

Large-Scale Food Fortification Programming Guide

United States Agency for International Development



Photo Credit: Global Alliance for Improved Nutrition (GAIN)

FOREWORD

Today's global crises—COVID-19, climate change, conflict—have increased the need for food systems to be sustainable and resilient and to provide safe food that meets everyone's nutritional needs, in particular the world's most vulnerable. Food system transformation is happening rapidly, but food systems are still not delivering affordable, safe, and nutritious diets year-round. Shifting dietary patterns present both new opportunities and challenges, and it is more necessary now than ever to use agriculture investments to deliver nutrition-sensitive food systems.

Large-scale food fortification (LSFF) is an evidence-based, and cost-effective system-level intervention that has the potential to improve diets and nutrition. Large-scale food fortification entails improving the nutrient content of regularly consumed staple foods and condiments during the industrial processing stage. It provides a safety net for essential vitamins and minerals, protecting households and families when they are unable to afford or access a diverse diet.

Clear examples are the addition of iodine to salt and the fortification of cereal flours to provide folic acid, and the addition of vitamin A to several fortification vehicles. Iodine has protected the minds of millions of children worldwide as iodine is transferred from the mother to the fetus and, through breast milk, to infants and young children. Folic acid in cereal flours prevents neural-tube defects that would occur within the first month of pregnancy before prenatal supplements are likely consumed. Vitamin A is incorporated into oil and sugar, making these two staples efficient and low-cost interventions to supply this vitamin whose deficiency causes child blindness and reduced resistance against infections.

The food industry has a central role in LSFF. We know that LSFF is mostly likely to succeed and be sustained when we take a whole-of-business approach, supporting processors by assisting in business planning, access to finance, operation efficiencies, compliance with food quality and safety standards broadly, and marketing—making this sector more economically viable and resilient, in addition to improving diets and nutrition. Supporting the growth of LSFF also creates an infrastructure that can improve other aspects of the food system, such as food safety, trade, regulation, and multi-stakeholder collaboration.

Since the 1960s, USAID has promoted LSFF with support to 34 countries. Most recently, in 2021, USAID made significant commitments towards LSFF at the UN Food Systems Summit and Nutrition for Growth Summit, including a \$38 million investment over five years to expand LSFF and deliver essential vitamins and minerals to those who need them most. This Large-Scale Food Fortification Programming Guide will support USAID and its partners to strengthen LSFF programming through central and bilateral mechanisms, recognizing that USAID will not take on the entirety of the LSFF Results Framework detailed in this guide. USAID will also coordinate and complement other stakeholders across government, the private sector, and civil society. We look forward to collaborating with our colleagues around the world to build LSFF and the provision of essential nutrients into the systems people rely on daily.

Onward to a more nutritious and fortified food system!

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ACRONYMS / ABBREVIATIONS

AfCFTA	African Continental Free Trade Area	GNCP	Global Nutrition Coordination Plan
AGRA	Alliance for a Green Revolution in Africa	HACCP	Hazard Analysis Critical Control Point
ASEAN	Association of Southeast Asian Nations	HCES	Household Consumption and Expenditure Survey
BHA	USAID Bureau for Humanitarian Assistance	IP	implementing partner
BMGF	Bill & Melinda Gates Foundation	IR/Sub-IR	Intermediate Result/Sub-Intermediate Result
CARICOM	Caribbean Community and Common Market	ISO	International Organization for Standardization
CDC	U.S. Centers for Disease Control and Prevention	LMICs	lower- and middle-income countries
CDCS	Country Development Cooperation Strategy	LOE	level of effort
CEO	Chief Executive Officer	LSFF	large-scale food fortification
CFO	Chief Financial Officer	MERCOSUR	Southern Common Market
COMESA	Common Market for Eastern and Southern Africa	MFI	Micronutrient Fortification Index
CSO	Civil society organization	MSMEs	micro, small, and medium enterprises
DFC	U.S. Development Finance Corporation	MSD	market systems development
DFI	development finance institution	MSP	Market Systems and Partnerships
DG	Democracy and Governance [section]	NGO	nongovernmental organization
DHA	docosahexaenoic acid	PFS	Partners in Food Solutions
DRI	Dietary Recommended Intake	PSE	private sector engagement
EAC	East African Community	PY	project year
EAR	Estimated Average Requirement	Q&A	question and answer
ECOWAS	Economic Community of West African States	QA	quality assurance
ECSA-HC	East, Central and Southern Africa Health Community	QC	quality control
EG	Economic Growth [portfolio]	RFS	USAID Bureau for Resilience and Food Security
FACT	Food Assessment Coverage Toolkit	SAARC	South Asian Association for Regional Cooperation
FAO	Food and Agriculture Organization of the United Nations	SADC	Southern African Development Community
FAQR	Food Aid Quality Review	SAFE	Solutions for African Food Enterprises
FCDO	United Kingdom Foreign, Commonwealth & Development Office	SAPFF	Strengthening African Processors of Fortified Foods
FDA	U.S. Food and Drug Administration	SOW	Scope of Work
FFI	Food Fortification Initiative	SUN	Scaling Up Nutrition
FFP	USAID Office of Food for Peace	UN	United Nations
GAFTA	Pacific Alliance, and Grain and Feed Trade Association	UNICEF	UN Children's Fund
GAIN	Global Alliance for Improved Nutrition	USAID	U.S. Agency for International Development
GFDx	Global Fortification Data Exchange	USDA	U.S. Department of Agriculture
GFSS	Global Food Security Strategy	UV	Ultraviolet
GH	USAID Bureau for Global Health	VAT	Value-Added tax
GMP	Good Manufacturing Practice	WFP	UN World Food Programme
		WHO	UN World Health Organization

GLOSSARY

Audit (technical audit): Review of written quality assurance and quality control procedures and records at food processors. The audit also includes observation of the fortification process. It is one component of external monitoring.

Bioavailability: The degree to which the human body can absorb vitamins and minerals from foods. Bioavailability is often dependent upon the type of micronutrient compound, the composition of an individual's diet, and the nutrient health status of the individual.

Biofortification: Improving the micronutrient content and/or bioavailability through plant breeding (e.g., new rice varieties with higher iron or zinc content) and/or genetic engineering (e.g. "Golden Rice" rich in B-carotene that is a plant precursor of vitamin A). Thus, biofortification adds nutrients in crops as they are grown, while conventional fortification adds nutrients post-harvest in processing.

Biomarker: A measure in an organism that is indicative of some biochemical or physiological process or condition; in the case of micronutrients, a reflection of functional adequacy or inadequacy of that nutrient.

Compliance: Fulfillment of the specifications outlined in a country's food quality and safety standard. Food manufacturers should monitor compliance of fortified foods through quality assurance and control procedures, while they are also monitored for compliance by government inspectors.

Condiments: Substances such as salt and fish sauce used to flavor foods.

Deficiency: Inadequate intake, absorption and metabolic availability of nutrients required to support basic physiological process required for health and development. Deficiencies can be caused by insufficient amounts of a micronutrient in the diet or by disease, infection, or loss.

Dietary Recommended Intake (DRI): A quantitative estimate of a nutrient intake that is used as a reference value for planning and assessing nutrient adequacy of diets for apparently healthy people. Examples include estimated average requirements (EARs), recommended daily allowances (RDAs), and upper limits (ULs).

Enrichment: Synonymous with fortification, referring to the addition of vitamin or mineral to a food irrespective of whether the nutrients were originally in the food before processing.

Essential micronutrient(s): Any vitamin or mineral needed for growth and development and the maintenance of healthy life, normally consumed as a constituent of food, and not synthesized in adequate amounts by the body.

Estimated Average Requirement (EAR): The average (median) daily nutrient intake level estimated to meet the needs of half the healthy individuals in a particular age and gender group. The EAR is used to derive the Recommended Dietary Allowance (RDA). This is the reference value to determine the adequacy of nutrients in the diet of populations.

External monitoring: Activities carried out by government inspectors to make sure that food industry follows specified processes to ensure that fortified foods: A) are produced in a manner that should achieve the specifications of the fortification standard and B) conform to the other specifications mentioned in the food standard. The two components of external monitoring include technical audits and factory inspections.

Extrusion: Processing technology to change the properties of cereals and other foods for improving their consumption by humans as, for example, fortified rice kernels by forcing rice flour dough containing a fortificant mix through small dies, producing kernels that are then blended into non-fortified rice in a ratio between 0.5–2 percent. Extrusion can use broken rice kernels as an input, reducing fortification costs.

Food control authority: The government entity responsible for ensuring that food products consumed by the population are safe to eat and adhere to certain quality standards. Inspectors of a country's food control authority often conduct external, import and commercial monitoring activities.

Fortificant: The chemical form of nutrients and additives (e.g., encapsulation substances and stabilizers) that are added to premix or directly to fortified foods.

Fortification: The practice of increasing the content of an essential micronutrients, other minerals required in relatively large amounts such as calcium, as well as essential amino acids and essential fatty acids, in a food so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health.

Fortification vehicle: Staple foods and condiments that are determined to be regularly consumed by the target population(s) to which fortificant or premix is added.

Import monitoring: The actions taken by government inspectors and customs personnel at border entry points to ensure that fortified foods entering a country adhere to labeling requirements and are fortified according to the country's fortification and food standard.

Inspection (factory inspection): Sampling and testing of foods conducted by government inspectors and laboratory personnel to verify that fortified foods are compliant with the specifications of the fortification standard.

Internal monitoring: The actions taken by food processing operators and quality management personnel to ensure that A) foods are manufactured in a manner that should achieve the specifications of the fortification standard and B) the final product adheres to the all the other requirements mentioned in the food standard. It includes both quality assurance (QA) and quality control (QC) procedures.

Large-scale or industrial food fortification: For the purposes of this LSFF Programming Guide and USAID's initiative to support LSFF, "large-scale" or "industrial" refers to those 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).

Mandatory fortification: Fortification that is mandated by government legislation and regulations and enforced by monitoring and regulatory control.

Market-driven fortification: Situation in which food manufacturers take the initiative to add one or more micronutrients to processed foods, usually within regulatory limits, in order to increase sales and profitability through marketing those foods as "fortified."

Monitoring: The continuous collection and review of data and information on program implementation activities for the purposes of identifying problems (such as non-compliance) and taking corrective actions so that the program fulfils its stated objectives.

Mutual recognition (equivalence): An international agreement by which two or more countries agree to recognize one another's regulatory conformity assessments, decisions or results (for example, certifications or test results for compliance with fortified food standards).

Nutrient adequacy: This refers to a diet that supplies sufficient quantities of specific vitamins or minerals that satisfies the recommended nutrient intakes for humans.

Nutrient deficiency: Inadequate intake, absorption, and metabolic availability of essential nutrients required to support basic physiologic processes necessary for health. Deficiencies can be caused by insufficient amounts of a micronutrient in the diet or by disease, infection/inflammation, parasitism, or bleeding.

Nutrient inadequacy: This refers to a diet that is unable to supply sufficient quantities of specific vitamins or minerals and therefore it fails to support good nutrition and health

Organoleptic properties: Sensory attributes of foods including flavor, texture, odor and visual appearance (color).

Premix: A blend of micronutrient fortificants and other specialty ingredients used to blend into and fortify bulk food commodities (e.g., flours and sugar).

Processed foods: Post-harvest foods treated industrially so as to manufacture and preserve food products for markets. Some may be formulated by mixing several different ingredients and including addition of fortificants.

Quality assurance (QA): Systematic activities necessary to ensure that products or services meet defined quality standards. The performance of quality assurance can be expressed numerically as the results of quality control metric exercises.

Quality control (QC): Techniques and assessments used to document compliance of food products with established technical standards using objective and measurable indicators.

Quality management system (QMS): QA and QC policies and processes put in place by food processors to facilitate the efficient production of products that are safe and meet food quality and safety standards and consumer requirements.

Regulatory monitoring: Actions taken by government inspectors to ensure that fortified foods comply with the specifications of the food standards. It includes external monitoring at food processors, import monitoring at border entry points, and commercial monitoring at retail and food distribution locations.

Restoration: The addition of essential nutrients to foods to restore amounts originally present in the natural product, but unavoidably lost during processing (such as milling), storage or handling.

Recommended Dietary Allowances (RDAs): Defined by the United States Food and Nutrition Board and conceptually the same as the Recommended Nutrient Intake (RNI), but may have slightly different values for some micronutrients. This is the reference value to determine the adequacy of nutrients in the diet of individuals.

Recommended Nutrient Intake (RNI): The daily intake that meets the nutrient requirements of almost all apparently healthy individuals in an age- and sex-specific population group. It is set at the Estimated Average Requirement (EAR) plus 2 standard deviations. This is the reference value to determine the adequacy of nutrients in the diet of individuals.

Segregation: In the context of fortification, the separation and uneven distribution of fortificant or premix in fortified foods, usually as a result of post-fortification handling, packaging, and distribution.

Stability: In the context of fortification, the resistance to change of the chemical properties of the fortificant or adverse effects in the interaction of the fortificant with other food vehicle compounds.

Standard: Technical specification(s) for foods that may include a section about fortification that may be voluntary or compulsory with the force of law.

Staple food: A food eaten routinely and in such quantities that it constitutes a dominant portion of a standard diet for a given person, supplying a large fraction of energy needs and generally forming a significant proportion of the intake of other nutrients.

Targeted fortification: Fortification of foods designed for specific population subgroups, such as complementary foods for infants and foods for social programs, such as school feeding.

Tolerable Upper Intake Level (UL) is the highest average daily nutrient intake level unlikely to pose risk of adverse health effects to almost all (97.5 percent) apparently healthy individuals in an age- and sex-specific population group. This value is used to confirm safety of the micronutrient supply to individuals and populations.

Universal Salt Iodization (USI) refers to the addition of iodine to all salt for human consumption, either used directly by the consumer (table and cooking salt) or added to processed foods.

Voluntary fortification: The type of fortification, for which there are standards but that is not mandatory for the food industry to apply. However, the industry must comply with standards to claim that their products are fortified.

Whole-of-business approach: In the context of fortification, providing support to food processors that extends to business planning, access to finance, product development, technological and operation efficiencies, QA/QC, distribution and marketing in order to reduce costs and improve overall profitability while promoting compliance with fortification standards.

HOW TO USE THIS LARGE-SCALE FOOD FORTIFICATION PROGRAMMING GUIDE

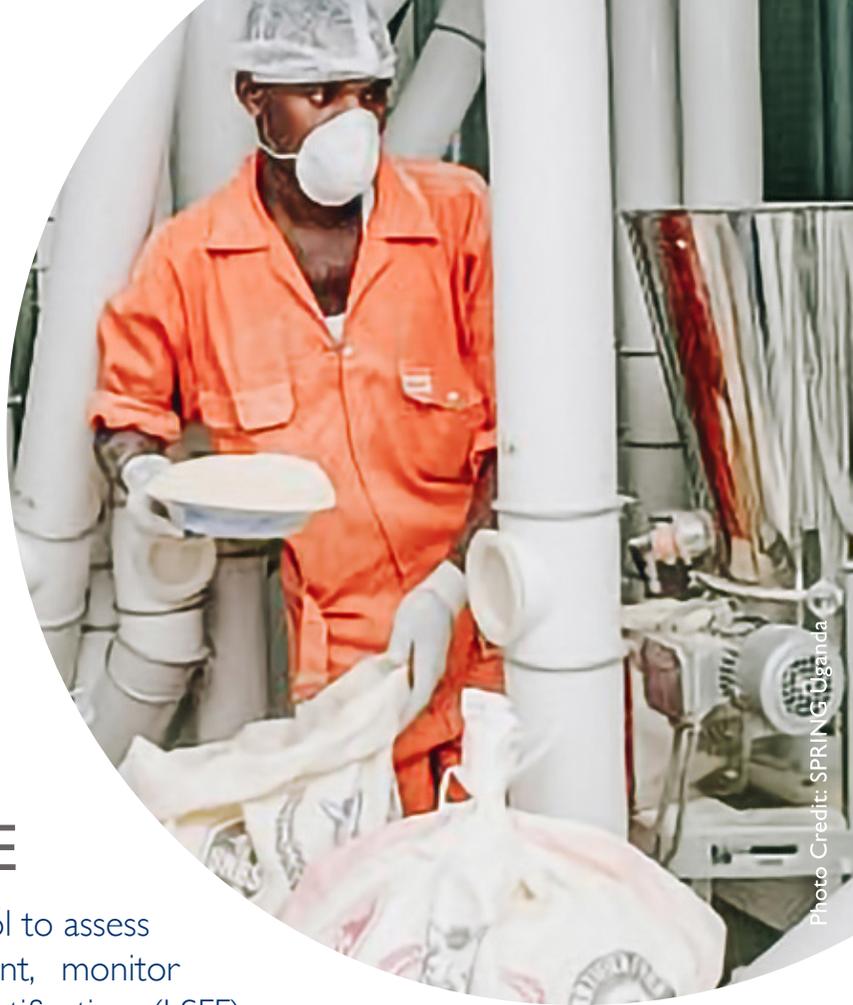


Photo Credit: SPRING Uganda

This guide is meant to serve as an ongoing tool to assess needs and opportunities, design, implement, monitor and evaluate, and adjust large-scale food fortification (LSFF) programming for low- and middle-income countries (LMICs) within their local context. It is based on a set of Guiding Principles for Large-Scale Food Fortification that are described in this document.

Local entities, with the support of U.S. Agency for International Development (USAID) Missions and implementing partners (IPs), should plan and adapt LSFF programs based on initial and periodic assessments of dietary inadequacies and the potential contribution of fortified food vehicles, food industry capacity, market reach, and the LSFF-enabling environment. Based on those assessments, the [USAID Large-Scale Food Fortification Results Framework](#) in this document should be used to prioritize Intermediate Results and Sub-Intermediate Results (IRs/Sub-IRs), and select specific activities under the Sub-IRs for which the Mission and its IPs are strategically positioned to support and implement using the suggested [Strategic Criteria for Activity Selection](#). The Results Framework is intentionally very comprehensive, covering the full range of potential global- regional- and country-level LSFF activities across government, private sector, and civil society sectors. However, it is not expected that Missions need to cover the full spectrum of the Results Framework—individual activities should be selected based on the local context, the identified constraints, and the Strategic Criteria for Activity Selection.

In addition, in the Annexes, there is a two-page [advocacy brief](#) for LSFF and a [Question and Answer \(Q&A\)](#) from the June 10, 2021, LSFF webinar that Shawn Baker and Rob Bertram conducted, titled Large-Scale Food Fortification: A Priority Approach for RFS, which together address many of the issues and questions that arise around LSFF and program challenges and opportunities that Missions may face within their countries and regions. There are also scopes of work (SOWs) for the development of LSFF assessment methodologies for (1) dietary inadequacies and potential LSFF food vehicles, (2) industrial food industry capacity to support LSFF, and (3) the policy-enabling environment for LSFF. These assessment methodologies will be shared with Missions and supported by USAID/Washington, as requested, to guide Mission LSFF programming.

THE GLOBAL CHALLENGE: MICRONUTRIENT INADEQUACY IN THE CONTEXT OF LOCAL DIETS

Micronutrient inadequacy refers to insufficient dietary intake of essential vitamins and minerals to meet individual nutrient requirements. Micronutrient deficiency is the physiological manifestation or symptom(s) due to insufficient availability of vitamins or minerals to support biological functions. Such symptoms are often due to dietary inadequacy, but also to illness, genetics, environment, and other factors that affect how micronutrients are metabolized and function within the body.

Micronutrient deficiencies afflict billions of people, both in LMICs as well as industrialized countries, particularly deficiencies of iron, zinc, and vitamins A, D, B9 (folate), and B12 (cobalamin). Iodine inadequacy is currently under control in many areas because of global programs for iodization of salt. While micronutrient deficiencies are assessed using biomarkers of nutrient status or functional indicators, assessment of inadequacies is based on nutrient composition and consumption of foods. The prevalence of dietary micronutrient inadequacies is likely to be substantially greater and more variable than that of deficiencies, depending on the availability, affordability, access to, and consumer preferences for nutritious foods across geographies and seasons. At the same time, prevalence of inadequacies is highly affected by macrofactors such as political instability and conflict, economic perturbations, climate and environmental degradation, and/or epidemics or pandemics that disrupt food systems. For example, the COVID-19 pandemic has decreased the purchasing power of many vulnerable families, while supply chains have been disrupted, resulting in lower availability and higher prices for the more nutritious foods (e.g., fruits, vegetables, legumes, and animal-source foods), resulting in greater reliance on cheaper, less nutritious staples such as refined flours, polished rice, oil, and sugar. Nevertheless, fortification of commonly consumed staples and condiments can provide a dietary “safety net” of essential micronutrients that otherwise can and ultimately should be received from a diverse diet of more nutritious foods.

Thus, programmatically, especially from a food systems perspective, household and market data are critical to determine what is being consumed, dietary nutrients gaps, potential food fortification vehicles, market availability of industrially processed staples and condiments, and costs of adequate diets that include fortified foods. Ideally, these data reflect current dietary trends within countries, disaggregated by geographic regions and urban/rural areas, socioeconomic strata, and seasonality of food availability and affordability. Such data provide a foundation on which to design and implement LSFF and other food systems programming.



Photo Credit: Global Alliance for Improved Nutrition (GAIN)

CURRENT STATUS OF GLOBAL LARGE- SCALE FOOD FORTIFICATION



Photo Credit: Global Alliance for Improved Nutrition (GAIN)

Iodine was first added to salt in Switzerland in 1922 and in the United States in 1924 to control goiter, followed by fortification of milk with vitamin D in 1933, and then the addition of thiamin (B1), riboflavin (B2), niacin (B3), and iron to flour (with the later addition of folic acid). Over the past 80 years, 142 countries have mandated the fortification of maize or wheat flour; rice, sugar; cooking oil, and/or salt. Iodized salt is now consumed in 88 percent of households globally and iodine deficiency is kept under control in more than 90 countries.

Fortification can either be *mandatory* or *voluntary*. Large-scale or industrial fortification of staples and condiments is largely mandatory in most countries. Legislation in the form of laws, standards, and/or regulations stipulates what foods should be fortified with what micronutrients in what amounts. The benefit of mandatory fortification is that, given set standards and regulatory control, food processors can be assured that all competitors must similarly comply and bear the associated costs (e.g., equipment, fortificant, and quality assurance (QA)/quality control (QC)), which are largely or entirely incorporated into the product price and passed on to consumers (typically, for flours, 2–3 percent of the market price)—assuring a level competitive playing field across the industry.

In addition, because greater consumption of most staples and condiments should be avoided because of their potential contribution to diet-related, noncommunicable diseases (particularly obesity, cardiovascular disease, hypertension, diabetes, etc.), mandatory fortification limits individual processors from unwarranted “health” marketing of products based on being voluntarily fortified versus the unfortified competition. At the same time, consumers should be informed and understand that fortification does not adulterate foods in any way other than to provide needed micronutrients that may be lacking in their diets.

Table I

Indicates the number of countries that have legislation for fortification, the primary staples and condiments that are mandated to be fortified, the percentage of those foods that are industrially processed, the percentage of industrially processed staples and condiments that are fortified, and the specific vitamins and minerals that can be added in fortificants.

Staple/ Condiment	Countries with Legislated Fortification	Nutrients Potentially to be Added	Percent Industrially Processed	Percent Industrially Processed that is Fortified
Maize flour	19	Iron, zinc, and vitamins A, D, B1 (thiamin), B2 (riboflavin), B3 (niacin), B6 (pyridoxine), B9 (folate), and B12 (cobalamin)	36	53
Wheat flour	93	Iron, zinc, selenium, and vitamins A, D, B1, B2, B3, B6, B9, and B12	79	32
Rice	14	Iron, zinc, selenium, and vitamins A, D, E, B1, B3, B6, B9, and B12	56*	1
Milk	14	Vitamins A and D, iron, and folic acid	NA	NA
Oil	36	Vitamins A, D, and E	NA	NA
Salt	137	Iodine, fluoride, and, under special cases, iron	NA	NA
Bouillon cubes	NA	Iodine, iron, and vitamin A	NA	NA
Sugar	10	Vitamin A and possibly others	NA	NA

NA: Not available.

* Note: Although rice is mostly processed by industrial mills, the limiting LSFF factor is the production of fortified kernels that can be manufactured as premix by only a few highly specialized factories.

Note: Complementary foods, not listed in this table, can be considered "staple foods" for children six-24 months of age and included in LSFF programs.

Globally, nearly two-thirds of cereal grains are now industrially milled, and it is expected that this will trend toward increased industrial processing over time. It is also evident in the table that there remains a significant gap in the fortification of those industrially milled grains. This presents a great opportunity to invest in an expansion of LSFF for these grains, as well as the other staples and condiments in the table that are industrially processed. While ideally these foods could all be fortified where there is demonstrable need, irrespective of the size of the processing operation, evidence indicates that there is a critical economy of scale with regard to LSFF equipment, fortificant, and operations that favors the business case for larger companies relative to micro, small, and medium enterprises (MSMEs). Larger companies also afford governmental food control authorities greater ease of inspection and regulatory control.

Practically, the definition of large- or industrial-scale food fortification is a size and technological/operational sophistication that allows the costs of fortification to be incorporated within the market price of foods—typically less than 3 percent—without significantly affecting market volume or share. There are limited data, but it is evident that small-scale processors, e.g., village maize hammer mills or artisan salt producers have not shown that they can achieve this business standard and thus require significant and indefinite external subsidization.

Table 2

Provides some threshold estimates for what constitutes “large-scale” in low- and high-income countries for the purpose of targeting our LSFF programming, but as part of that work, we will continue to evaluate at what scale and under what business models, fortification can be self-sustaining from a food industry perspective.

Commodity	Metric tons/hour		Metric tons/day		Metric tons/year	
	Low-Income Country	High-Income Country	Low-Income Country	High-Income Country	Low-Income Country	High-Income Country
Sugar	20	150	500	4,000	75,000	600,000
Wheat flour	20	100	150	1,000	45,000	300,000
Rice	10	20	100	500	30,000	150,000
Salt	10	15	100	200	30,000	60,000
Oil	5	20	50	150	15,000	45,000

A 508-compliant version of this table can be found in [Annex 7](#).

There remain a number of limitations to the implementation, scale-up, and sustainability of LSFF across countries that this Programming Guide and Results Framework is designed to overcome, including but not limited to:

Support for LSFF within governments as good governance, within food industry as good business, and within civil society as a public good;

- Data-driven fortification standards and regulations;
- An understanding of fortification program costs and sectoral responsibilities;
- Simple food industry LSFF QA/QC systems in the context of meeting food quality and safety standards for processed foods;
- Realistic, efficient, and transparent government inspection and enforcement mechanisms; and
- Periodic assessment of the contribution of LSFF to dietary adequacy.

The following set of Guiding Principles for Large-Scale Food Fortification have been developed within USAID in consultation with numerous stakeholders to provide a foundation for our Agency LSFF investments and programming using this guide and results framework.



GUIDING PRINCIPLES FOR LARGE-SCALE FOOD FORTIFICATION

1.

Food fortification, when it is appropriately designed and implemented, is a cost-effective intervention that provides essential vitamins and minerals provided the food vehicle is industrially processed and is widely and regularly consumed by the target population.

2.

While fortification can provide a safety net for intake of essential micronutrients added to and consumed with staples and condiments, increased consumption of these foods should not be promoted based on their being fortified, nor should they be considered substitutes for the consumption of recommended portions of fruits, vegetables, legumes, and animal-source foods in a healthy diet.

3.

Given trends toward greater consolidation of industrial processing of staples and condiments and increased urbanization, as well as penetration of centrally processed foods in rural markets, LSFF is positioned to have an expanded role over time.

4.

All LSFF programming should be based on local context and data, particularly regarding nutritional need and usual intake of fortification vehicles, population coverage, and estimation of the potential impact of food fortification. Such assessments should be based on the average nutrient content of the fortified foods at household level and their usual intake by the targeted populations (disaggregated by geography, socioeconomic wealth quintiles, and, when possible, age strata).

5.

While fortification programs, as well as other micronutrient interventions, need to be adjusted to account for evolving dietary patterns and coverage within countries, regional harmonization and mutual recognition (“equivalence”) of standards and regulatory control procedures among neighboring countries should be promoted to be compatible with and not represent a de facto barrier to intercountry food trade.

6.

There is a need for continual testing, adapting, and scaling-up of evidence-based interventions and innovation to address unmet programmatic needs and maximize coverage, as well as to improve the cost-effectiveness and cost-benefit of LSFF programming.

7.

Stakeholders, including governmental institutions, should recognize the private sector imperative that their operations must be profitable. The private sector should be encouraged and supported to be compliant with fortification standards because it is both socially responsible and good business to meet food quality and safety standards, while fortification costs can be largely or entirely offset by improved efficiencies, financing, and pricing of fortified foods.

8.

Government must ensure that there is a level competitive playing field by ensuring that fortification and other food quality and safety standards are equitably and universally enforced across the food industry.

9.

Civil society has an essential role in food fortification and should be a full participant in national LSFF coordination and programming, holding both government and food industry accountable with evaluation, documentation and dissemination of learning serving as a basis for scale-up and replication across countries and regions.

10.

Support for LSFF should be based on analyses of barriers and continuous improvement, with evaluation, documentation, and dissemination of learning serving as a basis for scale-up and replication across countries and regions.

SEQUENCING OF LARGE-SCALE FOOD FORTIFICATION PROGRAMMING AT COUNTRY LEVEL

This guide is intended to serve as a tool to inform USAID’s strategic investment and programming to address LSFF. The tasks align with the UNICEF Triple-A Cycle of nutrition programming – continuously **A**ssess problems, **A**nalyze their causes, and take **A**ction (UNICEF 1998) – and with the Food Systems Dashboard 3-D **D**escribe, **D**iagnose and **D**ecide [Decision-Making Tool](#) from the similarly sequenced Johns Hopkins University, Global Alliance for Improved Nutrition (GAIN), and the Food and Agriculture Organization of the United Nations (FAO).

As USAID engages diverse partners including government counterparts, agribusinesses, other private sector actors, and civil society organizations (CSOs), it is important to appreciate the broad and systemic food system challenges that must be overcome by country-led efforts to advance agricultural transformation. Such challenges include improving human health, addressing environmental degradation, and supporting competitiveness in the agriculture sector. To accomplish these goals, we need to form new types of partnerships and think in terms of systems, not only sectors. Many of these issues have been highlighted in 2021 at the recent [UN Food Systems Summit](#) and at the [Nutrition for Growth Summit](#).



A. ASSESS / DESCRIBE

1. Identify country professionals, technical working groups, and institutions with knowledge, credibility, and experience in public health nutrition who are recognized as or who have the potential to become leaders or influencers for an LSFF initiative.
2. Support a collaborative review among stakeholders of past LSFF experiences in the country and region to understand positive and negative experiences and potential perceptions regarding LSFF.
3. With relevant professionals and institutions, analyze the available national food consumption and micronutrient inadequacy or deficiency data and trends. Such data should be disaggregated by geographic areas and wealth strata (and by season, if data are available) to assess inadequacies and identify potential LSFF vehicles. Data sources include:
 - Market data;
 - House Consumption and Expenditure Surveys (HCESs) and/or other national dietary surveys;
 - Food/nutrient intake surveys; and
 - Micronutrient biomarker surveys.
4. Determine the potential industrially fortifiable staple and condiment food vehicles in the country based on an estimation of their household consumption profile (see 3 above), market availability, and analysis of current and potential processing capacity/market share by large-scale food industry companies. Data sources include:
 - HCESs;
 - Food Assessment Coverage Toolkit (FACT);
 - Food industry records and trend analyses;
 - Direct market research
 - [Global Fortification Data Exchange](#)
 - [Food Systems Dashboard](#)

5. Review regional and national LSFF policies, standards, and regulations, as well as regulatory control authorities and procedures related to food fortification and as it relates to compliance with food quality and safety standards broadly, including associated government costing and budgeting.
6. Review records of compliance with food fortification standards and regulations at production sites, as well as confirming reach and penetration of the fortified foods at retail stores/markets, focusing on the mean content of the added micronutrients.
7. Assess Mission capacity to support LSFF programming and potential for complementarity, collaboration, and synergies with existing activities.

B. ANALYZE / DIAGNOSE

1. Analyze initial assessments of household and market dietary data, food industry, and the policy enabling environment for LSFF, including specific supply-side and demand-side constraints to advancing LSFF within the country.
2. Model contributions of fortified foods relative to their intake to reduce dietary micronutrient inadequacies under three scenarios: (1) current situation of coverage and compliance; (2) with good compliance of current fortification standards or regulations; and (3) with adjusting the current standards and/or including fortification of other fortifiable vehicles.
3. Present data, analyses, and recommendations commissioned by relevant national agencies and other entities mandated to advance food fortification, as they exist, to key prospective representatives of government, food industry, CSOs, and development partners who will be engaged in LSFF.
4. Support the creation, integration, and operations of specific working groups to analyze the technological, business, economic, and political-social implications of possible LSFF solutions to address identified needs.
5. Promote and engage in multisectoral and multidisciplinary discussions to identify LSFF challenges and constraints to be addressed collaboratively and in coordination.
6. Support follow-up discussions aimed to establish realistic LSFF workplans, responsibilities, and budgets.

C. ACTION / DECIDE

1. Review the LSFF Results Framework (see below) and identify Sub-IRs and associated activities under each IR that will be most strategic for Mission investment in LSFF, applying the suggested LSFF Results Framework Strategic Criteria for Activity Selection (see below), informed by the above assessments and analyses of national context, and by considerations of how LSFF investments and activities can contribute to the Mission's Country Development Cooperation Strategy (CDCS), Global Food Security Strategy (GFSS) Plan, and its multisectoral nutrition strategy, if it has one.
2. Given that USAID will not have the resources necessary to bring the entire LSFF Results Framework to completion, USAID should attempt to promote an LSFF funding coalition and joint investment plan among stakeholders to garner commitments as to who is bringing what to the table, what their commitment is, and where or how they will be accountable.
3. Identify existing USAID bilateral or central mechanisms or the need for additional procurement(s) that can have the capacity and comparative advantage to implement IR/Sub-IR activities based on LSFF Result Framework Strategic Criteria for Activity Selection.
4. Fund activities and develop specific SOWs and work plans, including Performance Monitoring Plans and specific indicators/targets for tracking and evaluating implementation of LSFF activities.
5. Meet with and share planned support and progress with the national LSFF coordinating body and relevant stakeholders.
6. Promote exchange of LSFF implementation experience among countries with similar conditions, especially within regions.

CROSS-SECTORAL ENGAGEMENT FOR LARGE-SCALE FOOD FORTIFICATION PROGRAMMING AT COUNTRY LEVEL

USAID/Washington is fully committed to working with and supporting Missions within each and every stage of Assessment/Analysis/Action or Describe/Diagnose/Decide to advance and sustain LSFF programming across countries and regions. These will be applied in working with government, the food industry, and civil society, which constitute the first three Intermediate Results of the LSFF Results Framework. The following suggests how Missions can work across these sectors.

A. ENGAGING GOVERNMENT

1. Identify and engage national LSFF “champions” within government, covering health, agriculture, industry and trade, and finance, and support the regular convening and authority of a government-led LSFF coordination body in conjunction with other donors, multilateral agencies, and key stakeholders.
2. Support the appropriate national ministries/agencies to generate and analyze dietary and market data (with civil society/academia) to estimate nutrient gaps, potential food vehicles for fortification, and the suitable micronutrient contents in the fortification vehicles.
3. Support the formulation of national LSFF legislation and standards, and a regulatory control system mandated to monitor and enforce food quality and safety standards that includes LSFF.
 - a. Map the country’s current food quality and safety regulatory monitoring processes, including who does what, where, when, and how. Then work to streamline, as necessary and feasible, specifying roles and responsibilities of each ministry/agency, including designating a nodal entity that will lead and coordinate LSFF activities across agencies, including the development of a monitoring and regulatory control guideline document for the country.
 - b. Identify potential policy barriers and incentives to the planned LSFF program, including policies and regulations that might need to be promulgated, modified, or revoked.
 - c. Conduct manpower/level of effort (LOE) and cost analyses for the LSFF regulatory control system as a basis for national budgeting.
 - d. Conduct analyses of current and potential government revenues to be derived from LSFF, e.g., duties/levies/taxes on imported LSFF equipment and fortificant, and value-added tax (VAT) on the incremental market price increase attributable to fortification costs (typically less than 3 percent of product price).
 - e. Include line-item budgets for LSFF activities across national ministries and agencies (recognizing that these are at least partially offset by LSFF-associated revenues—see c above).
4. Support the establishment of a national recognition scheme, if determined to be desirable and feasible, that will incentivize food industry compliance with food quality and safety standards, including those for LSFF.



5. Foster regional coordination and harmonization of food quality and safety legislation, standards, policies, and regulatory control systems, including LSFF.
 - a. Work with both regional health and economic community structures.
 - b. Promote mutual recognition of “equivalence” of legislation, standards, policies, and regulatory control systems across countries.

B. ENGAGING FOOD INDUSTRY

1. Engage food industry leadership at ownership/Chief Executive Officer (CEO)/Chief Financial Officer (CFO) level of individual companies, as well as relevant industry and trade associations.
 - a. Promote LSFF corporate social responsibility “champions” within industry leadership, especially among companies with larger market shares.
 - b. Balance the business case for LSFF with the public health and societal economic benefits of LSFF.
 - c. Explore the possibility of national recognition and sanction of an enhanced brand identity program for products that fully and consistently meet food quality and safety standards, including those for LSFF.
2. Support a “whole-of-business” approach—business planning, financial services, operation efficiencies, QA/QC, and marketing—that recognizes industry needs to maintain market share and profitability while being compliant with LSFF standards.
3. Determine and foster the enabling environment necessary for industry to engage, fully implement, and sustain LSFF, particularly within the broader context of food processing, compliance with food quality and safety standards, and a comprehensive food systems approach.
4. Broker dialogue between government and food industry on details of acceptable LSFF QA/QC practices within industry operations, as well as government monitoring and enforcement of LSFF standards.
5. Engage financial institutions to support improved access to finance and financial terms for food companies that are compliant with LSFF standards.

C. ENGAGING CIVIL SOCIETY

1. Work with Mission Democracy and Governance (DG) section to engage and motivate civil society to support LSFF and hold both government and food industry accountable to regulate and fully comply with national LSFF and other food quality and safety standards.
2. Support mapping and capacity assessment of key civil society stakeholders, their constituents, and spheres of influence, e.g., consumer protection/advocacy associations, professional associations, and public health advocacy groups, and engage to mobilize and equip them with skills, data, tools, and resources to effectively advocate for LSFF.
3. Support the full representation and participation of CSOs in the national LSFF coordination body and other relevant nutrition forums and initiatives (e.g., Scaling Up Nutrition (SUN)) to advocate for LSFF on behalf of consumers.
4. Support engagement of local academic and research institutions in dietary assessments and LSFF design, implementation, monitoring, and evaluation activities.

VISION

Dietary adequacy of key micronutrients will be achieved and maintained in vulnerable populations across countries through large-scale, industrial fortification of staple foods and condiments where regular consumption of a diverse diet is not sufficient to meet nutrient requirements.

STRATEGIC OBJECTIVE:

To safely reduce micronutrient inadequacies and improve diets through large-scale food fortification (LSFF) of staple foods and condiments.

Intermediate Result 1 (IR1):

The enabling environment and regulatory monitoring and enforcement of LSFF is strengthened and extended through the public sector.

Sub-IR1.1:

National LSFF strategies, policies, regulations, and standards reviewed, harmonized regionally, promulgated, budgeted, implemented, monitored and evaluated.

Sub-IR1.2:

The capacity of national food control agencies to inspect and enforce food fortification standards, including labeling, claims and advertising (within overall monitoring and enforcement of food quality and safety standards) strengthened.

Intermediate Result 2 (IR2):

LSFF in compliance with national fortification standards expanded and sustained by the private sector.

Sub-IR2.1:

Food industry compliance with fortification standards through business development, food technology and quality assurance and control, and marketing guidance strengthened.

Sub-IR2.2:

Food industry compliance with fortification standards linked to improved access to finance and financing terms for general operations, as well as procurement of fortificant and food processing equipment.

Intermediate Result 3 (IR3):

Design, monitoring and evaluation of fortification programs strengthened, and the public sector and private sectors held accountable to maximize compliance with national food fortification standards through civil society.

Sub-IR3.1:

Academic institutions and NGOs strengthened and commissioned to work with government to conduct surveys, surveillance and analyses (market, household and individual data) to guide food fortification program planning, implementation, monitoring and evaluation.

Sub-IR3.2:

Organization, mobilization and capacity of consumer groups, professional associations and other thirdparty actors strengthened to hold food industry accountable to comply with fortification standards and hold government accountable to monitor and enforce those standards.

Intermediate Result 4 (IR4):

Global commitment, leadership and resources garnered and mobilized to support universal LSFF.

Sub-Intermediate Result 4.1 (Sub-IR 4.1):

Improved global coordination, collaboration, complementarity and synergies among donors, international organizations, partner countries and other stakeholders to strengthen capacity, enable public-private sector partnerships, and support adoption and implementation of national LSFF strategies.

Sub-Intermediate Result 4.2 (Sub-IR 4.2):

Increased support for the generation, dissemination and adoption of innovative practices, technologies and approaches for LSFF.

Sub-Intermediate Result 4.3 (Sub-IR 4.3):

Increased capacity at the global, regional and country levels to collect, analyze, synthesize and document LSFF data and programmatic experience.

STRATEGIC CRITERIA FOR ACTIVITY SELECTIONS

The activities described below under the USAID Large-Scale Food Fortification Results Framework Intermediate Results and Sub-Intermediate Results (IRs and Sub-IRs) are illustrative and represent a menu of possibilities that should be selected based on local assessments and analyses, as well as criteria with regard to what is most strategic for Missions to achieve specific results, including but not limited to:

- Is the activity strategic to address the specific Sub-IR and IR (if/then) within the Theory of Change?
- Does the activity address a documented unmet need, barrier, or gap?
- Is there an established evidence base for the (cost-)effectiveness of the intervention?
- Does it fit within a systems approach and does it anticipate system trends projected over the next 5/10/20 years?
- Is the activity within USAID's manageable interest?
- Is the activity within USAID's comparative advantage?
- Is there the necessary commitment from key stakeholders?
- Are there opportunities for complementarity and/or synergy with other activities? For integration, layering, and sequencing?
- Are there the necessary resources available to fully execute the activity during the needed time frame?
- Is it measurable with established indicators?
- Is it timely regarding sequencing of activities?
- Is it scalable, replicable, and sustainable?

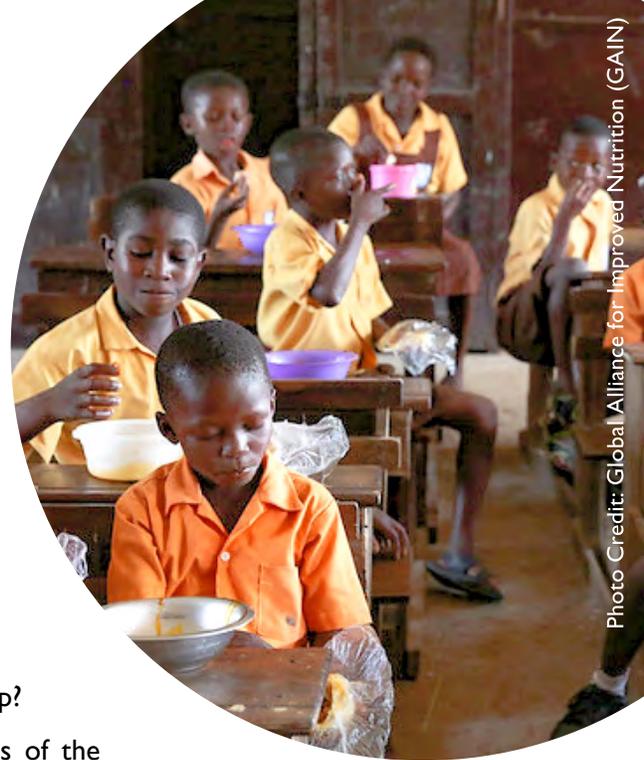
Note: The activities under individual Sub-IRs are not listed in order of priority, but should be considered and selected based on the above (and/or other) strategic criteria.

Vision: Dietary adequacy of key micronutrients will be achieved and maintained in vulnerable populations across countries through large-scale, industrial fortification of staple foods and condiments where regular consumption of a diverse diet is not sufficient to meet nutrient requirements.

Strategic Objective: To safely reduce micronutrient inadequacies and improve diets through LSFF of staple foods and condiments.

Intermediate Result I (IR1): The enabling environment and regulatory monitoring and enforcement of LSFF is strengthened and extended through the public sector.

Sub-IR1.1: National LSFF strategies, policies, regulations, and standards reviewed, harmonized regionally, promulgated, budgeted, implemented, monitored, and evaluated.



Sub-IRI.1.1 Activity: Support the development or review of national dietary guidelines, including the incorporation of fortified foods and assessment of their nutrient contribution to diets based on population surveys, e.g., household food expenditure and consumption and other dietary surveys, market data, and analyses of micronutrient status in target populations.

Sub-IRI.1.2 Activity: Support critical examination and regional harmonization (or rationalization) of LSFF standards, regulatory control, and trade policies (in conjunction with parallel work on food safety), and engaging regional health and economic communities (e.g., East, Central and Southern Africa Health Community (ECSA-HC), East African Community (EAC), Common Market for Eastern and Southern Africa (COMESA), Southern African Development Community (SADC), African Continental Free Trade Area (AfCFTA), Alliance for a Green Revolution in Africa (AGRA), Economic Community of West African States (ECOWAS), Association of Southeast Asian Nations (ASEAN), South Asian Association for Regional Cooperation (SAARC), Caribbean Community and Common Market (CARICOM), Central America Common Market (CACM), Southern Common Market (MERCOSUR), Pacific Alliance, and Grain and Feed Trade Association (GAFTA)).

Sub-IRI.1.3 Activity: Support analysis and strengthening of national strategies for LSFF in the public health interest, including the integrated design of food fortification programs and other micronutrient and dietary interventions, as well as links to food safety regulation and control, including food labeling, legitimate claims, public communication, and advertising.

Sub-IRI.1.4 Activity: Support the clarification and rationalization of roles and responsibilities of all agencies engaged in the supervision and management of national LSFF programs, particularly the monitoring and enforcement of food quality and safety standards.

Sub-IRI.1.5 Activity: Support the promulgation, adoption, and implementation of national policies that require that staple foods for all public programs (e.g., school feeding, hospital meals, and food assistance programs) be fortified, taking into consideration national LSFF standards.

Sub-IRI.1.6 Activity: Support mechanisms that favor the financial self-sustainability of LSFF programs, including governmental monitoring and enforcement; as for example waivers or reductions in duties/levies/taxes on imported fortificant and fortification equipment, transferring costs of fortification within food product price, and/or channeling government revenues from food-related duties/levies/taxes (e.g., value-added tax on the price differential associated with fortification of staple foods) to national and subnational budgets to strengthen inspection and enforcement of food quality and safety standards.

Sub-IRI.2: The capacity of national food control agencies to inspect and enforce food fortification standards, including labeling, claims, and advertising (within overall monitoring and enforcement of food quality and safety standards) strengthened.



Sub-IRI.2.1 Activity: Support food control reforms including, but not limited to, strengthening food quality and safety regulations, reconciling overlapping or conflicting mandates and scopes of regulators, improving operational efficiencies of shared services (e.g., laboratories), and establishing models for local regulatory monitoring, recognizing the increasing trend toward decentralization and devolution from central to local government authorities, focused on operational practices and less on chemical testing.

Sub-IRI.2.2 Activity: Support innovative, simple, low-cost, and practical modalities for routine monitoring and enforcement systems to improve compliance with food fortification standards and regulations, including for fortificant/premix, in conjunction with compliance with other food quality and safety standards, and systematic public reporting of the results and actions.

Sub-IRI.2.3 Activity: Support capacity-building within governments to strengthen food information systems, including the collection, analyses, and use of data on market availability, prices, and sales of foods, including fortified foods (by geography and seasons), and consumption, costs, and adequacy of diets at household and individual levels (by sex, age, geographic, and socioeconomic strata).

Sub-IRI.2.4 Activity: Strengthen processed food packaging, branding, labeling, and tracing regulations and compliance, particularly for fortified foods (and foods that may carry food safety risks), as well as imported fortificant/premix. Eliminate or regulate, as appropriate, sales of bulk fortified foods (e.g., edible oil), particularly those repackaged and resold in small volumes at market level and noncompliant with packaging and labeling standards.

Sub-IRI.2.5 Activity: Support public sector establishment of standardized technologies and procedures, in partnership with the private sector, academic institutions, and other nongovernmental organizations (NGOs), for assessment and compliance of fortificants and fortified foods with standards and regulations.

Sub-IRI.2.6 Activity: Support costing studies on national food regulatory control, monitoring, and enforcement as a basis for annual budgeting linked to revenues generated by taxation/levies/duties or other income (e.g., government laboratories providing services to food industry) associated with production and sales of fortified foods (including fortificant and fortification equipment).

Sub-IRI.2.7 Activity: Support regulation, design, and supervision of labeling, advertising, and marketing of fortified foods to ensure health promotion and prevention of misleading claims.

Intermediate Result 2 (IR2): LSFF in compliance with national fortification standards expanded and sustained by the private sector.

Sub-IR2.1: Food industry compliance with fortification standards through business development, food technology and quality control, and marketing guidance strengthened.

Sub-IR2.1.1 Activity: Food industry mapping/scoping/analyses of industrial/large-scale food processing and consumption of potential food fortification vehicles (e.g., cereal flours, rice, edible oil, sugar, salt, bouillon cubes, and dairy products) considering past trends and projecting forward 5/10/20 years, including geographic and socioeconomic coverage.

Sub-IR2.1.2 Activity: Support adoption and application of fortification standards by food industry and offsetting of the costs of fortification through improved business planning, operational efficiencies, simplified QA/QC, and marketing, distribution, and sales of fortified foods. Provide food technology and marketing assistance to food processors to maximize the value of by-products (e.g., bran drying) to offset fortification costs. Engage in dialogue with the government about how to fairly transfer fortification costs into the price of food products and improve access to loans to cover capital costs associated with fortification.

Sub-IR2.1.3 Activity: Strengthen compliance with labeling standards and digital systems for internal management and QC, as well as digital traceability and tracking of foods that may not meet food quality and safety standards, including compliance with food fortification standards.

Sub-IR2.1.4 Activity: Strengthen free market production, procurement processes (including financing), and distribution systems to ensure premix availability, quality, and traceability. Explore the potential of dedicated premix businesses, including regional operations, that would sell/distribute premix to millers or other food processors within/across countries, including long-term pricing agreements. Ensure compliance with the United Nations (UN) World Health Organization (WHO) Code of Practice for Food Premix Operations.

Sub-IR2.1.5 Activity: Improve the processing and packaging of cooking oils to increase stability of vitamin A and other nutrients (e.g., vitamins D and E and essential fatty acids) added as fortificants, including use of low-cost packaging that preserves quality of the food content, and use of ultraviolet (UV)-opaque containers to prevent oxidation and decay of nutrients.

Sub-IR2.1.6 Activity: Promote the use of fortified ingredients (i.e., fortified staples and condiments) in processed, blended foods. Explore the use of nutrient-dense food additives, such as long-chain essential fatty acid (e.g., docosahexaenoic acid (DHA))-producing algae and fish powder, to enhance the nutrient content of blended foods.

Sub-IR2.1.7 Activity: Support the development, deployment, and scaling-up of tools and brand/marketing indices to improve QC and compliance with fortification standards within the food industry, e.g., premix reconciliation calculation audits and the Micronutrient Fortification Index (MFI) piloted by Strengthening African Processors of Fortified Foods (SAPFF)/TechnoServe, as well as consumer advocacy to link brand identity with quality indices.

Sub-IR2.1.8 Activity: Promote private sector engagement to foster and support national fortification alliances using various platforms, including trade associations, CEO fora for fortified foods producers, industry leaders as champions for fortification, and the SUN Business Network.

Sub-IR2.2: Food industry compliance with fortification standards linked to improved access to finance and financing terms for general operations, as well as procurement of fortificant and food processing equipment.

Sub-IR2.2.1 Activity: Conduct studies on the capital and recurrent costs of staple food fortification within food industry and effects of costs on pricing and margin of profit (linked to Sub-IR1.2.6 Activity—assessment of government costs to monitor and regulate compliance with fortification standards).

Sub-IR2.2.2 Activity: Work with the U.S. Development Finance Corporation (DFC) to increase food fortification-compliant industry's access to finance (including foreign exchange transactions for fortificant and food processing equipment imports). Leverage additional financing support for food industry from other development finance institutions (DFIs), e.g., European Union DFIs.

Sub-IR2.2.3 Activity: Support advisory services to food companies engaged in food fortification to improve access and address gaps in financing.

Intermediate Result 3 (IR3): Design and monitoring and evaluation of fortification programs strengthened, and the public sector and private sectors held accountable to maximize compliance with national food fortification standards through civil society.

Sub-Intermediate Result 3.1 (Sub-IR3.1): Academic institutions and NGOs strengthened and commissioned to work with government to conduct surveys, surveillance, and analyses (market, household, and individual data) to guide food fortification program planning, implementation, monitoring, and evaluation.

Sub-IR3.1.1 Activity: Support collection of market and household food expenditure/consumption and other survey/surveillance data and analyses/modeling to assess dietary inadequacies and the potential of LSFF to alleviate dietary micronutrient inadequacies, including estimates of possible reductions in the cost of adequate diets through fortified foods.

Sub-IR3.1.2 Activity: Explore and pilot innovative and cost-effective data collection tools and approaches to make it affordable for governments to collect



fortification and national and subnational dietary data, e.g., utilization of data crowd-sourcing and geospatial data collection with mobile technology.

Sub-Intermediate Result 3.2 (Sub-IR3.2): Organization, mobilization, and capacity of consumer groups, professional associations, national research centers, and other third-party actors strengthened to hold the food industry accountable to comply with fortification standards and hold government accountable to monitor and enforce those standards.

Sub-IR3.2.1 Activity: Support engagement and strengthening of consumer groups and other third-party civil society actors, e.g., SUN Civil Society Alliances, to advocate for and hold government and food industry accountable to comply with fortification (and food safety) standards, including working with and through USAID/Washington and Mission DG programming.

Sub-IR3.2.2 Activity: Work with food industry associations and other professional associations to advocate for and hold government and food industry accountable to comply with fortification (and food safety) standards.

Sub-IR3.2.3 Activity: Promote and facilitate studies aimed to assess the market availability, contribution, and impact of fortified foods to address dietary inadequacies in combination with other micronutrient strategies introduced or considered in countries.

Intermediate Result 4 (IR4): Global commitment, leadership, and resources garnered and mobilized to support LSFF.

Sub-Intermediate Result 4.1 (Sub-IR 4.1): Improved global coordination, collaboration, complementarity, and synergies among donors, international organizations, partner countries, and other stakeholders to strengthen capacity, enable public-private sector partnerships, and support adoption and implementation of national LSFF strategies.

Sub-IR4.1.1 Activity: Foster the establishment of an alliance or “federation” of donors, international agencies, and other stakeholders (e.g., USAID, Bill & Melinda Gates Foundation (BMGF), Rockefeller Foundation, United Kingdom Foreign, Commonwealth & Development Office (FCDO), World Bank, UNICEF, World Health Organization (WHO), the Food and Agriculture Organization of the United Nations (FAO), and the UN World Food Programme (WFP)) to coordinate support for LSFF, including declarations of commitment at the United Nations (UN) Food Systems and Nutrition for Growth Summits, and the International Congress of Nutrition.

Sub-IR4.1.2 Activity: Work with and through SUN, including the SUN Business Network, and local stakeholders to support food fortification as an essential public health and food system activity through government, food industry, and civil society engagement.

Sub-IR4.1.3 Activity: Support the promulgation, adoption, and implementation of global, regional, and national policies in support of LSFF including, but not limited to:

- Analyses of barriers to trade and free movement of fortified foods among countries and implications of those barriers on food availability, affordability, and adequacy
- Regional harmonization of food fortification and food safety standards, food labeling, traceability, and regulatory control systems, including associated trade policies
- Regional harmonization and support for food information systems (production, market, and household levels—surveys and surveillance) to assess availability, affordability, and adequacy of diets (by season, geography, and socioeconomic strata), and guide food system policies and programs, including LSFF
- Elimination or reduction of duties/tariffs/taxes associated with food fortification (e.g., importation of equipment and fortificant and value-added tax on increased prices of fortified foods) and/or earmark those revenues to regulatory control for food quality and safety, including compliance with fortification standards

Sub-IR4.1.4 Activity: Work with the Development Finance Institutions (e.g., U.S. Development Finance Corporation) and Development Banks to increase government and industry access to finance to support LSFF (including foreign exchange transactions for fortificant and food processing equipment imports).

Sub-IR4.1.5 Activity: Strengthen regional and national capacity to design, implement, monitor, and evaluate LSFF



Photo Credit: Global Alliance for Improved Nutrition (GAIN)

activities through academic, vocational and technical training, mentoring, internship, certification, and other human resource programs, including food processing curriculum development, training, and certification programs covering:

- Food technology and product development
- Food quality and safety operational procedures and systems, including quality management/quality assurance (QA)/QC (quality control) (e.g., Hazard Analysis Critical Control Point (HACCP), International Organization for Standardization (ISO), and Good Manufacturing Practice (GMP) standards) specific to food fortification
- Packaging, labeling, and product tracing systems
- Product sampling and compositional analyses
- Raw material (ingredients and packaging) supplier approval, procurement, and handling
- Food regulations—monitoring, compliance, and enforcement

Sub-IR4.1.6 Activity: Support curricula development and training for government (or third-party) food factory auditors/inspectors for food fortification and food safety.

Sub-IR4.1.7 Activity: Promote and coordinate U.S. Government support for LSFF through the Global Nutrition Coordination Plan (GNCP), led by the GNCP Micronutrient Sub-Group.

Sub-IR4.1.8 Activity: Work with the U.S. Department of Agriculture (USDA) McGovern-Dole School Feeding Program and other food assistance programs (e.g., Office of Food for Peace (FFP) and WFP) to promote the use of fortified staples and condiments by governments for all national school feeding and other public assistance programs.

Sub-Intermediate Result 4.2 (Sub-IR 4.2): Increased support for the generation, dissemination, and adoption of innovative practices, technologies, and approaches for LSFF.

Sub-IR4.2.1 Activity: Support studies on the feasibility, stability, and retention of nutrients and relative costs of fortificants and fortification approaches, e.g., rice fortification by coating versus extrusion, relative to time, temperature, humidity, packaging, and household preparation, including cost-benefit of using broken kernels for extruded rice, as well as salt, bouillon cubes, and other fortification vehicles.

Sub-IR4.2.2 Activity: Support research and consultation(s) to define how samples of fortified foods for QC and inspection should be obtained and processed, as well as allowable variation relative to standards, as a basis for acceptable compliance. Currently, fortification standards typically are too stringent, specifying a very narrow range of variation

around the mean of micronutrient content and do not reflect the normal distribution of values expected when mixing a solid (premix) with another solid (the food matrix).

Sub-IR4.2.3 Activity: Support research and development of novel or alternative forms of vitamins, minerals, and other fortificant components to improve stability and retention of nutrients while reducing fortificant costs.

Sub-IR4.2.4 Activity: Explore use of food/feed additives (e.g., DHA-producing algae and fish powder) and food processing by-products as additives in blended foods to increase nutrient density, including key micronutrients.

Sub-IR4.2.5 Activity: Continue and expand the USAID Bureau for Humanitarian Assistance (BHA)/FFP and the USAID Bureau for Resilience and Food Security (RFS) Innovation Laboratory support for food fortification technology and effectiveness research (e.g., Food Aid Quality Review (FAQR)), provision of fortified staple foods within food assistance programs, and advocacy with host governments to promote national food fortification programs. Coordinate and collaborate with WFP and other international food assistance programs.

Sub-Intermediate Result 4.3 (Sub-IR 4.3): Increased capacity at the global, regional, and country levels to collect, analyze, synthesize, and document LSFF data and programmatic experience.

Sub-IR4.3.1 Activity: Support collection, aggregation, and reporting of global, regional, and national fortification data through dashboards/tools, such as the Global Fortification Data Exchange (GFDx), FortifyMIS and the Johns Hopkins University/Global Alliance for Improved Nutrition (GAIN)/FAO Food Systems Dashboard.

Sub-IR4.3.2 Activity: Strengthen regional and government capacity to establish and maintain food information systems, including the collection, analyses, and use of data on market availability, prices, and sales of foods, including fortified foods (by geography and season), as well as consumption, costs, and adequacy of diets at household and individual levels (by sex, age, geographic, and socioeconomic strata).

Sub-IR4.3.3 Activity: Support the review or development of national dietary guidelines, including standards for food fortification, based on population surveys, e.g., household food expenditure and consumption and other dietary surveys and market data.

Sub-IR4.3.4 Activity: Strengthen regional and national laboratory capacities to establish efficient, low-cost, and reliable enforcement and monitoring systems, including access to reference laboratories, to analyze nutrient composition of fortificant, premix, fortified foods, and natural foods, and the development of national food composition tables.



Photo Credit: SPRING Jganda

REFERENCE

UNICEF. 1998. The State of the World's Children. New York, UNICEF. <https://www.unicef.org/reports/state-of-worlds-children>

A photograph showing a row of industrial flour millstones in a factory. The millstones are large, cylindrical, and arranged in a line. They are mounted on metal stands. The background shows a window with a view of the outdoors. The word "ANNEXES" is overlaid in blue text in the center of the image.

ANNEXES



ADVOCACY BRIEF

LARGE-SCALE FOOD FORTIFICATION:

Building Nutritious, Resilient and Sustainable Food Systems

Why?

1. Good nutrition is vital to human health and development. Yet, insufficient dietary intake (inadequacies) of vitamins and minerals continue to affect much of the world's population, particularly women and children, limiting their future potential and lifelong well-being and, in severe situations, even threatening their survival.¹
2. LSFF is cost-effective. When appropriately designed and implemented, one of the most proven, cost-effective nutrition interventions is LSFF, which entails enhancing the nutrient content of foods during the processing stage. Fortification typically costs less than 2-3 percent of the staple food or condiment market price, and those costs are then included in product pricing.²
3. LSFF provides a safety net against vitamin and mineral inadequacies that often occur seasonally or during times of crisis when food availability is limited and not sufficiently diverse, as during the current COVID-19 pandemic.
4. Uptake is easy for target populations as effective LSFF strategies target food items that are already regularly consumed (e.g., flours, rice, oil, sugar, and salt), and thus do not require consumers to change or adopt new dietary behaviors.

How?

1. Partner with the private sector. The food industry—specifically the food processing sector—has the central role in LSFF. LSFF is most likely to succeed and be sustained when we take a whole-of-business approach, supporting processors by assisting in business planning, access to finance, operation efficiencies, compliance with food quality and safety standards, and marketing. This comprehensive approach makes the food processing sector more economically viable and resilient, in addition to improving diets and nutrition.
2. Partner with governments, civil society, and academia. For LSFF to be successful, governments must set feasible standards for the food industry and establish and execute monitoring and regulatory control systems that are extensive, equitable, and effective to assure a level competitive playing field. Civil society and academia have roles in enhancing accountability, monitoring, and evaluation of LSFF programs.
3. USAID can help determine where to invest and how. Recently, USAID developed an [LSFF Results Framework](#), and an LSFF Programming Guide. The USAID Bureau for Resilience and Food Security's Center for Nutrition (RFS/CN), with the coordination and support of the USAID Bureau for Global Health (GH) and the USAID Bureau for Humanitarian Assistance (BHA), will collaborate actively and strategically to support LSFF activities.

USAID and global partners are elevating LSFF as a feasible, sustainable food system intervention to improve public health, create economic growth, and build resilience by providing people with essential vitamins and minerals that are insufficient in their diets.

¹ Interventions For Addressing Vitamin and Mineral Inadequacies. USAID, 2019: <https://www.usaid.gov/global-health/health-areas/nutrition/technical-areas/vitamins-and-minerals-brief>.

² Guidelines on Food Fortification with Micronutrients. WHO, 2006: <https://www.who.int/publications/i/item/9241594012>.

Evidence for Large-Scale Food Fortification

Studies have demonstrated the benefits that well-designed and regulated fortification systems can yield in multiple countries. A 2019 systematic review examined the effects of LSFF across a range of food vehicles (including wheat and maize flour, rice, cooking oil, sugar, and salt) in multiple countries. The results showed that LSFF was associated with a 41 percent reduction in the odds of neural tube defects and a 34 percent decline in anemia prevalence, with the greatest impact for women of reproductive age. It also estimated that LSFF with vitamin A has the potential to reduce global vitamin A deficiency in 2.7 million children per year, protecting children from impaired immune response and altered growth and development.³ Another review published in 2021 showed that zinc-fortified foods, consumed alone or with other vitamins and minerals, decreased the prevalence of zinc deficiency by 55 percent.⁴ Evidence also shows that LSFF is cost-efficient: iron fortification of staples costs about \$0.1008 per child per year and fortification with iodine and zinc is even lower.⁵

USAID'S Approach to Large-Scale Food Fortification

Globally, LSFF has been embraced and practiced by many countries for decades.⁶ Over the past five decades, USAID has been a leader in mitigating vitamin and mineral inadequacies through multiple and complementary interventions, including LSFF fortification. Historically, USAID food fortification initiatives have been primarily funded and driven programmatically by USAID Bureau for Global Health and Mission health offices. However, LSFF has significant and strategic equity under the Economic Growth (EG) and Agriculture portfolios. LSFF supports the Agency's efforts to achieve Feed the Future objectives by leveraging a comprehensive food system focus extending beyond the farm level and across market actors, particularly regarding food processing. Furthermore, it is an intervention that complements and builds on existing EG interventions that are maximizing food systems to improve diets—specifically, private sector engagement, food processing, food safety, policy, and trade. Ultimately, LSFF should be an integral part of all Feed the Future programs. It can deliver results across the three Strategic Objectives of the Global Food Security Strategy, including our work in private sector engagement and food system policy work.

The Global Agenda for Large Scale Food Fortification

A nutritious, resilient, and sustainable food system includes processed foods that meet quality and safety standards, including LSFF standards for staple foods and condiments. The importance of LSFF is globally recognized and is a re-emerging priority for international convenings in 2021, particularly the United Nations (UN) Food Systems and Nutrition for Growth Summits. USAID is well positioned to continue leading efforts for LSFF through global leadership, context-specific technical expertise, and partnerships with governments, the private sector, and civil society. With continued commitment and collaboration for such proven and system-based solutions, the vision of dietary adequacy and reducing preventable morbidity and mortality through fortifying foods is one that can be achieved.

Questions? Comments? Requests for assistance?

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³Keats, Emily C., et al. "Improved micronutrient status and health outcomes in low- and middle-income countries following large-scale fortification: evidence from a systematic review and meta-analysis." *The American journal of clinical nutrition* vol. 109,6 (2019): 1696-1708. <http://doi.org/10.1093/ajcn/nqz023>.

⁴Tsang, Becky L., Erin Holsted, Christine M. McDonald, Kenneth H. Brown, Robert Black, Mduduzi N.N. Mbuya, Frederick Grant, Laura A. Rowe, Mari S. Manger. "Effects of Foods Fortified with Zinc, Alone or Co-fortified with Multiple vitamins and minerals, on Health and Functional Outcomes: A Systematic Review and Meta-Analysis, *Advances in Nutrition*," 2021, nmab065, <https://doi.org/10.1093/advances/nmab065>.

⁵Hoddinott, J., H. Alderman, J.R. Behrman, L. Haddad, and S. Horton. (2013). "Economic rationale for stunting reduction." *Matern Child Nutr*; 9: 69-82. <https://doi.org/10.1111/mcn.12080> Horton, S. 2006. The Economics of Food Fortification. *Journal of Nutrition* Vol. 136 (2006):1068-1071. <https://doi.org/10.1093/jn/136.4.1068>.

⁶Mkambula, Penjani, et al. "The Unfinished Agenda for Food Fortification in Low- and Middle-Income Countries: Quantifying Progress, Gaps and Potential Opportunities." *Nutrients* vol. 12,2 354. 29 Jan. 2020, <http://doi.org/10.3390/nu12020354>.

2.

QUESTION AND ANSWER

LARGE-SCALE FOOD FORTIFICATION:

A Priority Approach for RFS – Q&A from Webinar by Shawn Baker and Rob Bertram
June 30, 2021

Q: There have been some “failures” in the past—what have been some of the major challenges/causes to watch out for when initiating LSFF programs?

Some common failures occur during design—an example of a common misstep is the choice of food to fortify (or the food vehicle). Food vehicles need to be widely and regularly consumed and industrially processed, particularly for those whose diets are most likely to provide inadequate vitamins and minerals (i.e., micronutrients), while the fortificant should not alter the food in a way that is noticeable and objectionable to consumers.

A lack of focus during implementation to address policy and enabling environment constraints is a common cause of failure. Fortification works/is sustainable when it is supported by formal and centralized industries, and almost always when it is made mandatory for primary staple foods and condiments. Regulations create incentives and disincentives that affect competitiveness for businesses within the food industry. For example, failing to work with policy stakeholders to apply consistent regulatory control can lead to significant difficulties and the overall failure of a food fortification program. Governments need to establish monitoring and regulatory control systems that are extensive and effective, but not excessively onerous or illogical for food industry compliance.

Additionally, the food industry can face challenges to efficiently integrate LSFF into their processing operations, particularly with regard to quality assurance and quality control (QA/QC). These challenges can be amplified in developing economies, where supply chains may be more compromised in terms of storage, handling, purity, etc. We know, therefore, that LSFF is most likely to succeed and be sustained when we take a whole-of-business approach, supporting processors by assisting in business planning, access to finance, operation efficiencies, compliance with food quality and safety standards broadly, and marketing—make this sector more economically viable and resilient, while improving diets and nutrition.

Donors have also inappropriately focused on behavior change in LSFF programming and dedicated too much funding and attention to social marketing. LSFF does not/should not require or encourage consumers to change or adopt new dietary behaviors. Greater consumption of LSFF food vehicles should not be promoted; they should be foods or condiments that are already a common and consistent component of the diet. Nevertheless, advocacy and social behavioral programs aimed at policy makers and the food industry might be valuable. The role of consumers, and civil society broadly, should be to hold the government and food industry accountable to comply with LSFF standards in the public health interest.

And finally, another common mistake of the past has been that food fortification programs have been donor-driven and “top-down.” The work must be locally led and locally owned. Implementing food fortification is an art of local leaders more than providing novel technologies and tools, and it requires a deep knowledge of the production and trade of staples and condiments, as well as the interests of all involved players in the country and region. Political economy analysis can help assess willingness to act among critical stakeholders.

Q: Under forging partnerships, how about engaging with food industries to cofund USAID interventions on the production and consumption of fortified products?

Engaging and partnering with food industries is critically important for the success of LSFF. We would caution against directly subsidizing food industry costs of fortification, but rather focus on securing incentives, e.g., improved access to

finance and reduced duties, levies, and fees on imported equipment and fortificant. Beyond financial partnerships, USAID plays many value-adding roles with the private sector, including food industries. These include co-creator, risk mitigator, convener, broker/facilitator, thought leader, expert, advocate, and investment catalyst. USAID is a firm believer in partnering with the private sector as co-creators of market-oriented solutions.

One of the beauties of LSFF is that the level of financial support required is relatively limited; much of the costs are taken on by the industry and then passed on to consumers, as are other costs of meeting food quality and safety standards (e.g., packaging and labeling). When programs are working successfully, there is a small price increase of food products—typically about 2–3 percent. The cost aspect needs to be discussed and agreed upon with partners in industry.

USAID's comparative advantage in this arena is understanding the whole landscape. We are well positioned to identify and help address gaps, thus improving the effectiveness of interventions across government, food industry, and civil society so that LSFF can be sustained at scale.

Q. Does making fortification of industrially processed primary staples and condiments mandatory by law to the food industry yield intended results?

If standards are appropriate and enforced, then yes. The evidence shows that making fortification mandatory is an important step in the process, as it creates a level competitive playing field for all producers. This is especially important in the case of staples and condiments that are frequently purchased regardless of the brand and selected based on price.

Q. Why not start by working with industry on voluntary guidelines instead of jumping to legal mandates that can't be met?

Voluntary fortification, particularly by early adopters and according to standards, may be a gateway to mandatory fortification. However, mandatory fortification ultimately protects those companies that comply by assuring that all processors must bear the same costs to fortify those foods. Voluntary fortification opens the door to those companies that might promote increased consumption of foods because they are fortified, asserting they are healthier, when greater consumption of these vehicles (e.g., flours, salt, sugar, and cooking oil) would be unhealthy.

Businesses can be our biggest allies. They are often the ones asking the government for a level competitive playing field (i.e., standards, regulatory control, and enforcement). In general, businesses see these programs being mandatory as a good thing. The only risk with a blanket mandate is if the mandate does not set good standards or feasible regulatory control measures. Another risk is that the mandates are not consistent in their application. We need to be sensitive to industry's other needs as well, particularly the need to recover costs and remain profitable.

Q. What do you mean by “nonnegotiable”? Legal mandates? You seem to be assuming that reformulation is a no-cost proposition for the food industry. And what about public acceptance? There are examples of the public rejecting food additives.

We recognize that there are costs borne by the food industry for fortification—equipment, fortificant, training, management, and operations, including QA/QC. We can offset some of these costs through improved access and terms of finance, reduced costs, and revolving funds for fortificant procurement, etc., and then the remaining costs, as with other production costs, can be incorporated into product pricing.

While the costs of fortification are minimal for the consumer—typically less than 3 percent of the product price and generally indiscernible to consumers relative to market price fluctuations—they may be significant for food industries' margin of profit if those costs are not incorporated into the product's price. Moreover, in spite of the small price increment, it may create unfair competition if one company claims to, but does not fortify versus those companies that comply—hence, regulation, inspection, and supervision by governmental authorities is essential. Changes to food and price due to fortification should be assessed relative to the cross-price elasticity of demand—the price of the food/condiment cannot become too high for the target population.

Public acceptance has not been identified as a large issue with LSFF if it doesn't change the taste or appearance of the food vehicles, and the market price differential is minimal. However, LSFF should not be perceived as a “solution” coming from outside, because it may create mistrust. Consumers and civil society have a role in holding the government and food

industry accountable to comply with LSFF standards for the public's benefit.

Q. Thinking of the essential micronutrients that can be added during processing, what considerations are key for ensuring stability and quality? How reliably can organic molecules versus minerals, like Zn and Fe, be maintained?

Some of the vitamins (e.g., A, D, and B12) are microencapsulates that have been developed by the food industry to remain stable in storage and food preparation when added to dry food matrices. Similarly, mineral chemical forms (e.g., ferrous fumarate or NaFeEDTA) are selected to minimize interaction with food components and maximize bioavailability. Those are the ones we use for the flours and other dry foods. The small losses of vitamins are compensated by “overages” of added micronutrients when foods are fortified.

This is one gap that we haven't sufficiently addressed. As diets evolve and as more staples and condiments are industrially processed, we will need to identify additional vehicles and fortificants that can address micronutrient inadequacies identified in populations. At the same time, complementary efforts should focus on making micronutrient-dense foods (e.g., fruits, vegetables, legumes, and animal-source foods) more available and affordable to improve diets at scale.

Q. Has anyone done an analysis of the energy costs and carbon footprint of large-scale production of functional vitamins and minerals used in food fortification?

This is an interesting question. Not to our knowledge. We expect it to be low. However, we wouldn't want to get drawn into a comparison, for example, between the carbon footprint of an animal-source food versus a fortified staple. We want people to eat a diverse diet, including fortified staples and condiments that provide a safety net for essential micronutrients, especially for lower-income individuals whose diets tend to rely heavily on cereal staples.

Q. Does Codex Alimentarius address fortification with micronutrients?

The part of the Codex Alimentarius of greatest direct relevance to food fortification is the General Principles for the Addition of Essential Nutrients to Foods (CAC/GL 07-1987, amended 1989, 1991). This section, which covers the addition of essential nutrients for the purposes of restoration, nutritional equivalence of substitute foods, as well as fortification, provides guidance to governments with regard to the planning and implementation of national food fortification programs.

Q. What are the considerations that are required to apply and be followed by each stakeholder in a country where there is inadequate policy, poor implementation of policy and law, poor monitoring systems, and wide availability of other processed foods items that are also fortified?

Great question. A [LSFF Results Framework](#) and this Large-Scale Food Fortification Programming Guide has been developed to guide USAID programming to support LSFF through central and bilateral mechanisms, while recognizing that USAID will not take on the entirety of the Results Framework and needs to coordinate and complement other stakeholders across government, the private sector, and civil society.

Additionally, the Center for Nutrition has committed funds to develop dietary, food industry, and enabling environment/policy assessment methodologies to assist Missions in determining what may be most strategic to address LSFF within the Results Framework.

And finally, we have started the design of a new central mechanism that can support Missions in their LSFF programming, directly and/or through Missions' bilateral mechanisms.

Q. Do we have advice for Missions with budgetary constraints and limited staff on making choices across the different approaches—LSFF, biofortification, supplementation, etc.?

Another great question! We should start by clearly differentiating the approaches. These approaches are often lumped together, but they are separate programmatically. They are implemented by different actors through different programs and will achieve different types of results.

Biofortification is in the realm of on-farm plant breeding/crop diversification, typically focused on single micronutrients (e.g., high-iron or zinc cereals or high beta-carotene (pro-vitamin A) orange-fleshed sweet potatoes or maize).

Supplementation is often provided through the health system and targeted to a certain population (e.g., iron/folic acid (IFA) for women of reproductive age). Supplementation is the term used to describe the provision of relatively large doses of

micronutrients, usually in the form of pills, capsules, or syrups. It has the advantage of being capable of supplying an optimal amount of a specific nutrient or multiple nutrients and is often the fastest and only available way to control deficiency targeted to specific individuals or population groups that have been identified as being deficient. However, supplementation usually requires the procurement and purchase of micronutrients in a relatively expensive prepackaged form, the creation of an effective distribution system, and keeping strong communication campaigns to attain a high degree of consumer compliance (especially if supplements need to be consumed on a long-term basis).

LSFF is a post-farm food processing activity that can provide a mix of micronutrients adjusted to dietary inadequacies across populations. In many situations, this strategy can lead to relatively rapid improvements in the micronutrient status of a population, and at a very reasonable cost, especially if advantage can be taken of existing technology and local food system distribution networks. Since the benefits are potentially large, LSFF can be a very cost-effective public health intervention that is delivered by the food system.

Ideally, LSFF is a part of a broader approach to improve dietary adequacy. USAID's strategic choice about what approach(es) to support (and how to support it/them), needs to come from assessments of the diet of the target population and the enabling environment for implementation—for example, is there a commonly consumed food vehicle that is appropriate for LSFF and can be fortified to meet specific dietary inadequacies?

Resources

Guidelines on Food Fortification with Micronutrients, UN World Health Organization and the Food and Agriculture Organization of the United Nations: <https://www.who.int/publications/i/item/9241594012>

3.

PRIMARY LARGE-SCALE FOOD FORTIFICATION

Stakeholders and Partners

United States (U.S.) Government

- U.S. Agency for International Development (USAID)
 - Bureau for Global Health (GH)
 - Bureau for Resilience and Food Security (RFS)
 - Bureau for Humanitarian Assistance (BHA)
 - USAID Missions
- [U.S. International Development Finance Corporation \(DFC\)](#)
- U.S. Department of Agriculture (USDA)
- U.S. Centers for Disease Control and Prevention (CDC)
 - [International Micronutrient Malnutrition Prevention and Control Program \(IMMPaCt\)](#)
- [U.S. Food and Drug Administration \(FDA\)](#)
- Global Nutrition Coordination Plan (GNCP) Micronutrient Subgroup

United Nations (UN) and International Initiatives

- [UN World Food Programme \(WFP\)](#)
- [UN Children's Fund \(UNICEF\)](#)
- [Food and Agriculture Organization of the United Nations \(FAO\)](#)
- [UN World Health Organization \(WHO\)](#)
- [Scaling Up Nutrition \(SUN\)](#)
 - [SUN Business Network](#)

Foundations

- [Bill & Melinda Gates Foundation \(BMGF\)](#)
- [Rockefeller Foundation](#)

Multilateral/Bilateral Donors and Development Banks

- European Union
- United Kingdom Foreign, Commonwealth and Development Office (FCDO)
- German Federal Ministry of Economic Cooperation and Development (BMZ)
- World Bank (WB)
- International Finance Corporation (IFC)
- African Development Bank (AfDB)

Food Industry

- [Partners in Food Solutions \(PFS\)](#)
- [DSM](#)
 - [Sight and Life](#)
- [BASF](#)

Implementing Organizations/Technical Advisory Groups/Relevant Entities

- [Global Alliance for International Nutrition \(GAIN\)](#)
 - [GAIN Premix Facility](#)
- [Food Fortification Initiative \(FFI\)](#)
- [TechnoServe](#)
 - [Alliance for Inclusive and Nutritious Food Processing \(AINFP\)](#)
 - [Strengthening African Processors of Fortified Foods \(SAPFF\)](#)
- [Institute for Smallholder Finance \(ISF\)](#)
- [Helen Keller International \(HKI\)](#)
- [Global Fortification Data Exchange \(GFDx\)](#)
- [USAID Advancing Nutrition](#)
- [Micronutrient Forum](#)
- [Nutrition International](#)
- [International Zinc Nutrition Consultative Group \(IZiNCG\)](#)
- [Iodine Global Network \(IGN\)](#)
- [International Food Policy Research Institute \(IFPRI\)](#)
- [Micronutrient Action Policy Support \(MAPS\)](#)
- [Food Fortification Advisory Services \(2FAS\)](#)

4.

SCOPE OF WORK / USAID ADVANCING NUTRITION

Note: Annexes 4, 5, and 6 are Scopes of Work (SOWs) for the development of assessment methodologies— (1) dietary assessment to determine micronutrient inadequacies, identify potential food fortification vehicles, and penetration of industrially processed fortified foods in markets (USAID Advancing Nutrition); (2) assessment of industrial food processor capacity and barriers to LSFF (Market Systems and Partnerships); and (3) assessment of the LSFF policy enabling environment (Innovation Lab for Food Security Policy, Research, Capacity, and Influence)—that can be used by USAID Missions and partners to understand the current context and inform the Mission’s use of this Programming Guide and selection and implementation of specific activities within the Results Framework to advance LSFF.

USAID Advancing Nutrition

Concept note for dietary assessment to inform large-scale food fortification programming

USAID is reaffirming its decades-long commitment to reducing micronutrient inadequacies and their associated deficiencies through the large-scale food fortification (LSFF) of edible products. LSFF is a cost-effective strategy when implemented appropriately, which consists of the addition of vitamins and minerals during processing of commonly consumed staple foods (e.g., rice, wheat, or maize flours) or condiments and food ingredients (e.g., salt, sugar, and oil). Major advantages of LSFF are that it delivers nutrients to consumers without requiring a change of dietary habits and that it uses already existing delivery systems (the supply chain of the fortifiable products). However, barriers exist at various stages of the food supply chain, preventing LSFF from reaching its full potential. Among these barriers are the proper choice of staple food vehicles, fortification formulation, selection of the fortificants (i.e., source of the micronutrients), and efficient practices of quality control, monitoring, and evaluation.

Chosen food vehicles should be centrally processed, consumed widely and regularly by the target population, and their micronutrient content should provide sufficient amounts to correct the micronutrient gaps of individuals while assuring safety among those consumers whose micronutrient intake is adequate. The choice of fortificant is relevant to ensure nutrient bioavailability and avoid potential interactions between nutrients and/or other food components. Local contexts, including prevailing dietary patterns and national food-based dietary guidelines, must be taken into account when considering food vehicles. National laws/regulations need to be developed, implemented, and enforced to ensure compliance by all stakeholders. Guidelines for food fortification with micronutrients are available (WHO 2006— <https://www.who.int/publications/i/item/9241594012>), but do not reflect recent developments, current policy environments, or prevalent gaps that allow for a complete understanding of how LSFF can complement other public health interventions to mitigate micronutrient inadequacies and deficiencies. Furthermore, recent assessments of dietary intake and/or biomarker surveys of sufficient quality are lacking from many countries and populations. Low cost, simple, and practical systems to measure reach, coverage, and epidemiological benefit of fortified foods are also needed.

In project year (PY) 3, USAID Advancing Nutrition will develop a concept note for a PY4/PY5 activity with the aim of developing a process to identify when food fortification is appropriate and useful as an intervention to supply micronutrients. This will include how to assess dietary inadequacies and the cost of an adequate diet, and subsequently estimate how the introduction of appropriate fortified foods and condiments might improve the nutritional quality of current diets with available resources. This work is needed to support Missions in finding the most efficient options for engaging in LSFF. Our work will be informed by a recently developed USAID LSFF Results Framework.

The scope of this activity, to be described in detail within the concept note, will likely include:

- I. A review of the current state of LSFF, particularly:
 - a. Available dietary assessment methods and tools at population, household and individual levels¹
 - b. Prevalent dietary evidence gaps and barriers
 - c. Modalities and costs associated with collecting representative dietary intake data for assessing the nutrient adequacy of diets to inform LSFF programming

This process will draw on experience from USAID's Solutions for African Food Enterprises (SAFE) and the Alliance for Inclusive and Nutritious Food Processing (AINFP), as well as the Bill & Melinda Gates Foundation's Strengthening African Processors of Fortified Foods (SAPFF) and other stakeholders involved in LSFF (e.g., Helen Keller International (HKI), Food Fortification Initiative (FFI), Nutrition International (NI), and Global Alliance for Improved Nutrition (GAIN)). Part of this effort will also be to synthesize findings with those from our other activities, such as assessing the applicability of consumption data collected in large population surveys, such as the Household Consumption and Expenditure Surveys (HCES) to understand dietary adequacy (related to USAID Advancing Nutrition work plan sections 2.4.K, 2.4.N, and 3.2.D), and measuring market food environments to support healthy and safe diets in low- and middle-income countries (1.2.C). We expect this review to be completed in the second quarter (Q2) of PY4.

2. Informed by the review, we will develop a synthesis of methodologies to assist Missions in identifying viable options to engage in LSFF, also being opportunistic to collect additional dietary data that may guide USAID's broader nutrition-sensitive programming. This may also include market data and cost of an adequate or recommended diet with current or projected fortification of staples/condiments. The methodology, which will be refined through an iterative process, will facilitate policy decision-making by providing a suite of options based on a local context, and will also include rough cost estimates. We expect an initial version of this deliverable to be available in Q3 of PY4 and will refine through learnings gained from 3 below.
3. Using the developed methodology, USAID Advancing Nutrition will engage with USAID Missions (e.g., Uganda and Liberia) with the aim to support capacity-building/strengthening of food information systems within governments. Specific activities may include:
 - a. Support of the collection of market and household expenditure/dietary intake data and their analysis to assess dietary inadequacies and the potential of LSFF to alleviate dietary micronutrient inadequacies, including estimates of possible reductions in the cost of adequate diets through fortified foods.
 - b. Collection, analyses, and use of data on market availability, prices, and sales of foods, including fortified foods (by geography and seasons), as well as consumption, costs, and adequacy of diets at population strata and household levels (by geographic and socioeconomic strata) and, when possible, at individual level (e.g., by sex or age).

USAID Advancing Nutrition is well positioned to assist USAID Missions and partners in this endeavor, specifically to assess diets and micronutrient inadequacies, and the overall programmatic costs, to improve the design, monitoring, and evaluation of LSFF.

Deliverable

- I. Brief (8–10 page) concept note describing the steps needed to develop, test, and finalize a methodology using dietary intake/consumption/expenditure data to provide sufficient information to design, monitor, and evaluate LSFF programming (Q4); Funding: 100 percent Bureau for Resilience and Food Security (RFS).

¹The application of Household Consumption and Expenditure Surveys (HCES), when available, appears to be an attractive methodology.

5.

SCOPE OF WORK / FEED THE FUTURE MARKET SYSTEMS AND PARTNERSHIPS ACTIVITY

Overview of Feed the Future Market Systems and Partnerships

The Feed the Future Market Systems and Partnerships (MSP) Activity aims to advance learning and good practice on market systems development (MSD) and private sector engagement (PSE) within USAID (Washington and Missions), USAID implementing partners, and market actors by providing and improving upon the evidence, capacity, tools, technical assistance, and/or services required to design, implement, monitor, and/or evaluate activities. MSP supports USAID in bringing about a major cultural transformation by integrating PSE across all activities, while at the same time deepening MSD and facilitative approaches across the program cycle to lead to inclusive and resilient economic growth, improved food security and nutrition, and increased incomes for the poor. MSP will achieve this goal by facilitating transformative private sector partnerships; supporting USAID in the design, implementation, monitoring, and evaluation of market systems and PSE activities; advancing learning on PSE and MSD; and building capacity of USAID and implementers to design, implement, monitor, evaluate, and learn from MSD and PSE activities.

Through MSP's buy-in mechanism, the Center for Nutrition (CN) within USAID's Bureau for Resilience and Food Security (RFS) aims to provide a methodology for Missions to analyze the current and future capacity of food processors to fortify staple foods and condiments, particularly at a large scale. MSP will pilot the methodology in two to three countries and draw from this experience to refine the assessment tool before promoting uptake.

Background

USAID is reaffirming its decades-long commitment to reducing micronutrient inadequacies and improving diets through large-scale food fortification (LSFF) of staple foods and condiments. LSFF, when appropriately implemented, has been shown to be a cost-effective intervention that provides essential vitamins and minerals when the food vehicles are industrially processed and widely and regularly consumed by the target population. With trends toward greater consolidation of industrial processing of staples and condiments and increased urbanization, as well as greater penetration of centrally processed foods in rural markets, LSFF is positioned to have an expanded role over time.

Across countries, foods are increasingly processed and an increasing proportion of marketed food prices are attributable to post-farm processing by food companies. However, relative to on-farm inputs and support, development of this commercial food processing "hidden middle" sector of the farm-to-fork food system has received limited attention and investment. LSFF is a key aspect of food processing and meeting national food quality and safety standards. Experience through USAID's Solutions for African Food Enterprises (SAFE) and the Alliance for Inclusive and Nutritious Food Processing (AINFP), as well as the Bill & Melinda Gates Foundation's Strengthening African Processors of Fortified Foods (SAPFF) indicate that processors of staple foods and condiments are most likely to comply with LSFF standards through a whole-of-business approach that works with those companies to improve business plans, access to finance, technologies and operational efficiencies, cost reductions, and marketing. In most cases, these improvements can significantly offset the costs of LSFF, in addition to a small increase in product price that does not adversely affect market share.

An LSFF Results Framework has been developed to guide USAID programming to support LSFF through central and bilateral mechanisms, including:

Intermediate Result 2 (IR2): LSFF in compliance with national fortification standards expanded and sustained by the private sector, and

Sub-Intermediate Result 2.1 (Sub-IR2.1): Food industry compliance with fortification standards through business, and development, food technology and quality control, and marketing guidance strengthened,

and

Sub-IR2.2: Food industry compliance with fortification standards linked to improved access to finance and financing terms for general operations, as well as procurement of fortificant and food processing equipment.

The LSFF RF also includes illustrative activities that can contribute to achieving the Sub-IRs, including:

Sub-IR2.1.1 Activity: Food industry mapping/scoping/analyses of industrial/large-scale food processing and consumption of potential food fortification vehicles (e.g., cereal flours, rice, edible oil, sugar, salt, bouillon cubes, and dairy products) considering past trends and projecting forward 5/10/20 years, including geographic and socioeconomic coverage.

Sub-IR2.2.1 Activity: Conduct studies on the capital and recurrent costs of staple food fortification within food industry and effects of costs on pricing and margin of profit (linked to Sub-IR 1.2.6 Activity—assessment of government costs to monitor and regulate compliance with fortification standards).

USAID Missions require the necessary tools to implement the LSFF Results Framework. MSP will develop guidance for USAID Missions to identify opportunities and engage with commercial food processors to expand and strengthen industrial fortification of staple foods and condiments.

Activity Description

MSP will develop a user-friendly methodology to support Missions in assessing the current and projected capacity of industrial-scale food processors to fortify staple foods and condiments that may serve as effective food fortification vehicles based on wide and regular consumption within a given country context. Assessment findings will enable Missions to identify and strategically engage with private sector firms that are well-positioned to effectively and sustainably conduct LSFF in accordance with national standards. The methodology will include, at a minimum, guidance to assist the Missions in assessing the following:

- Identification and ranking of primary food processors of potential LSFF staple and condiment products, including data on firms' production volumes; market share, ownership structure, average customer profile (by geographic region, rural/urban, and socioeconomic status, if available), and average household consumption levels of each product, if available
- National and regional LSFF trends over at least the past 5–10 years and projecting forward 5–10 years
- Processors' LSFF operations and associated quality assurance (QA) or quality control (QC) procedures
- Costs attributable to LSFF (e.g., capital and recurrent equipment, such as dossifiers and mixers, fortificant/premix, QA/QC, and other LSFF-specific operation costs such as personnel, testing, etc.)
- Source and pricing of LSFF equipment and fortificant including taxes, duties, and levies
- LSFF costs as a percentage of product price and as a percentage of product margin of profit
- Opportunities and challenges for LSFF financing
- Profile ownership and shareholders (if applicable)
- Relevant national food industry associations

MSP will pilot test, and later refine, the methodology to ensure the assessment tool is effective and useful in a Mission environment. Finally, in collaboration with the CN, MSP will promote uptake of the final methodology across Missions.

Statement of Work

MSP's implementation approach for this engagement with the CN will have five phases:

1. **Desk Review:** MSP will synthesize the protocols and methodologies that have been previously used for food processor assessments, particularly those intended to guide LSFF activities (e.g., SAFE, AINFP, SAPFF, Global Alliance for Improved Nutrition's Fortification Assessment Coverage Toolkit (GAIN FACT), and Food Fortification Initiative (FFI)).
2. **Tool Development:** Based on the desk review, MSP will develop a tool that outlines a methodology for USAID Missions to conduct country-level assessments of existing and potential capacity of industrial-scale food processors to fortify staple food and condiment products from a whole-of-business perspective and in the context of local diets, national LSFF legislation, sanitary and phytosanitary standards, and regulatory control.
3. **Tool Trial:** MSP will pilot the food processor LSFF assessment tool in two to three countries. Country selection will be based on RFS/CN consultations and MSP partners' on-the-ground presence.
4. **Tool Refinement:** MSP will revise the food processor LSFF assessment tool based on: observation and results from piloting in Phase 3, feedback from Mission and RFS/CN clients based on their experiences in Phase 3, and additional consultation of key LSFF global stakeholders.
5. **Uptake:** MSP will promote the adoption and use of the LSFF assessment methodology to USAID Missions via webinars, global technical convenings, and other key pathways identified by RFS/CN.

DAI will draw from its own cadre of technical experts and/or may identify one or more partners to assist in the completion of this SOW in a subcontractor relationship to DAI. DAI will work closely with the USAID/RFS CN during all stages of this work.

Phase I: Desk Review. MSP will synthesize existing research, tools, and methodologies that have been used to assess the food processor LSFF landscape (e.g., major private sector firms, policy, and regulatory framework) including: SAFE, AINFP, SAPFF, GAIN FACT, FFI, and USAID's A2Z Micronutrient and Child Blindness Project.

The desk review will combine the strengths and resources developed by previous USAID work, as well as identify key sources of reliable data and information that Missions can leverage while using the methodology to conduct their analysis. In the absence of key data sources, the desk review will identify the kinds of sources Missions can leverage to localize their analysis.

Phase II: Tool Development. MSP will develop a user-friendly methodology that Missions can leverage to analyze the national LSFF landscape, assess strategically placed food processors, identify strategic opportunities for investment or engagement, and contextualize potential food fortification opportunities within the policy landscape and local dietary preferences.

RFS/CN will share USAID Advancing Nutrition's analyses on country-level dietary nutrient gaps and fortification opportunities, as well as assessments of LSFF policies and enabling environments conducted by the Food Security Policy, Research, Capacity, and Influence (PRCI) Innovation Lab, Akademiya2063, and Partnership for Inclusive Agricultural Transformation in Africa (PIATA)/Alliance for a Green Revolution in Africa (AGRA) as key background information, as available, and will facilitate key informant interviews with USAID Advancing Nutrition as needed.

Phase III: Tool Trial. To ensure that the tool is relevant, user-friendly, and practical, MSP will pilot the tool with two or three Missions. Mission participation will be determined by a variety of factors, including Mission demand, RFS/CN consultation, USAID Advancing Nutrition analysis (if applicable), and available on-the-ground presence of the MSP partners implementing the activity.

MSP will pay close attention to Missions' user experience throughout the pilot process to identify opportunities to improve the methodology. In addition, pilot Missions will provide feedback on the methodology's clarity, practicality, ease-of-use, and quality of results to assist MSP in determining if the tool meets end-user needs.

Phase IV: Tool Refinement. In consultation with RFS/CN, pilot Missions, and key LSFF global stakeholders and informants (e.g., fellow donors, relevant USAID implementing partners, multilateral institutions, and food processing thought leaders), MSP will revise the food processor LSFF assessment methodology to make it more practical, accurate, efficient, and user-friendly.

Phase V: Promotion. MSP will prepare and deliver two to three presentations (e.g., webinars and conference workshops) to promote the adoption and use of the food processor LSFF assessment methodology by USAID Missions. The appropriate format and venue will be determined by MSP and RFS/CN.

Timeframe

Activity	Timeframe
Phase I: Review protocols/methodologies that have been previously used for food processor assessments, particularly those intended to guide LSFF activities (e.g., SAFE/AINFP, SAPFF, GAIN FACT, and FFI).	Three months, starting on October 1, 2021
Phase II: Based on reviews (Phase I), develop a protocol/methodology for conducting country-level assessments of existing and potential capacity of industrial-scale food processors to fortify potential staple food and condiment vehicles from a whole-of-business perspective and given national LSFF legislation, standards and regulatory control.	Three months, starting on January 3, 2022
Phase III: Conduct food processor LSFF assessment using draft protocol/methodology (Phase II) in two to three countries identified through RFS/CN consultations with Missions.	Five months, starting on April 5, 2022
Phase IV: Refine food processor LSFF assessment protocol/methodology based on results from its use in two to three countries, MSP and RFS/CN observation of piloting, and additional stakeholder input.	Four months, starting on September 6, 2022
Phase V: Promote adoption and use by USAID Missions. The final format and deployment of promotion activities will be determined by MSP and RFS/CN.	Three months, starting on January 3, 2023

Deliverables

- 1. Desk Research Summary:** Succinct summary of tools, methodologies, protocol, and data sources MSP identified and synthesized in developing the LSFF methodology. Approximately 10–15 pages, not including annexes. The document will be branded as Feed the Future.
- 2. Draft Food Processor LSFF Tool:** Succinct, user-friendly tool describing the methodology for Missions to identify opportunities and strategically engage private sector firms that can effectively and sustainably develop, scale, and/or maintain a business model to process and deliver fortified staples and condiments that are affordable and accessible, and in accordance with national standards. This deliverable will be submitted in draft form in Phase II and in final form in Phase IV. The document will be branded as Feed the Future.
- 3. Food Processor LSFF Assessments for 2-3 Missions:** Final report of each assessment’s findings (two to three reports in total) will serve as the deliverable for the assessment pilots. Report length will depend on final methodology specifics and the participating Missions’ needs and context. The documents will be branded as Feed the Future.
- 4. Summary of Learning from Tool Trial:** Summary of the assessment process and outcome, following the pilot of the draft methodology with two to three Missions, Mission participant feedback, MSP and RFS/CN observations in an After-Action Report, and a summary of proposed revisions to the methodology.
- 5. Final Food Processor LSFF Tool:** Refined, finalized methodology, incorporating insights gained from the pilots in Phase III.
- 6. Promotion Activities:** Host a series of two to three Mission-focused outreach activities (e.g., webinars and conference workshops) to explain and disseminate the final food processor LSFF methodology. This deliverable will include output from all phases of work.

Market Systems and Partnerships Support

Under this buy-in scope of work, MSP will assign an Engagement Manager. The MSP Engagement Manager will be the key point of contact for USAID's RFS/CN and will be responsible for overseeing all implementation activities with support from the broader MSP team. Additional technical team members may include consultants to provide technical assistance, if needed. The consultants will be sourced either directly by DAI or from potential subcontractors. Ahead of the October start date, MSP will participate in bimonthly or quarterly meetings (frequency and timing still to be determined) with other partners to share workstream status and to ensure alignment.

USAID Support

The USAID/RFS CN has assigned Senior Nutrition Advisor, Rebecca Egan, as Activity Manager for this activity and will directly coordinate with the MSP Engagement Manager on activity implementation, providing input to and feedback on draft deliverables, providing ongoing feedback in regular meetings, and facilitating introductions and information sharing as needed.¹

Period of Performance

October 2021–April 2023

Place of Performance

Remote and in-country work.

¹ Note: Some household-level and policy data can be gathered and analyzed in conjunction with USAID Advancing Nutrition. RFS/CN will coordinate with both parties should the opportunity arise.

6.

SCOPE OF WORK / INNOVATION LAB FOR FOOD SECURITY POLICY

Innovation Lab for Food Security Policy, Research, Capacity, and Influence Large-Scale Food Fortification Policy Enabling Environment Assessment Scope of Work

Objective:

Development of a method to assess the policy enabling environment for large-scale food fortification (LSFF). The method should be logical, simple, efficient, and low-cost to implement. The method will highlight the strengths and limitations of LSFF to increase its sustainability and local ownership, identify its constraints, and make recommendations. LSFF is “safe and effective to address inadequate micronutrient intake when appropriately designed and implemented”.

Activities:

This work will take place in four phases.

1. **Review of the literature, data, past, current, and priority policies**

Conduct a literature review (including secondary data) to identify: 1) previous methods used to assess the policy enabling environment for large-scale food fortification (LSFF) and other relevant agricultural/food policies; 2) standard definitions of policy enabling environment and large-scale (industrial) food fortification; and 3) past and current policies as well as policy priorities related to large-scale food fortification in Kenya.

This step will help us answer the following questions, which will inform the development of the assessment method: (1) What is a policy-enabling environment? (2) How is large-scale food fortification defined? (3) What methods exist to assess the policy enabling environment broadly for agri-food systems and specifically for large-scale food fortification?

Furthermore, the review of the gray literature and secondary data in Kenya will allow us to identify the status of LSFF in the country in terms of coverage, governance, production, regulatory, planning, and monitoring policies, demand creation, and monitoring and evaluation.

2. **Development of an assessment method**

We know very little about the key actors, factors, and policies that influence the development and expansion of sustainable and locally owned LSFF. LSFF requires a high level of coordination among all parties: public, private, and civil society sectors. Otherwise, the intervention is not going to work well. Building on previous methods, we will develop a method to assess the policy-enabling environment for LSFF. The developed method will be aligned with USAID’s LSFF Result Framework.

3. **Testing of the developed method—Kenya as a case study.**

We will pilot test our proposed method to ensure that it is logical, simple, efficient, and low costs to implement. The proposed method will be revised based on observations and results obtained through our case study. Through this case study application, we will:

- Identify the LSFF programs being implemented (and products being fortified) in the country and review and

document the program’s design, implementation, coverage, and outcomes;

- Characterize these LSFF programs;
- Review the policy, regulatory, planning, and monitoring structures
- Identify key challenges in program implementation (i.e., level of industry compliance with the fortification standards);
- Identify allies and opponents;
- Identify knowledge gaps and data gaps; and
- Make recommendations to increase the sustainability and local ownership of LSFF.

4. **Gathering feedback**

During the fourth and last phase, we will share our method and gather feedback within Kenya (e.g., USAID, Kenya National Food Fortification Summit). The developed method should be tested in other countries first before promoting it more broadly.

Timeframe:

Activity	Oct-Dec 2021	Jan-Mar 2022	Apr-Jun 2022	July-Sept 2022
1. Review of the literature, data, past, current, and priority policies	•			
2. Development of an assessment method		•	•	
3. Testing of the method- Kenya		•	•	
4. Gathering feedback				•

Deliverable:

One final methodological report that provides a step-by-step guideline to assess the policy enabling environment for LSFF and its application to a case study (Kenya).

7.

TABLE 2. SIZE PARAMETERS OF LARGE-SCALE FORTIFICATION BASED ON PROCESSING RATE

Commodity	Metric tons/hour	
	Low-Income Country	High-Income Country
Sugar	20	150
Wheat flour	20	100
Rice	10	20
Salt	10	15
Oil	5	20

Commodity	Metric tons/day	
	Low-Income Country	High-Income Country
Sugar	500	4,000
Wheat flour	150	1,000
Rice	100	500
Salt	100	200
Oil	50	150

Commodity	Metric tons/year	
	Low-Income Country	High-Income Country
Sugar	75,000	600,000
Wheat flour	45,000	300,000
Rice	30,000	150,000
Salt	30,000	60,000
Oil	15,000	45,000



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