotion, respectively, within the Ministry of Health. Gladys Mugambi spearheaded the fortification program when she was at the helm of the Division of Nutrition and Dietetics. When fortification of edible oils was first being considered, government enthusiasm for the program was high, and Kenya ambitiously aimed to have fortified oil available on the market within 100 days. It should be acknowledged that promotion of the LSFF program is not absolute, and the Ministry of Health understandably shifted its focus during the Covid-19 pandemic away from food safety and fortification.

Champions in Kenya also include the "fraternity" of processors that have been complying with food fortification regulations and standards. Some millers such as Unga Millers Ltd. and Mombasa Maize Millers Ltd. adopted fortification before it became mandatory, and the Cereal Millers Association has played a key role in the Kenya National Food Fortification Alliance (KNFFA) from its inception. The establishment of KNFFA in 2005 created an opportunity to enhance coordination of the fortification activities and advocate to policy makers for greater attention to fortification.

Among development partners, GAIN, Nutrition International, and TechnoServe have provided funding and other types of support for the introduction of fortification for maize and wheat flour in Kenya. These partners supported the drafting of the National Food and Nutrition Security Policy and Implementation Framework, which identifies food fortification as a major tool to address micronutrient deficiencies in Kenya, as well as the Kenya National Food Fortification Strategic Plan. They have also focused on strengthening the capacity of regulatory agencies to monitor and enforce food fortification regulations and providing technical assistance to establish quality assurance and quality control systems for the processors. As will be discussed later, the extent to which support for LSFF comes from development partners rather than being wholly government-owned is viewed as a weakness for the long-run sustainability of the program. Nevertheless, powerful advocates are present in Kenya and are not limited to development partners.

Consultation with stakeholders in policy design:

Stakeholders in Kenya generally felt quite positive regarding the extent of consultation in the initial design of legislation for the LSFF program, earning Kenya a value of 4 for this indicator. From the start, it seems a diverse set of stakeholders were engaged in the process of developing the fortification standards. In fact, we heard that the introduction of mandatory standards was partly motivated by industry, as firms that were fortifying in accordance with recommendations (at the time) wanted this to be required of their competitors to foster a level playing field.

The KNFFA was established in 2005, with stewardship from the Ministry of Health, to coordinate and supervise all activities associated with food fortification. The chairmanship comes from the private sector, while government officials comprise the secretariat. In 2012, when the LSFF mandate was first extended to maize and wheat flours and edible oils, we heard there was "a large convening", inclusive of industries, research/training institutes, various arms of government, and at least one consumer outreach organization, among others. For example, the Consumer Information Network (CIN) has been involved in the design of the LSFF program since 2012 and was part of team that developed the logo, standards, and testing procedures.

However, we did learn of certain oversights in terms of stakeholder engagement at the point of policy agenda setting. Specifically, industry engagement in the initial stages of the LSFF program were limited to associations representing large-scale firms; for maize flour, the CMA was engaged, while the UGMA was not engaged. The legal framework was already in place before the small- and medium-scale millers had even formed their associations or organized their involvement in LSFF.

Existence of laws and regulations:

> "As a county, we need to sit down and customize some of those [national] policies to address some of our [county-specific] needs."
>
> –*Representative of county government*

As noted in section 4.1, Kenya has had national fortification requirements for salt since 1978, and for vegetables oils and maize and wheat flour since 2012. The latter is found in an amendment to the Food, Drugs and Chemical Substances Act of the Laws of Kenya CAP 254, Notice No. 62. The law was reviewed in 2015 to harmonize the Kenyan standards with those of the East African Bloc, and the standards for oils and flour were made explicit within Kenyan policy in CAP 254, Notice No. 157 (GoK 2018). The national standards for premix have been reviewed as recently as 2020. The existence of these laws and regulations earns Kenya a value of 4 for this indicator.

It seems that some counties are starting to contextualize these laws and regulations by crafting county-level policies around fortification. For example, GAIN has supported four counties (Mombasa, Nairobi, Nakuru, and Kiambu) to draft food fortification and safety policies; as of the time of writing, they are each at different stages of the policy design process.

Clarity of legislation:

Stakeholders in Kenya generally felt positive regarding the extent to which the legislation on LSFF is clear (easy to understand), with 78% of survey respondents either "completely" or "somewhat" agreeing on this point. Overall, the legislation is clear on which processors are required to fortify which products, with which specific fortificants, and at what level. This earns Kenya a value of 4 for this indicator, even as we can identify some room for improvement.

The Food, Drugs, and Chemical Substances Act (in which food fortification is anchored) identifies public health officers as the implementers of the program, and their mandate is considered to be clear. The roles of different stakeholders are defined in the terms of reference (ToRs) and not in the law itself. The TORs are found in program-level documentation (e.g., strategy or guidance documents) produced by the KNFFA. In Kenya, health is a devolved function, and county public health officers are mandated to ensure the standards are met at the market level. Additionally, the Ministry of Health has contracted KEBS via a Memorandum of Understanding (MoU) to check if industry is complying with the mandate and to take enforcement measures if necessary. While the

roles of various players are not spelled out precisely in the legislation, this does not seem to be a major source of confusion for stakeholders.

There are, however, two areas where clarity of the legislation can be improved. First, according to informants, the food fortification law does not specify penalties for noncompliance. In fact, penalties are not delineated in *any* document, leaving regulatory agencies and prosecutors with room for discretion. In at least some counties, firms that are noncompliant are first issued a warning. Thereafter, the prosecutor discusses each case with the magistrate, deciding on a penalty that fits the magnitude of the problem. In contrast, if someone is found guilty of adulteration of food, a fine is prescribed in the law. This lack of specificity has both drawbacks and benefits, as will be discussed in detail below.

> "There are so many small millers who have not been involved, so it appears like a double standard. We wish that all of them would be involved."
>
> –*Representative of county government*

Second, the mandate for fortification applies only to packaged products. For the maize flour industry, which includes many posho mills that do not package their product, this variation in the requirement has generated some confusion in terms of who ought to be fortifying their product and who should be targeted in terms of outreach and support. For example, the measures of "compliance" with the mandate often seem to treat small-scale mills as though they are out of compliance, yet they are not legally required to participate in the LSFF program. At the same time, the variation also gives the appearance of a double standard that may undermine support for the mandate among medium- and large-scale mills.

Program meets needs:

> "[When selecting food vehicles for a LSFF program], there's a need to be clear on the landscape of individual food vehicles and the willingness of the players to collaborate. Partners need to enter this space in the right way."
>
> –*Representative of national government*

Informants largely approved of the LSFF program structure. Eighty-five percent of respondents in the survey "completely" or "somewhat" agreed that the national standards are appropriate in terms of the choices of food vehicle, with informants noting that these are the main staple foods. Some of the products, such as oil, wheat flour, and salt, are especially suitable for fortification owing to the industry structure, as almost all production in the country is large-scale. There are ongoing discussions with the World Food Program to consider rice fortification, as Kenyans are now shifting their consumption patterns towards rice. Eighty-two percent of respondents also agreed that the standards are appropriate in terms of the types and amounts of nutrients. Seventy-two percent of respondents "completely" or "somewhat" agreed with the statement, "Overall, the large-scale food fortification program is well-designed to meet the population's needs in terms of fortified food availability, affordability, and quality." With little equivocation heard among the informants, this earns Kenya a value of 4 for this indicator.

Domain II: Policy Implementation

Sustained consultation:

This indicator captures the extent to which consultation among all relevant stakeholders is sustained in the course of policy implementation, i.e., after the initial policy design stage. Seventy percent of survey respondents "completely" or "somewhat" agreed that "there is consultation and coordination among stakeholders in the implementation of the large-scale food fortification program." The key

informant interviews revealed general satisfaction with the extent of consultation and communication, earning Kenya a value of 4 for this indicator.

> "KNFFA is doing a commendable job in that it is a coordinating mechanism which brings together all stakeholders to share their experiences."
>
> *–Representative of development partners*

As noted earlier, the KNFFA's mandate is to spearhead the planning, implementation, and monitoring of fortification initiatives and to guide public-private sector coordination. It is comprised of multiple national government agencies (with the Division of Nutrition & Dietetics serving as the coordinator), research institutes (e.g., KEMRI, JKUAT), industry associations for millers and oil processors, premix manufacturers, and civil society organizations (e.g., Spina Bifida and Hydrocephalus Association of Kenya (SHAK), Consumer Information Network (CIN)), and others. Membership in the alliance was recently extended to the Ministry of Finance and Planning, given the latter's involvement in budgetary allocation for the fortification agenda.

The KNFFA was established in 2005—before the creation of county governments in Kenya. Prior to devolution, the LSFF program was largely conducted and managed at the national level. Now that responsibilities for fortification have been cascaded to the county level, county governments have also been invited to join the alliance. Nevertheless, in Uasin Gishu, we spoke with a PHO who was not aware of the existence of the KNFFA and has not participated in any of their meetings, though they had been in the position for a year. This is indicative that coordination with the counties, and inclusion of county-level actors, is lacking in the KNFFA.

The alliance has grown over time in at least one other direction: Initially, large-scale millers served as the chair for the KNFFA. However, as these large-scale millers have come on board and widely implemented the food fortification requirements, while fortification is much lower among medium- and small-scale millers, the latter group of millers has assumed the chair position. This has directed the alliance's energy toward the areas requiring greater attention.

The KNFFA is considered by many informants to be very effective, with regular meetings and frequent sharing of experiences, ideas, and information. Meetings are held on a quarterly basis, specifically on the first Tuesday of the first month in the quarter. The rate of participation among members has increased from 65% to 75% since the Covid-19 pandemic began, perhaps facilitated by use of virtual platforms. While the milling industries, inclusive of premix suppliers, are active in these meetings, it was noted that the salt and oils industries are not as engaged. The alliance has subcommittees (of about 10 people each) organized around various functions, such as communication (sensitization), development of standards, monitoring and evaluation, and other topics. This allows for deep involvement on the part of stakeholders. A representative of the Consumer Information Network (CIN) expressed that their input is taken into consideration during KNFFA meetings.

We did hear that consultation is more successful at the national than the county level, and several informants noted that the sort of consultation that occurs via the KNFFA ought to be cascaded to the county level. Nairobi County has successfully formed a county multi-sectorial food safety coordination committee, with the public health department hosting the secretariat. The main functions of the committee are to formulate food safety policies and a supportive legal framework, and to implement food safety control activities, including food testing and analysis, surveillance, inspection, and enforcement. The Nairobi County Fortification Alliance is regarded as successful and inclusive, though this success is not mirrored in all counties.

Effective coordination:

Stakeholders were somewhat less positive about the effectiveness of coordination in the implementation of the LSFF program. (Note that this distinction between consultation and coordination was not initially reflected in the survey as administered in Kenya (Figure 5), though it is reflected in the questionnaire offered in Annex 2.) In terms of monitoring, 41% of respondents felt that there is adequate coordination among stakeholders, while 35% felt there is adequate trust among stakeholders (Figure 6). Given the gaps we observed in the key informant interviews, Kenya earns a value of 2 for this indicator.

> "KNFFA has not really played a key role in ensuring success in food fortification. A lot of talking has been done, with little action except at the institutional level."
>
> –*Representative of industry*

We did hear of numerous instances of coordination and purposeful collaboration amongst the stakeholders. For example, counties receive support for monitoring/surveillance from the Divisions of Nutrition and Food Safety at the national level. GAIN, a development partner, supported Mombasa County in its advocacy with the county assembly and engaged the finance and health committees to sensitize them on the value of food fortification and safety. As another example, Food Safety and Fortification Coordination Committees have been established in some counties to collaborate with various ministries (e.g., ministry of agriculture, department of trade); Nairobi County developed its food safety policy with the help of JKUAT.

Nevertheless, we also heard of frustrating obstacles to coordination, especially among different levels of government. Food fortification in Kenya is a devolved function, and the 47 counties are responsible for inspections. However, it seems that there is considerable bureaucracy. Since devolution, the Division of Food Safety must communicate with the counties through the Council of Governors (CoG). PHOs in different counties likewise communicate with one another through the CoG. This channel of communication can be tedious and bureaucratic, with extended delays before a response is received. Such a slow process impedes coordination among different levels of government. We also heard of other obstacles to coordination. The Division of Food Safety (in collaboration with development partners) engages in capacity building for PHOs and industry players. While it would be convenient to hold trainings for multiple counties together, this becomes expensive as *per diems* must be paid to anyone who travels to another county.

Continued support from stakeholders:

This indicator captures sustained enthusiasm, engagement, and active assistance from stakeholders in the implementation of the LSFF program. We judge Kenya to earn a value of 3 for this indicator. Overall, the government and other players remains proud of the LSFF program; this sentiment was displayed in almost all interviews. Furthermore, we heard of efforts made by various stakeholders to support the program. To incentivize leadership within industry, organizers of the Food Fortification Summit presented trophies, gifts, and other tokens of appreciation for companies and other players that have been excelling in their food fortification activities. This points to instances of diligent engagement from industry, and it demonstrates creativity on the part of organizers.

At the same time, there was some variation in the level of enthusiasm. For example, while the milling industries are active in KNFFA meetings, the salt and oils industries are not as "energetic" to attend these general meetings, though they still collaborate around specific needs. The associations for different food vehicles and firm types (e.g., CMA, UGMA) also vary in their commitment. They tend to support fortification only through trainings and the provision of information on different premix

suppliers. There is also variation across counties in terms of their active attention to LSFF. Thus far, we heard that five counties (Nakuru, Mombasa, Nairobi, Kiambu, and Turkana) have demonstrated a notable commitment to fortification, while enthusiasm is lower elsewhere.

Capacity of industries:

The capacity of processors to comply with the fortification mandate varies with the food product and firm size/company size. For this reason, it is difficult to assign a single value to capture the overall capacity of relevant industries in Kenya. In total, 28%, 42%, and 39% of survey respondents felt that industry actors have adequate financial, human, and physical capacities, respectively, to meet the fortification requirements. Kenya earns a value of 2 for this indicator.

There are several reasons why large-scale firms have a greater capacity to engage in fortification. They are likely to already have in place a system of quality control with logbooks, a quality assurance manager, and perhaps their own laboratory to test the quality of the premix used. They also already have financial resources and purchase patterns in place such that the additional requirement to procure premix is not a burden. For example, most wheat millers already import their wheat, and it is straightforward to complement this with imported premix. Most large-scale firms also have a brand that they do not want to see tarnished; if they are caught not complying with the fortification mandate, their brand may be pulled from the shops. While large firms do struggle with other challenges, such as the power supply or the availability of grain to be milled, they generally do not find fortification to be a burden.

> "The government did nothing to support the SMMs [small and medium millers]; they had to navigate their way and look for partners to support them."
>
> –*Representative of industry*

In contrast, medium-scale firms are likely to face more difficulty absorbing the cost of fortification. They do not have personnel whose primary responsibility is quality assurance; they lack the capacity to install the micro-dosers and conduct internal monitoring of their systems; and without their own laboratory facilities, they can only trust that the premix they procure is of high quality. Their limited human capacity means that employees of small, medium-scale firms generally do not attend training and sensitization sessions. These millers also face a mismatch in terms of the scale production and the units in which premix is available for purchase, as a 25-kg bag is the typical size of premix.

Small- and medium-scale processors are also less likely to possess the necessary equipment. Development partners such as GAIN and TechnoServe have assisted large-scale millers to acquire micro-dosers, providing some equipment for free and advising some millers on where they can access quality equipment. The price of a micro-doser is said to range from KES 300,000 to 1M, and there are no tax waivers or VAT incentives for the processors to make micro-dosers more affordable. Medium- and small-scale milers tend to use batch mixers that lack an agitator to stir the premix; this leads to non-homogenous mixing of the flour and premix. Imported (Chinese-origin) micro-feeders are particularly prone to malfunction and error, requiring constant calibration.

Processors do receive support from development partners. For example, TechnoServe has worked through the Technical Assistance Accelerator Prelude Project (TAAP) and the Strengthening African Processors of Fortified Foods (SAPFF) project to support large-scale millers allied with the Cereal Millers Association (CMA). They provided a customized technical assistance to the millers to help them comply with the national food fortification standards. They have also held industry convenings

for high level staff and managing directors to build capacity and generate buy-in and commitment among the senior management level staff in industry. TechnoServe has provided support for firms acquiring dossing technologies; kits to undertake qualitative analysis; fortification logbooks to help monitor their processes; and BioAnalytic kits to undertake quantitative analysis of iron and vitamin A. The World Food Program is now working with small-scale millers in Turkana County. Members of the UGMA have also been supported by various development partners to train their members and give matching grants to buy equipment. We learned that the UGMA plans to launch an umbrella organization for medium- and small-scale millers in collaboration with five other associations, inclusive of posho millers. We also learned that SANKU (a business entity of Project Healthy Children) will soon be entering the Kenyan market with dossifiers for small mills and will offer technology support through organized groups. At least one informant also indicated that JKUAT is now fabricating equipment suitable for food fortification, which should ease some of the equipment-related constraints for millers.

As noted earlier, the difference in capacity between large- and smaller-scale entities also translates into different capacities across different food vehicles. This is because the industry structure for salt, vegetable oils, wheat flour, and maize flour are so varied (Table 5). Salt is by far the most concentrated industry with just three large-scale processors. The vegetables oils and wheat flour industries are also relatively concentrated and are dominated by medium- or large-scale companies. However, the maize flour industry is far less concentrated than the other three industries, with numerous medium- and small-scale mills. It follows that industry capacity is lower for maize flour than for the other products.

Capacity of regulatory agencies:

Regulatory agencies lack human, physical, and financial capacity to surveil and enforce the LSFF program. Only thirty-five percent of survey respondents felt that regulatory agencies have adequate capacity to monitor fortification activities, and 46% felt they have adequate capacity to enforce the fortification requirements. Kenya earns a value of 2 for this indicator.

> "A few counties do engage more with the industries and the communities. Some counties do this very well; for others, food fortification is such a remote thing to them—not a priority. ...Overall, it boils down to leadership."
>
> –*Representative of national government*

According to at least one key informant, training and stakeholder meetings on food fortification have taken place at the national level and at the level of county management; however, knowledge has not been disseminated to the subcounty levels and to the level of technicians. Though PHOs know their mandate, they often lack adequate technical capacity and "know-how". In Uasin Gishu County, we heard that the county is handicapped in matters of food fortification due to inadequate personnel in the department. Counties vary in their level of capacity and in how they have gone about building their own capacity. There are about 21 counties with County Food Safety and Fortification Coordination Committees. However, these committees are sometimes in flux; they can be dissolved or reconstituted with each election. A lack of local government commitment to fortification can undermine the capacity of those actually tasked with monitoring and enforcement.

> "Every county has different strengths. It is important to learn from them how they were able to achieve or how they failed."
>
> –*Representative of county government*

In terms of financial capacity, several key informants acknowledged that Kenya relies on its development partners to finance LSFF activities and that it was unclear whether government would sustain the activities without donor support. With budget limitations, KEBS is unable to conduct impromptu visits to the premises of food processors to take samples for analysis. This sharply limits the effectiveness of industry surveillance. PHOs must also take samples from marketplaces and send them to Nairobi for analysis. However, surveillance at the market level is particularly weak due to financial constraints at the county level; regulators simply do not have the financial capacity to carry out their mandate. One informant noted that PHOs must "dig into their own pockets" to do their jobs. This was corroborated by other informants who noted that their counties had a budget for food safety and food hygiene but no specific funds for food fortification activities. This underscores the need to include a budget for fortification in the annual budget planning of all levels of government that are partners in the LSFF program.

Regulatory authorities also lack laboratory capacity. All (or almost all) samples collected throughout the country are sent to Nairobi for analysis, and only KEBS is able to analyze samples to determine compliance. However, the National Public Health Laboratory (NPHL) seems to be slow in turning around the samples, sometimes taking three to six months to report results when testing for fortificants. In comparison, tests for aflatoxin will often be returned within two weeks. The NPHL lacks funds for reagents and equipment, and while they are able to test for zinc and iron, we learned that they must send the samples elsewhere to test for vitamin A.

According to several informants, KEBS has signed an MoU (or is working towards this goal) with other accredited labs in the country to decentralize their analysis and supplement their monitoring services. For example, GAIN has worked with JKUAT to establish a laboratory with support from the European Union. Nakuru County, with assistance from GAIN, has established a lab to facilitate testing and reporting for Nakuru and neighboring counties, and they are now mobilizing resources to equip the lab and make it operational. In addition, we heard that Meru County has established a food laboratory that will be able to serve neighboring counties such as Isiolo, Tharaka Nithi, and Laikipia, and the county is in the process of having the lab accredited. Nairobi, Mombasa, and Kiambu Counties are now working to establish county labs. Such resources will enable regulators to conduct surveillance in a more consistent and timely manner.

Level of compliance:

> "If you get [large-scale food fortification] right in Nairobi, you will have gotten it 70 percent right in Kenya."
>
> –*Representative of county government*

Two caveats accompany the level of compliance indicator. First, as with several other indicators, it is difficult to assign one value to the whole LSFF program, as compliance varies considerably across food products and firm sizes. Second, as will be discussed in section 4.4, it is not always clear what is meant by "compliance" in a context where the fortification mandate only applies to processors that produce packaged products. More specifically, in the measures published, it is often unclear whether the measure of adherence to the fortification requirements include (or should include) firms that are not legally required to follow the mandate. It also was often unclear whether each measure of compliance referred to the share of firms that fortify, the share of quantity sold on the market that is fortified, the share of households that consume fortified products, or something else. In the stakeholder perceptions survey, 46% of respondents "completely" or "somewhat" agreed that there is a satisfactory level of compliance with the fortification requirements (Figure 5). This earns Kenya a value of 2 for this indicator.

Overall, compliance in the LSFF program is on a positive trajectory. For example, we heard of survey results released in June 2022, which indicated that compliance in wheat flour increased from about 51% in 2018 to 60% in 2021, and compliance in maize flour increased from 28% in 2018 to 45% in 2021[12]. About 49% of the large-scale maize millers are fortifying their products, and these millers have a market share of 50% to 60%. We did hear of other figures from other informants; for example, that the overall compliance levels went up from 16% and 27% in 2017 to 28% and 35% in 2020 for maize flour and wheat flour, respectively, and that compliance at the industry level (i.e., the percent of brands fortifying) was 46% and 84% for maize flour and wheat flour, respectively (GoK 2020). Not surprisingly, we also heard that compliance varies with the scale of maize flour processor, from 30% for small-scale to 41% and 58% for medium-scale and large-scale processors, respectively. Compliance for edible oils was about 80%, while compliance for salt has been very high—about 98%. Some informants noted, however, that herbal and sea salts are not fortified, indicating that the "true" compliance rate for salt is lower. According to at least one informant, compliance is considered successful if above 80%.

On the part of premix suppliers, there is a noteworthy gap in compliance, one that surely affects the monitored level of compliance among even firms that wish to comply with the law. This occurs because KEBS only has capacity to monitor for three (iron, zinc, and vitamin A) of the nine or more micronutrients that are mandated. The assumption seems to be that if firms are meeting standards for these three micronutrients, then the whole "cocktail" of micronutrients must be present. However, this could lead to dishonest behaviors, where suppliers lower their quality to meet the requirements for the three monitored micronutrients only. By doing so, they could charge less for their product than their competitors.

Domain III- Policy monitoring and evaluation

Guidelines for monitoring:

Guidelines for monitoring the LSFF program in Kenya exist, as in the Monitoring Guideline KS 2765 (KBS 2017) and the National Monitoring and Evaluation Framework, which accompanies the National Food Fortification Strategic Plan. Kenya earns a value of 2 for this indicator.

We learned that technical manuals and protocols for regulatory monitoring were first developed at the regional level by the East, Central and South Africa Health Community (ECSA-HC) with support from development partners. These guidelines were for the monitoring of food fortification at industrial and market levels, as well as points of entry. However, we also heard that these manuals are not comprehensive and are rather offered as general tools. They have been assimilated and contextualized by member countries, including Kenya. Nutrition International has also produced national guidelines to be used in all counties for uniformity.

Some counties, such as Nairobi County, have also formulated their own guidelines for monitoring. However, the availability of local guidelines is highly variable. According to one informant, no document for monitoring is available at the county level where they work; however, the Department of Public Health typically indicates the number of samples to be collected and analyzed in their annual plans. We heard inconsistent information from others about the availability of guidelines at the level of specificity that would be useful to a public health officer (PHO) working "in the field".

[12] We were unable to get a copy of the report to cross check the information provided.

Guidelines for enforcement:

There seem to be very limited guidelines for enforcement of the fortification mandate. For this reason, Kenya earns a value of 2 for this indicator.

> "Can the government leave its people to go hungry by preventing them from taking unfortified flour?"
>
> –*Representative of development partner and industry*

According to informants, the food fortification law (CAP 254) does not specify the penalties to be applied in the case of noncompliance. To the extent that penalties are addressed, they are discussed in a general manner, applying to all offences under the Act with respect to "adulteration of food, drugs and chemical substances and for matters incidental thereto and connected therewith". In fact, certain or even potential penalties for noncompliance are not delineated in a specific way in any document; rather, penalties are at the discretion of local officials. In addition, a penalty of five hundred thousand shillings is deemed too low to deter industries from noncompliance. In response to this, Nairobi County has prepared the Nairobi County Food Safety and Fortification Bill, 2022 that contains a specific penalty of two million shillings for noncompliance with the fortification requirements. It seems that this light approach to enforcement reflects an intention to be supportive rather than punitive; officials do not want the regulatory authorities to be viewed as police officers but rather as partners in a shared goal to achieve compliance with the mandate. Moreover, food processors contribute to national food security, and a lack of fortification does not render flour unfit for human consumption. Therefore, punitive actions such as shutting down a firm are regarded as too harsh. In contrast to the loose specifications around fortification, if a person is found guilty of adulteration of food, a fine is clearly prescribed in the law.

The enforcement agents conducting surveillance typically notify firms that have not complied, giving them an opportunity to check what is wrong and rectify the problem. Thereafter, if the firm does not come into compliance, the local prosecutor discusses each case with the court (i.e., the magistrate), deciding on a penalty that seems to fit the magnitude of the problem. This may vary with the number of repeat offenses or the quantity of product that is unfortified. We did not gain clarity on how often any penalties have been dispensed, or whether this discretion opens additional opportunities for corruption.

Nevertheless, several of the more proactive counties seem to be specifying penalties in their local policies. In Meru, the next county assembly intends to customize the food fortification regulations, and in Nairobi, the county food safety and fortification bill of 2022 is clear on the fortification requirements as well as penalties. A fine of KES 2M will be charged to any miller out of compliance with the fortification requirements.

Enforcement of standards and regulations:

> "Enforcement with devolved government is a challenge, with many interferences which affects the compliance levels. There is good will, but if there is any an issue with the products in the market, there are challenges from all quarters—including political."
>
> –*Representative of county government*

Forty-one percent of survey respondents felt the fortification requirements are adequately enforced (Figure 6). However, information gleaned in the key informant interviews suggests that, in some key areas, Kenya is failing when it comes to the enforcement of standards and regulations. Kenya earns a value of 1 for this indicator.

The surveillance and oversight mandates of different entities had initially been somewhat overlapping, with KEBS and the Ministry of Health, Department of Public Health (i.e., PHOs) tasked with visiting the same markets to sample the same products. However, the two entities distinguished and clarified their respective roles with a MoU in 2012. The PHOs are now responsible for sampling food products at the market level, while KEBS is responsible for monitoring/sampling at the industry level. At points of entry, KEBS and the PHOs work together to monitor food imports.

Nevertheless, we did hear somewhat fuzzier narratives about the responsibilities of each entity in the field, with some county-level public health departments saying that they also visit maize mills while KEBS also works at the market level. For market surveillance, PHOs have "authority of entry" to any business, and their visits are usually unannounced. KEBS visits industries once or twice per year. They usually inform the industries beforehand, though they may initiate impromptu visits if they suspect a problem. The scheduling of visits by KEBS is partly a function of budget limitations and partly a matter of courtesy. Furthermore, as the contents of premix are now being surveilled, a discrepancy in treatment has arisen whereby premix suppliers seem to take their own samples for submission, while processors have samples taken by regulators. This was a source of consternation for at least one industry representative who insisted that samples should be taken using the same method at both nodes of the value chain.

Multiple informants expressed the view that the regulatory structure is disjointed, with KEBS and county health department personnel working in isolation from one another. KEBS is headquartered in Nairobi, the public health department technicians are based at the county level, and interaction only occurs at infrequent meetings.

> "[The regulatory structure] is not streamlined. Currently, we work as independent units. If we were working as a team, it could be much better. We haven't been able to come together and organize. KEBS and [the county] could sit together and come up with a way forward."
>
> –*Representative of county government*

We heard conflicting accounts of the level of trust between government inspectors and food processors. One government informant claimed that processing firms will alert the government if a batch of their product was (unintentionally) not fortified properly, and they will also report one another if a firm is not adhering to the mandate. However, a somewhat less positive story was heard from representatives of industry. For example, we heard that firms feel they are being "harassed from two sides", i.e., they have to provide the same information twice to different arms of government.

At the same time, it seems that tension between government and industry has decreased over time. This improvement is partly attributed to the support, technical assistance, and facilitation offered by entities such as TechnoServe, Nutrition International, and the JKUAT Food Fortification Laboratory. Trust has also increased in response to the lack of punitive actions being taken against firms that are out of compliance, suggesting that a decision to be lenient may be wise.

There are several additional causes for concern around the enforcement of fortification standards. First, counties may be forceful in enforcing fortification requirements among the processors operating within the county, but less firm when it comes to controlling the fortification status of products that come from elsewhere but are sold in the markets within the county. In such a case, local processors feel they face an unfair level of competition from foods sourced from elsewhere. Second, the lack of codified penalties for noncompliance with the fortification mandate means that the mindset and behavior of local prosecutors is a key component of enforcement within a given county. However,

this means that there is need for greater awareness and capacity building among prosecutors around the topic of food fortification.

Existence of assessment data:

Kenya has mostly fallen short when it comes to the collection of data on LSFF activities and impacts. Just 26% of survey respondents either "completely" or "somewhat" agreed that data on food fortification are tracked and reported consistently, and 32% agreed that there are adequate efforts to evaluate the impact and effectiveness of the LSFF program. For this reason, Kenya earns a value of 1 for this indicator.

The Ministry of Health initially set up an online platform through which industries would be required to report the amount of premix imported and/or used and the amount of fortified product produced. The intention of this portal was to continuously and seamlessly estimate the level of compliance with the fortification mandate. However, the ministry ran into some trouble with the entity hosting the website, and the database was subsequently moved into the Ministry of Health website. Currently, the database is being housed and managed by JKUAT free of charge. This transition has been very slow; as of the time of this study, the data portal still is not functional. The absence of this data resource precludes triangulation of other measures of compliance with the fortification mandate. For example, we heard of some millers cutting corners by fortifying only the samples provided to regulatory officers but not the products brought to market. The discrepancy between the amount of premix procured and the amount that should have been used might be discernible in the industry data portal—if it were functional.

Separate from government oversight, TechnoServe is aiming to introduce its Micronutrient Fortification Index (MFI) to Kenya in early 2023. This company-level index is based only on industry self-assessment and reporting, with the thought that food processors will be motivated to participate in order to demonstrate their quality and commitment to consumers. This will promote industry self-regulation.

We also heard of other data gaps and oversights. As discussed earlier, general surveillance is a challenge due to the lack of laboratories at the county level. At the county level, local governments also seem to lack comprehensive databases of millers operating within the county. According to one county government representative, they simply do not have data with which to measure how well they are doing in terms of fortification. Nairobi County seems to stand out in this regard, as the public health department meets with millers on a quarterly basis and advises them on how to use fortification logbooks in their reporting.

> "Millers have been asking for a long time, 'What is the impact of this fortification program?'"
>
> –*Representative of industry*

According to one key informant, millers have long been asking, "What is the impact of this fortification program?" Such a question could potentially be addressed with a national micronutrient consumption survey to ascertain whether the Kenyan population has seen improvements in the level of micronutrient malnutrition with the introduction of the LSFF program. However, the last such survey was conducted in 2011 (KNBS 2011). While some program-level data are available, there are no updated national statistics on micronutrient consumption. Apparently, initial steps to prepare for the next Kenya National Micronutrient Survey and the next Kenya DHS have now been taken, suggesting that this data gap may soon be filled if adequate funding can be secured.

Program reach and effectiveness:

In terms of the future trajectory of the LSFF program, many informants seemed to feel positive about its direction, although additional efforts are needed to reach more consumers. Acknowledging the limited data and sometimes questionable data quality to ascertain the program reach and effectiveness, Kenya earns a value of 2 for this indicator.

> "In five to ten years, other countries will be coming to see how we got it right."
>
> –*Representative of national government*

Initially, millers were concerned that the premix would be expensive and that this would have a large effect on their bottom line; however, at least one informant maintained that there has not been a large effect on the retail price of maize flour. Many informants expressed a desire for LSFF activities to be fully funded by government rather than development partners, and they felt optimistic that industries would someday engage in self-regulation. Although many challenges are recounted around fortification by small-scale maize millers, we heard that in recent years, smaller millers have also wanted to be counted as contributing to the "Big Four Agenda", former President Kenyatta's overarching plan for Kenya's betterment. Nevertheless, the large share of maize flour that is not fortified, especially in rural areas and on the part of populations that rely on posho mills, indicates that Kenya has considerable room for improvement.

In terms of the program's impacts on public health, there is some promising evidence related to the management of goiter, which is caused by iodine deficiency. Since 1978, it has been mandatory for salt meant for human consumption to be fortified with iodine. Accordingly, the prevalence of goiter in the Kenyan population has been in steep decline over several decades, at 16% in 1994, 6% in 2004, and <0.5% today. Though evidence of impact is limited, and challenges in the program persist, informants' confidence in the LSFF program's effectiveness suggests that Kenya is on its way to achieving this indicator.

Consumer education and awareness:

Consumers in Kenya overwhelmingly seem to lack an awareness of, or appreciation for, fortified foods. Just 27% of survey respondents "completely" or "somewhat" agreed that consumers know how to identify fortified products on the market, and 19% felt that consumers are aware of the importance of fortified foods. For this reason, Kenya earns a value of 1 for this indicator.

According to the key informants, a study conducted in Kenya in 2017 revealed low levels of knowledge around fortification. Civil society organizations such as the Consumers Federation of Kenya (Cofek) or the Kenya Consumers Organization (KCO) lack the resources and human capacity needed to raise awareness of fortification. It follows that consumers are not informed of fortification activities, and they purchase products based almost entirely on the price. Currently, almost no efforts are made to raise awareness of the value of fortified products, and according to one informant, "there's the idea that when something has been made mandatory, there's no purpose in educating." In other words, because fortification is required, it is also no longer the basis for advertising, as it confers no advantage to one firm over another.

> "The question we should be asking ourselves is: Do the consumers know there are fortified foods in the market and what are their benefit?"
>
> –*Representative of civil society*

To the extent that attention is given to the topic, there have been some rumors that "drugs" are being put in the food products in the process of fortification. Interestingly, one informant related that many consumers insist on visiting posho mills specifically so they can monitor food safety by observing what is done to their maize; unfortunately, this means that fewer consumers are accessing fortified maize flour, as these mills generally opt out of fortifying. We heard that GAIN has been encouraging CMA to play more of a leading role in consumer education to ensure that consumers themselves demand more fortified foods. However, we did not hear of any activities on the part of industry in this regard.

> "There's a joke that "fortified" flour refers to flour that can make "45" chapatis. The public doesn't seek out fortified products or appreciate their value."
>
> –*Representative of industry*

4.4 Conclusion and Policy Implications

This assessment of the policy enabling environment for LSFF was based on a novel tool designed to be replicable in other countries. The study indicates that Kenya has achieved the greatest success around policy agenda setting: the prioritization of large-scale fortification, the codification of fortification requirements, and the process for designing the LSFF program. Somewhat less success is found in terms of policy implementation: the extent of sustained stakeholder engagement, the level of capacity among stakeholders and regulators, and the level of compliance observed. The least success is observed in the realm of policy monitoring and evaluation: the surveillance and enforcement of fortification standards and the collection of data necessary to evaluate the program's outcomes and impacts. In aggregate, we find that Kenya has a "moderately favorable" policy enabling environment.

We frequently heard that Kenya has improved over time in indicators found in each of the three domains of the policy enabling environment framework. It is therefore important to acknowledge that the LSFF program in Kenya is just 10 years old. One would not expect such a young program to be highly successful in all areas. Moreover, the positive trajectory points to a promising future for Kenya's LSFF program.

To consolidate and maintain the successes of the program, several policy implications of the discussion in section 4.3 should be noted. First, financial sustainability seems to be a persistent challenge. There is need for both national and county governments to commit resources to undertake LSFF activities, to establish the necessary institutional structures, and to build capacity for their surveillance teams. Particularly at the county level, funds for food fortification activities should be earmarked so that money in a joint account is not always directed toward other priorities.

Second, effort should be focused on improving the processes and reliability of surveillance and enforcement of LSFF. More trainings are required to ensure the PHOs have the capability to monitor adequately in their jurisdictions. Even if penalties are rarely applied, KEBS should strongly consider having its officers make impromptu, not only pre-scheduled, visits to firms. Beyond verifying that fortification equipment is installed and functioning, these visits should ascertain that premix is being stored under proper conditions to maintain its quality. There is a need to ensure the quality of premix sold in Kenya by testing it for all fortificants and also by ensuring that licensed, high-quality premix suppliers can be identified easily.

Third, data around LSFF in Kenya needs urgent improvement. This yields several specific policy prescriptions: KEBS needs to sharply reduce the turnaround time for testing samples to ensure the accuracy and usefulness of the results. This may be achieved by devolving the testing function to other

satellite laboratories, helping counties to set up new laboratories, and guiding counties to organize their laboratory needs through regional blocs. The data portal for industry reporting should be resuscitated to ensure that there is some scope for triangulating measures of compliance, and a new round of the Kenya National Micronutrient Survey should be conducted soon.

Fourth, the definition of "compliance" should be clarified. This will help stakeholders understand what is being measured (i.e., what is in the numerator and denominator) when a given measure of compliance is reported. If some firms are not required to adhere to the fortification mandate, then the measure of "compliance" should be limited to those firms that do face a legal mandate, while another term (such as "coverage" or "participation") might be used to capture the share of all firms that fortify or the share of all supply that is fortified. Moreover, the measure of compliance should be presented in a way that makes the source of noncompliance clear. Currently, it is unclear whether noncompliance on the part of a firm is due to the unintentional use of poor-quality premix or more purposeful decisions to avoid fortifying.

Fifth, structures and processes should be created to promote learning across counties. There is considerable variation across counties in the extent to which they prioritize LSFF and effectively surveil and enforce the mandate. Rather than thinking of training as an activity that is mostly conducted *by* the national government *for* the counties, structures can be created to allow counties to learn from one another. They can learn about others' best practices, brainstorm different ways to handle the program on a tight budget, and benchmark their progress. One such learning opportunity may be the Devolution Conference, where PHOs meet one another but there have been no dedicated sessions in which they can share their experiences with LSFF.

Sixth, efforts should continue to reach out to medium-scale and small-scale millers. These millers are especially stymied by the poor quality of low-cost micro-dosers. This suggests a need to monitor the quality of imported micro-dosers and facilitate the design or introduction of more appropriate equipment in Kenya. Medium- and small-scale millers are also likely to be more unnerved than their large-scale counterparts by the costs associated with fortification. This suggests that more consideration be given at this time to waiving taxes on equipment and fortificants. Outreach to (and oversight of) small millers should be pursued even when it is challenging, as when small millers operate "underground" without revealing their physical locations. Premix suppliers might also be encouraged to make premix available in smaller quantities. Finally, there is an opportunity for large-scale firms to train their smaller-scale siblings in fortification practices, and such cooperation can be facilitated by government and development partners.

References

Badstue, L., Elias, M., Kommerell, V., Petesch, P., Prain, G., Pyburn, R., and Umantseva, A. 2020. Making Room for Manoeuvre: Addressing Gender Norms to Strengthen the Enabling Environment for Agricultural Innovation. *Development in Practice,* 30(4): 541-547.

Bailey, R.L., West, K.P., and Black, R.R. 2015. The Epidemiology of Global Micronutrient Deficiencies. *Annals of Nutrition and Metabolism*, 66(2): 22-33.

Braun, V., Clarke, V., Boulton, E., Davey, L., and McEvoy, C. 2021. The Online Survey as a Qualitative Research Tool. *International Journal of Social Research Methodology*, 24:6: 641-654.

Cairney, P. 2019. *Understanding Public Policy: Theories and Issues*. 2nd edition. London: Bloomsbury Academic.

Center for Disease Control and Prevention (CDC). 2018. Gaining Consensus Among Stakeholders Through the Nominal Group Technique. U.S. Department of Health and Human Services. Evaluation Briefs, No. 7.

Dunn, M.L., V. Jain, B.P. Klein. 2014. Stability of Key Micronutrients Added to Fortified Maize Flours and Cornmeal. *Annals of the New York Academy of Sciences*, 1312(1):15-25.

Enzama, W., Afidra, R., Johnson, Q., and Verster, A. 2017. Africa Maize Fortification Strategy 2017–2026. Online: Smarter Futures.

FAO, IFAD, UNICEF, WFP and WHO. 2022. The State of Food Security and Nutrition in the World 2022. Repurposing food and agricultural policies to make healthy diets more affordable. Rome, FAO. https://doi.org/10.4060/cc0639en

Fiedler, J.L. R. Afridra, G. Mugambi, J. Tehinse, G. Kabaghe, R. Zulu, K. Lividini, M.-S. Smitz, V. Jallier, C. Guyondet, and O. Bermudez. 2014. Maize Flour Fortification in Africa: Markets, Feasibility, Coverage, and Costs. *Annals of the New York Academy of Sciences*, 1312(1): 26–39.

Global Fortification Data Exchange (GFDx). 2022. Accessed on July 14, https://fortificationdata.org/map-availability/

Gomes, R. 2018. There's More to Policy Than You Think: the Three Legs of the Policy Stool. AGRILINKS. June 6.

Government of Kenya- Bureau of Standards (KBS). 2017. *Monitoring and Sampling of Fortified Foods – Guidelines*. Republic of Kenya: Nairobi.

Government of Kenya. 2020. Market Level Food Fortification and Aflatoxin Surveillance for Maize and Wheat flour in Kenya; Technical Report 2020

Government of Kenya, Ministry of Health. 2020a. *The Kenya Nutrition Monitoring and Evaluation Framework, 2018 –2022*. Republic of Kenya: Nairobi.

Government of Kenya, Ministry of Health. 2020b. *Kenya National Nutrition Action Plan, 2018 –2022*. Republic of Kenya: Nairobi.

Government of Kenya, Ministry of Health. 2018. *Kenya National Food Fortification Strategic Plan 2018-2022*. Republic of Kenya: Nairobi.

Green J. and Thorogood N. 2004. *Qualitative Methods for Health Research*. London: Sage.

Hoogendoorn, A., Luthringer, C., Parvanta, I., and Garrett, G.S. 2016. Food Fortification Global Mapping Study 2016. Landell Mills and Global Alliance for Improved Nutrition. Document prepared for the European Commission.

International Food Policy Research Institute (IFPRI). 2022. Women's Empowerment in Agriculture Index (WEAI). Accessed on December 9, 2021. https://www.ifpri.org/project/weai

International Labor Organization (ILO). 2022. Enabling Environment for Sustainable Enterprises. Accessed on July 27, 2022. https://www.ilo.org/empent/units/boosting-employment-through-small-enterprise-development/eese/lang--en/index.htm

Kenya Bureau of Standards (KEBS). 2012. *Monitoring and Sampling of Fortified Foods – Guidelines*. Government of Kenya: Nairobi.

Kenya National Bureau of Statistics (KNBS). 2011. *The Kenya National Micronutrient Survey*. Government of Kenya: Nairobi.

Khamila, S., D. S. Ndaka, A. Makokha, F. Kyallo, P. K. Kinyanjui, O. J. Kanensi, and J. Mwai. 2019. Status of Commercial Maize Milling Industry and Flour Fortification in Kenya. *African Journal of Food Science*, 13: 65–82.

Khamila, S., D. N. Sila, and A. Makokha. 2020. Compliance Status and Stability of Vitamins and Minerals in Fortified Maize Flour in Kenya. *Scientific African*, 8: e00384.

Knol, A.B., Slottje, P., van der Sluijs, J.P., Lebret, E. 2010. The use of expert elicitation in environmental health impact assessment: a seven-step procedure. *Environmental Health*, 9(19):1-16.

Lalani, B., Bechoff, A., and Bennett, B. 2019. Which Choice of Delivery Model(s) Works Best to Deliver Fortified Foods. *Nutrients*, 11(7): 1594. doi: 10.3390/nu11071594

Leyvraz, M., David-Kigaru, D.M., Macharia-Mutie, C., Aaron, G.J., Roefs, M., Tumilowicz. 2018. Coverage and Consumption of Micronutrient Powders, Fortified Staples, and Iodized Salt Among Children Aged 6 to 23 Months in Selected Neighborhoods of Nairobi County, Kenya. *Food and Nutrition Bulletin*, 39 (1): 107-115.

Makhumula P, Dary O, Guamuch M, Tom C, Afidra R, Rambeloson Z. 2014. Legislative Frameworks for Corn Flour and Maize Meal Fortification. *Annals of the New York Academy of Sciences*, 1312(1):91-104.

Maggino, F. 2014. Multi-Indicator Measures. In: Michalos, A.C. (eds) Encyclopedia of Quality of Life and Well-Being Research. Springer, Dordrecht. https://doi.org/10.1007/978-94-007-0753-5_1876

Marketlinks. Business Enabling Environment- Overview. Accessed on December 9, 2021. https://www.marketlinks.org/good-practice-center/value-chain-wiki/business-enabling-environment-overview

Meija, L.A. 1994. Fortification of Foods: Historical Development and Current Practices. *Food and Nutrition Bulletin*, 15(4): 1-4.

National Academy of Sciences (NAS). 2003. Overview of Food Fortification in the United States and Canada. Institute of Medicine (US) Committee on Use of Dietary Reference Intakes in Nutrition Labeling. Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification. Washington D.C: National Academies Press.

Nutrition International. 2022. Fortification. Accessed on July 20, 2022 https://www.nutritionintl.org/our-work/how-we-help/fortification/

Olson, R., Gavin-Smith, B., Ferraboschi, C., and Kraemer, K. 2021. Food Fortification: The Advantages, Disadvantages, and Lessons from Sight and Life Programs. *Nutrients*, 13(4):1118. doi: 10.3390/nu13041118.

Osendarp, S.J.M., H. Martinez, G. S. Garrett, L.M. Neufeld, L.M. De-Regil, M. Vossenaar, and I. Darnton-Hill. 2018. Large-scale Food Fortification and Biofortification in Low- and Middle-Income Countries: A Review of Programs, Trends, Challenges, and Evidence Gaps. *Food and Nutrition Bulletin*, 39(2): 315-331.

Resnick, D., Haggblade, S., Babu, S., Hendriks, S.L., Mather, D. 2018. The Kaleidoscope Model of Policy Change: Applications to Food Security Policy in Zambia. *World Development*, 109(2018):101-120.

Roseboom, J. (2012). Creating an Enabling Environment for Agricultural Innovation. *Agricultural Innovation Systems- An Investment Sourcebook*. World Bank: Washington D.C.

Schang L, Blotenberg I, Boywitt D. What Makes a Good Quality Indicator Set? A Systematic Review of Criteria. *International Journal for Quality in Health Care*. 2021 Jul 31;33(3):mzab107. doi: 10.1093/intqhc/mzab107. PMID: 34282841; PMCID: PMC8325455.

Sitko, N., Babu, S., and Hoffman, B. 2017. Practitioners' Guidebook and Toolkit for Agricultural Policy Reforms: The P.M.C.A. Approach to Strategic Policy Engagement. Feed the Future Innovation Lab for Food Security Policy Research Paper 49. East Lansing: Michigan State University.

Strengthening Partnerships, Results, and Innovations in Nutrition Globally (Spring). 2018. National Policies and Plans to Address the Dual Burden of Malnutrition: A Multi-Country Policy Review. Brief. Accessed on July 11, 2022 at https://www.spring-nutrition.org/sites/default/files/publications/briefs/spring-national-policies-dual-burden-brief.pdf

TechnoServe. 2016. Handbook on food fortification in Kenya.

Tripp, R. 2003. The Enabling Environment for Agricultural Technology in sub-Saharan Africa and the Potential Role of Donors. *Natural Resource Perspectives*, 84(April).

Turoff, M., and Helmer, O. 2002. The Delphi Method. Techniques and Applications. Linstone, H.A., Turoff, M., and Helmer, O. (eds). New Jersey Institute of Technology: New Jersey. Accessed on September 12, 2022 https://web.njit.edu/~turoff/pubs/delphibook/delphibook.pdf

United Nations Children's Fund (UNICEF). 2021. Advancing Large-scale Food Fortification. UNICEF's Vision and Approach. Document. Nutrition and Child Development Section, Programme Group. New York, USA.

United Nations /Economic and Social Council (UN/ESC). 2022. Progress toward the Sustainable Development Goals. Report of the Secretary-General. https://sustainabledevelopment.un.org/content/documents/29858SG_SDG_Progress_Report_2022.pdf

USAID. 2021. *Large-scale Food Fortification Programming Guide*. USAID: Washington, D.C. https://www.agrilinks.org/sites/default/files/media/file/LSFF%20Programming%20Guide_final508.pdf

Vasileiou, K., Barnett, J., Thorpe, S., and Young, T. 2018. Characterising and Justifying Sample Size Sufficiency in Interview-based Studies: Systematic Analysis of Qualitative Health Research over a 15-Year Period. *BMC Medical Research Methodology*, 18(148):2-18.

World Bank. 2022. Business Enabling Environment. Accessed on July 27, 2022. https://www.worldbank.org/en/programs/business-enabling-environment

World Health Organization. 2022a. Anemia. Accessed on July 15, 2022, https://www.who.int/health-topics/anaemia#tab=tab_1

World Health Organization. 2022b. Food fortification. Accessed on July 15, 2022, https://www.who.int/health-topics/food-fortification#tab=tab_2

World Health Organization. 2018. Food fortification Q&A- Why implementing Decree 09 is so important? Accessed on July 15, 2022, https://www.who.int/vietnam/news/feature-stories/detail/food-fortification-q-a

Annex

Annex 1: Guiding Questions for Semi-Structured Interviews with Key Informants

The following questions for semi-structured interviews are framed around the LSFF policy enabling environment framework (section 3.1), covering topics related to the policy agenda setting, policy implementation, and policy monitoring/evaluation within a given country. Interviews should be conducted with representatives from government (at the national, regional, and local levels); industry (across the various food vehicles, inclusive of both large and small firms, and inclusive of rural and urban firms); civil society organizations; development partners; and academia. As key informants would be drawn from a diverse set of stakeholders, the following questions would not be asked in each and every interview but would be selectively referenced to guide the conversations.

Policy Agenda Setting

Policy prioritization

Major events

- Did the country participate/organize any major events on food fortification?
- What value does participation in major events, such as a National Food Fortification Summit, bring to the LSFF program?

Presence of powerful advocates

- Who are the policy "champions" (powerful advocates of LSFF)?
- Who are the veto players that have decision making power within the policy system and vis-à-vis the advocated policy response? Who holds hidden power?
- Do policy champions have a strong relationship with the veto players and those with hidden power? If so, is the relationship positive or negative?

Policy formulation

Consultation with stakeholders

- Was there consultation between policy makers, civil society, and private sector in the design of the LSFF legislations?
- Were food processing industries engaged in the process of developing fortification standards?
- Was there collaboration among different ministries with responsibility for LSFF?

Existence of laws and regulations

- Which laws and regulations exist on LSFF?

Clarity of legislation

- Is the legislation on food fortification clear and understandable? If not, what is not clear?
- Are the enforcement mechanisms and consequences of noncompliance widely understood? If not, what are the points of confusion?
- Do the laws in place clearly present the roles of different stakeholders? If not, what is ambiguous?
- Do the laws clearly convey the array of enforcement mechanisms that can be used legally to enforce the fortification mandate?
- Do public officers responsible for fortification have clear mandates? If not, what is ambiguous?
- Do the fortification mandates apply to all firms (in an even manner) producing the relevant food items? In other words, does the application and enforcement of the law

foster a level playing field across the industry, or does it advantage some firms over others?
- Are the regulations facilitative or punitive? What can be improved?

Program meets needs

- Does the LSFF legislation meet the needs of the population? Why or why not?
- Are the national standards appropriate in relation to the micronutrient deficiencies in the population and industry capacity? Why or why not?

Policy Implementation

Stakeholder engagement

Sustained consultation

- Is there sustained consultation among stakeholders in the implementation of the program?
- Do all stakeholders understand well how to implement the LSFF program and the need for it?
- Are all stakeholders invited to actively participate in meetings and other fora on LSFF?

Effective coordination

- Is there a coordination mechanism across different sectors to manage fortification activities? What works well, and what does not work well, when it comes to coordination?
- Are all relevant levels of government engaged in this coordination mechanism?
- Are industry representatives meaningfully engaged in this coordination mechanism?
- Are civil society organizations meaningfully engaged in this coordination mechanism? Are development partners engaged in a meaningful way?
- Are the coordinating bodies adequately funded?
- How would you characterize coordination between the national and regional/provincial governments when it comes to LSFF implementation?

Continued support from stakeholders

- Are stakeholders supportive of the implementation of the LSFF programs?
- Is there technical and financial support from regional bodies?
- What kind of assistance is provided to the different stakeholders and by whom?
- Is there adequate public investment in food fortification in the country?
- Is there adequate private sector investment in food fortification in the country.

Capacities

Capacity of industries

- What do you perceive to be the barriers to compliance with national fortification standards at the industry level?
- Are there strong, representative industry or producer associations?
- Do these industry associations (producers' associations or manufacturers' associations) support fortification, for example by facilitating the joint procurement of equipment and premixes?
- Do firms keep records of food fortification, premix supplies and usage, laboratory tests and analysis reports?

Capacity of regulatory agencies

- Is there adequate funding at the level of regulatory agencies to implement food fortification?
- Is funding for regulatory industries sustainable over the next five years? Is the intervention financially sustainable when donor support diminishes?

- Do public officers responsible for fortification have technical and logistical capacity? Is there adequate technical and laboratory capacity in the relevant national government ministries?
- Are there enough staff, and have they been trained to undertake industry-level inspection and audits?
- Are public laboratories available at the regional or local level to facilitate timely testing and reporting?

Level of compliance

- Is the level of industry compliance satisfactory? Why or why not?
- How does this differ across products (e.g., salt, oil, wheat flour, maize flour), firm size, geography and/or market concentration?

Policy Monitoring and Evaluation

Oversight and enforcement

Guidelines for monitoring

- Are there guidelines and standardized processes for monitoring fortification?
- Are the guidelines clear and easy to understand?
- Is there a central database for monitoring?
- Is there trust between government inspectors and food processors? Do private sector stakeholders have trust in government officials?
- Are there mechanisms for ensuring mutual accountability between governments, donors, the private sector, and citizens?
- Are the monitoring processes manageable for firms or unduly burdensome?
- Do the relevant industries have their own internal standards for fortification Quality Assurance/Quality Control (QA/QC)?

Guidelines for enforcement

- Are there guidelines for enforcement?
- Are the guidelines clear and easy to understand?
- Among political leaders, are there perceived political risks of enforcement?
- Is there bureaucratic autonomy in enforcement?

Enforcement of standards/regulations

- Are the standards and regulations enforced (consistently, fairly, transparently)?
- Are the penalties in place effective? If not, why do you feel they are not effective?

Evaluation and reform

Existence of assessment dataset

- Does a database on food fortification volumes and/or compliance rates exist? If yes, how is the data tracked and reported? By whom? How is it utilized?
- Does a database on population micronutrient deficiencies exist? If yes, how is the data tracked and reported? By whom? How is it utilized?

Program reach and effectiveness

- What is known about the effectiveness of the LSFF program in this country?
- What efforts are underway to gather evidence? Are these efforts adequately funded?
- Are results taken into consideration by policy makers in terms of policy evaluation and reform?

Consumer education and awareness

- To what extent are consumers aware of the importance of LSFF, accept fortified foods, and how to identify fortified products in the market?
- What role do civil society organizations play in consumer education and awareness of LSFF?

Annex 2: Questionnaire to Evaluate Perceptions of the Policy Enabling Environment for LSFF

The following questionnaire was developed to elicit stakeholder perceptions of the policy enabling environment for LSFF—information that would feed into a country's index. The questionnaire is expected to take about 10-15 minutes to complete.

Stakeholder Perceptions Survey

A. INFORMATION ABOUT YOURSELF AND THE ORGANIZATION YOU REPRESENT

A1. Name: _____

A2. Position: _____

A3. Organization: _____

A4. Stakeholder group:

- ☐ Government (National level)
- ☐ Government (County level)
- ☐ Civil society
- ☐ Development partner
- ☐ Industry
- ☐ Research/academia
- ☐ Other: _____

A4.1 If A4 = "Industry", please specify the relevant food product(s) with which you work. *Select all that apply.*

- ☐ Maize flour
- ☐ Wheat flour
- ☐ Vegetable oils and fats
- ☐ Salt
- ☐ Other: _____

A5. County/Region of residence: _____

A6. Is your place of residence rural, peri-urban, or urban?

- ☐ Rural
- ☐ Peri-urban
- ☐ Urban

B. GENERAL PERCEPTIONS OF LARGE-SCALE FOOD FORTIFICATION IN THE COUNTRY

B1. Policy Agenda Setting

To what extent do you agree or disagree with the following statements?

	Completely agree	Somewhat agree	Somewhat disagree	Completely disagree	Do not know
A major event (i.e., crisis, summit) has attracted the attention of the public, industry and/or policy makers to large-scale food fortification.	☐	☐	☐	☐	☐
There are powerful advocates for large-scale food fortification in the country.	☐	☐	☐	☐	☐
There was consultation among stakeholders in the design of the large-scale food fortification legislations.	☐	☐	☐	☐	☐
There exist laws and/or regulations on large-scale food fortification in the country.	☐	☐	☐	☐	☐
The legislation related to large-scale food fortification is clear/ easy to understand.	☐	☐	☐	☐	☐
The large-scale food fortification program is well-designed to meet the population needs in terms of types and amounts of nutrients and choice(s) of food vehicle.	☐	☐	☐	☐	☐

B1.1 (Optional) Use this space to clarify any of your responses in B1.

B2. Policy Implementation

To what extent do you agree or disagree with the following statements?

	Completely agree	Somewhat agree	Somewhat disagree	Completely disagree	Do not know
There is sustained consultation among stakeholders in the implementation of the FF program (i.e., the program is well communicated and understood).	☐	☐	☐	☐	☐
There is effective coordination among stakeholders in the implementation of the LSFF program (i.e., roles and responsibilities are well defined and complementary).	☐	☐	☐	☐	☐
There is continued support in terms of enthusiasm, engagement, and assistance from the stakeholders in the implementation of the LSFF program.	☐	☐	☐	☐	☐
Industries have adequate financial/human/physical capacity to meet the fortification requirements. *Industry actors include maize/wheat flour, oil, and salt processors that produce packaged products.*	☐	☐	☐	☐	☐
Regulatory agencies have adequate financial/ human/ physical capacity to monitor and enforce the fortification requirements.	☐	☐	☐	☐	☐
There is a satisfactory level of industry compliance with the fortification requirements.	☐	☐	☐	☐	☐

B2.1 (Optional) Use this space to clarify any of your responses in B2.

B3. Policy Monitoring and Evaluation

To what extent do you agree or disagree with the following statements?

	Completely agree	Somewhat agree	Somewhat disagree	Completely disagree	Do not know
There exist clear guidelines for monitoring of large-scale food fortification.	☐	☐	☐	☐	☐
There exist clear guidelines for enforcement of large-scale food fortification.	☐	☐	☐	☐	☐
The fortification requirements are adequately enforced (i.e., they are enforced consistently, fairly, and transparently).	☐	☐	☐	☐	☐
Data on large-scale food fortification (i.e., volumes/compliance rates) and population micronutrient deficiencies are tracked and reported over time.	☐	☐	☐	☐	☐
Program reach and effectiveness is satisfactory.	☐	☐	☐	☐	☐
Consumers are aware of the importance of fortified foods, accept fortified foods and know how to identify fortified products in the market.	☐	☐	☐	☐	☐

B3.1 (Optional) Use this space to clarify any of your responses in B3.

Annex 3: Key Informants in Kenya

Note: Names have been removed to preserve anonymity.

No.	Organization/Affiliation	Stakeholder group
1	Route to Food Alliance	Civil society organization
2	TechnoServe	Development partner
3	Nairobi County	Government (county)
4	Nutrition International	Development partner
5	Kiambu County (Directorate of Public Health)	Government (county)
6	Meru County	Government (county)
7	Uasin Gishu County	Government (county)
8	Ministry of Health	Government (national)
9	Bakels East Africa Ltd.	Industry
10	SANKU/ Project Healthy Children	Development partner/Industry
11	Kilifi County	Government (county)
12	Kiambu County	Government (county)
13	United Grain Millers Association (UGMA)	Industry
14	Food Safety Division (MoH)	Government (national)
15	Consumer Information Network	Civil society organization
16	Global Alliance for Improved Nutrition (GAIN)	Development partner
17	Kenya Consumer Organization	Civil society organization
18	Jomo Kenyatta University Of Agriculture And Technology (JKUAT)	Research/Academia
19	N/A (Independent consultant)	Development partner
20	IMDC Kenya	Industry

Annex 4: Takeaways from the Validation Workshop in Kenya

A validation workshop was held in October in Nairobi, Kenya. The workshop's objectives were to review the methodology to ensure that it is logical, simple, and low-cost to implement, as well as to review, discuss, and validate the preliminary results from the application of the framework to the large-scale food fortification program in Kenya. Sixteen key stakeholders, including representatives of government at national and county levels and representatives of industry, research/academia, development partners, and civil society organizations, participated in the validation workshop. The framework was well received by the participants. Below are the main takeaways from the validation workshop.

- The framework for assessing the policy enabling environment for LSFF is versatile in its application. For instance, the index can be calculated to assess: a whole program (i.e., across the three domains); a specific domain and, a specific policy or an array of policies that are related to or affect food fortification.

- Stakeholders were in agreement with the scores for Kenya across the three pillars. However, they observed that scores assigned to some indicators were high. Hence, scores for the following indicators were reduced by one point: effective coordination, guidelines for monitoring and program reach.

- The standards and penalties should be clear and specific to ensure common understanding and implementation across counties. The Food, Drugs & Chemical Substances Act, known as CAP 254, is seen as too general and not punitive enough to discourage repetitive offenses. An amendment to the law was proposed by workshop participants.

- Counties are incapacitated in terms of resources to implement and monitor food fortification activities. As such, there is a need for counties to share available resources. For instance, functional laboratories could be shared by a few counties, possibly within the framework of collaboration and cooperation within economic blocs.

- The level of compliance should be clearly defined to ensure a common understanding from one person (or laboratory) to another and across regions. Likewise, clear instructions on when and how to measure compliance are needed to ensure uniformity in testing procedures, regardless of changes in prices and types of laboratories (private vs. public).

- The level of consumer education and awareness around food fortification is very low. To curb the challenge of double standards (i.e., different standards applied to foods processed within a county versus foods imported from other counties), there is a need to build awareness across all counties. Information available to consumers should be the same across all counties.

- The role of small-scale processors (i.e., hammer mills/posho mills) should be revisited. Although they serve many consumers across all counties, they are not explicitly targeted by the food fortification program. This means that there is a missed opportunity to address micronutrient deficiencies in the country. The processors lack capacities such as micro dossers), processes and skills (for internal quality assurance), but they are currently receiving support from stakeholders such as SANKU and TechnoServe.

- Commitment to and priority in fortification, and related capacity building efforts in the counties have been a challenge, due to changes in leadership, and the high turnover of staff involved in fortification activities. Advocacy, through the Council of Governors, is urgently needed to resolve this challenge.

- Reliance on donor support to undertake fortification activities can hamper the overall success of LSFF. There is a need for both national and county governments to allocate more resources to ensure the sustainability of this important policy.

- Updated data are needed. There is a need to fund KNBS to conduct surveys, as the available data is outdated. For instance, the last Kenya National Micronutrient Survey (KNMS) was conducted in 2011. Currently, the government relies heavily on data collected by JKUAT and TechnoServe.

- An initiative on *Micronutrient Fortification Index* by TechnoServe will enhance industry self-regulation in food fortification.