Guiding Principles for Large-Scale Food Fortification

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

2. While fortified staples and condiments can provide a safety net through the passive intake of essential micronutrients, 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. With trends towards greater consolidation of industrial processing of staples and condiments and increased urbanization, as well as penetration of centrally processed foods in rural markets, large-scale food fortification (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 based on the average nutrient content of the fortified foods at household level and their usual intake by the targeted populations (disaggregated by geography, socio-economic wealth quintiles and, when possible, age strata).

5. While fortification programs need to be adjusted to account for evolving dietary patterns within countries, regional harmonization and mutual recognition (“equivalence”) of standards and regulatory control procedures among neighboring countries should be promoted to be compatible with inter-country food trade.

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

7. Stakeholders, including government, 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 fairly and universally enforced across food industry.

9. Civil society has an essential role in food fortification, holding both government and food industry accountable to comply with food quality and safety standards, including fortification.

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.
USAID Large-Scale Food Fortification Results Framework

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.

Strategic Objective:

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

Strategic Criteria for Activity Selection:

The activities described below under the LSFF 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 timeframe?
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-IR1.1.1 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-IR1.1.2 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., ECSA, EAC, COMESA, SADC, AfCFTA, AGRA, ECOWAS, ASEAN, SARC, CARICOM, MERCOSUR, Pacific Alliance, and GAFTA).

Sub-IR1.1.3 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-IR1.1.4 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-IR1.1.5 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-IR1.1.6 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 sub-national budgets to strengthen inspection and enforcement of food quality and safety standards.
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.

Sub-IR1.2.1 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 towards decentralization and devolution from central to local government authorities, focused on operational practices and less on chemical testing.

Sub-IR1.2.2 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-IR1.2.3 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 socio-economic strata).

Sub-IR1.2.4 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 non-compliant with packaging and labeling standards.

Sub-IR1.2.5 Activity: Support public sector establishment of standardized technologies and procedures, in partnership with the private sector, academic institutions and other NGOs, for assessment and compliance of fortificants and fortified foods with standards and regulations.

Sub-IR1.2.6 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-IR1.2.7 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 socio-economic 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 quality assurance and control, 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 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 quality control, 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 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 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., 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 quality control and compliance with fortification standards within food industry, e.g., premix reconciliation calculation audits and the Micronutrient Fortification Index (MFI) piloted by 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, utilizing 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, 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 to hold food industry accountable to comply with fortification standards and hold government accountable to monitor and enforce those standards strengthened.

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/W and Mission Democracy & Governance (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 penetration, contribution, and impact of LSFF 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, BMGF, Rockefeller, FCDO, World Bank, UNICEF and WFP) to coordinate support for LSFF, including declarations of commitment at the UN Food Systems and Nutrition for Growth Summits, and the International Congress of Nutrition.

Sub-IR4.1.2 Activity: Work with and through Scaling Up Nutrition (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 socio-economic 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 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/quality control (e.g., HACCP, PRP, ISO, and 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 USG 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 USDA McGovern-Dole School Feeding Program and other food assistance programs (e.g., 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 of 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 quality control 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, 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 BHA/FFP and 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 JHU/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 socio-economic 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.