REPUBLIC OF UGANDA

Mapping the Food Fortification Regulatory Monitoring Systems and Processes for Quality and Safety of Fortified Foods in Uganda

Photo Credit: USAID Advancing Nutrition Uganda. A Laboratory Analyst at Bidco (Uganda) Limited conducting a quantification test for A content in oil sample picked from a production shift.

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Acronyms

ASYCUDA	Automated System for Customs Data
CDC	Center for Disease Control and Prevention
CIMS	Certification Information Management System
EAC	East African Community
ECSA	East, Central and Southern Africa
FACT	Fortification Assessment Coverage Tool
FFI	Food Fortification Initiative
GAIN	Global Alliance for Improved Nutrition
GMP	Good manufacturing Practice
GOU	Government of Uganda
HACCP	Hazard Analysis Critical Control Point
HRMIS	Human Resource Management Information System
ISO	International Organization for Standardization
LIMS	Laboratory Information Management System
MDA	ministries, departments, and agencies
MEAL	monitoring, evaluation, adaptation, and learning
MoES	Ministry of Education and Sports
MOFPED	Ministry of Finance, Planning, and Economic Development
MOH	Ministry of Health
MT	Metric Tonne
MTIC	Ministry of Trade Industries and Cooperatives
NAPR	National Annual Performance Report
NDA	National Drug Authority
NDAMIS	National Drug Authority Management Information System
NWGFF	National Working Group on Food Fortification
OPM	Office of the Prime Minister
PSFU	Private Sector Foundation Uganda
QA	Quality Assurance
QC	Quality Control
SANAS	South African National Accreditation System
SPS	Sanitary and Phytosanitary Measures
SUN	Scaling Up Nutrition
SWOT	strengths, weaknesses, opportunities, and threats
UBOS	Uganda Bureau of Statistics
UESW	Uganda Electronic Single Window

UIRI	Uganda Industrial Research Institute
UNBS	Uganda National Bureau of Standards
UNPS	Uganda National Panel Survey
URA	Uganda Revenue Authority
USAID	U.S. Agency for International Development
WHO	World Health Organization
WTO	World Trade Organization

Definition of Terms

Audit (technical audit): The review of written quality control (QC) and quality assurance (QA) procedures, records, and observation of the fortification processes in the food industry.

Certificate of Conformity: This is a document certifying that batches of fortified food and premix comply with the country's fortification standard and relevant specifications.

Commercial Monitoring: This is the process of collecting and analysing product samples and reviewing product packaging at retail stores and other food distribution sites to confirm that the product follows specifications, such as fortificant content and labelling requirements, as outlined in the fortification standards.

Compliance: This refers to the fulfilment of technical specifications as outlined in fortification standards. Food processors typically monitor their compliance through QC and QA procedures. In addition, food processors are also monitored for compliance by the food control authorities (Uganda National Bureau of Standards, National Drug Authority, and district local government authorities).

External Monitoring: These are activities carried out by government inspectors to make sure that food processors follow specific processes to ensure that fortified foods are produced in a manner (a) that achieves the specifications of the fortification standard and (b) conforms to the other specifications mentioned in the food standard. The two components of external monitoring include technical audits and factory inspections.

Food Fortification: The practice of deliberately increasing the content of an essential micronutrient (i.e., vitamins and minerals in food, including trace elements) to improve the nutritional quality of the food supply and provide a public health benefit with minimal health risks.

Food Vehicle: The foodstuff that is selected to carry added micronutrients—maize flour, wheat flour, salt, and edible oils and fats.

Fortificants/Premixes: The compound that contains the specified micronutrient intended to be added to a food vehicle.

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

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 processors 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 all the other requirements mentioned in the food standard. It includes both QC and QA procedures.

Quality Assurance: The systematic activities that are necessary to ensure products or services meet defined quality standards. The performance of QA can be expressed numerically as the results of QC metric exercises.

Quality Control: The techniques and assessments that are used to document compliance of food products with established technical standards using objective and measurable indicators.

Quality Management System: QC and QA 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.

Standard: The technical specification(s) for foods may include a section about fortification, which may be voluntary or compulsory by law.

Universal Salt Iodization: This 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.

Executive Summary

Micronutrient deficiencies, also known as hidden hunger, remain a public health concern globally, particularly deficiencies of iron, zinc, and vitamins A, D, B9 (folate), and B12 (cobalamin).

Micronutrient deficiencies persist in Uganda, particularly for children under five years and women of reproductive age. According to the Uganda National Panel Survey (UBOS, 2020):

- One-quarter of children 6–59 months (23.9 percent) are stunted.
- Almost one-third (31.7 percent) are anaemic, of which 6.9 percent have iron deficiency anaemia and 13.7 percent have iron deficiency.
- Vitamin A deficiency among children 6–59 months is 5.4 percent using the modified relative dose response; vitamin B12 deficiency (serum B12 <203 pg/mL) and depletion (serum B12 <300 pg/mL) are 4.7 and 16.3 percent, respectively; and folate deficiency is 1.5 percent.
- Among nonpregnant women, prevalence of anaemia is 16.7 percent, of iron deficiency anaemia is 7 percent, and of iron deficiency is 16.7 percent.

Over the past two decades, the Government of Uganda has taken a pragmatic approach to reducing micronutrient deficiencies by adopting several interventions, including industrial food fortification. The industrial food fortification program focuses on four food vehicles: salt, wheat flour, maize flour, and edible oil and fats. The program has advanced from voluntary to mandatory regulations for food products that fulfil specific criteria, leading to an increase in coverage of fortified foods for human consumption.

The food fortification program is coordinated by the Ministry of Health (MOH) through the multi-sectoral National Working Group on Food Fortification (NWGFF). Despite the program's successes, enforcement and compliance challenges remain for regulators and food processors, which hinders the achievement of desired public health outcomes.

In support of the Ministry of Trade Industries and Cooperatives (MTIC) and MOH, USAID Advancing Nutrition commissioned a review that sought to document existing regulatory monitoring systems, define regulatory information flow, and identify best practices, barriers, and opportunities for data utilisation to streamline implementation and track compliance with food fortification standards and regulations.

We employed a mixed method approach, conducting a desk review of the literature followed by key informant interviews with select members of the multi-sectoral NWGFF. The interview tool was designed to define monitoring and enforcement systems and information exchange across the subcomponents of regulatory monitoring, as recommended by the World Health Organization. We reviewed national and global reports and interviewed 29 respondents, including policymakers, regulators, and program managers from ministries, departments, and agencies (MDA), industries producing fortified foods, fortificants/premixes suppliers, research and laboratory actors, civil society, and academia.

The **findings** from the exercise provide highlights on the stakeholders involved in regulatory monitoring; the legal and policy framework for regulatory monitoring; the external, internal, and commercial monitoring; and a strengths, weaknesses, opportunities, and threats (SWOT) analysis of the existing monitoring systems.

The findings fostered understanding of the multiple stakeholders that operate and collaborate within the food fortification monitoring system: (1) Policy actors, including MoH; MTIC; Ministry of Finance, Planning, and Economic Development; Ministry of Education and Sports; and the Office of the Prime Minister. (2) Regulatory agencies, including Uganda National Bureau of Standards (UNBS), National Drug Authority (NDA), and Uganda Revenue Authority (URA). (3) Food industries that fortify the food vehicles. (4) Supporting implementers, like Uganda Bureau of Statistics, the Private Sector Foundation Uganda, and Uganda Industrial Research Institute. The **policy and legal framework** specific to food fortification provides the basis for regulatory monitoring, ensuring product quality,

safety, and the achievement of public health nutrition goals. The food fortification regulations and standards for maize flour, wheat flour, salt, and edible oils and fats, are anchored under the food and drug law and provide guidance to regulatory agencies on enforcement and to industries for compliance. Uganda is a signatory to global multilateral trade agreements under the World Trade Organization and to several regional economic communities, including the East African Community, Common Market for Eastern and Southern Africa, the Tripartite Agreement, the African Continental Free Trade Agreement with Sanitary and Phytosanitary Measures monitoring obligations, fragmented across several MDA.

External monitoring, including imports, and commercial/market monitoring are the procedures implemented by government entities responsible for food control to ensure compliance with fortification standards and regulations.

External monitoring was delegated to UNBS, NDA however some roles overlap between the two agencies and MOH. The MOH delegated quality assurance (QA) and regulatory monitoring of fortified foods to UNBS. In the execution of this mandate, UNBS developed, regularly reviews, and enforces the food fortification standards through external regulatory monitoring activities, like audits to verify that industry QA activities are performed according to plan and inspections to confirm that the fortified product complies with the food fortification standard. The UNBS conducts external audits and has integrated fortification under the certification scheme. The role of the NDA, as indicated in the regulatory framework, was intended to include inspection of fortificants/premixes and licensing of premix manufacturers, importation, and suppliers; however, this has not been institutionalised due to unclear supportive NDA legal frameworks because fortificants/premixes is classified as a food ingredient, not a drug, which is the mandate of NDA.

Import monitoring is part of Uganda's fortification program, which is enforced under the Inspection and Clearance of Imports Regulation 2021. It ensures that all imported commodities compete under the same conditions as locally produced fortified products. Imported fortificants/premixes are monitored under the same scheme for compliance with current national standards harmonised at the regional level. Import monitoring and inspections are conducted jointly by border inspectors from UNBS and URA. The UNBS border inspectors clear the imports based on quality requirements and forward them to the customs department, where a team from URA checks for conformity to the custom requirements. The controls enforced at custom inspections are meant to verify that imported consignments are accompanied by a Certificate of Analysis for each batch as part of the clearing process. Additionally, there are existing secondary controls that include sampling of imported fortified food products for corroborating testing.

Internal monitoring is enforced and monitored by the UNBS to ensure consistent production of quality and safe fortified foods that meet national standard requirements. The established internal monitoring controls observed and reported from the industries included QA (i.e., activities that are undertaken during production to ensure that the products meet standards) and quality control (QC) procedures and tests carried out by producers to document and prove that the process and product meet standards. Fortifying industries have in-house quality management systems and procedures for raw material control process control and final product control.

Market monitoring or market surveillance of fortified foods in Uganda is part of the strategy to assess industries' compliance with national standards. The surveillance occurs at retail points of sale and is designed to enhance consumer protection and promote fair trade. Although market surveillance takes place, it has not been done regularly—largely because of limited resources. In circumstances where market surveillance happens, the scope is not focused on fortification to draw representative samples that would infer national compliance. Market surveillance of fortified foods has been partner supported.

An analysis of existing regulatory monitoring systems and information flow pathways presented as SWOT and discussed across policy and governance, external monitoring, and internal monitoring is elaborated in the main document. Specifically, the **weaknesses or challenges** in regulatory monitoring systems and information pathways are largely attributed along policy and governance, external monitoring, and internal monitoring and include the following: (1) The multi-agency approach employed for regulatory monitoring of the food fortification program in Uganda has led to

inefficiency in enforcement of the regulation, which has resulted in fragmented and incoherent implementation. (2) Gaps in governance and supervision, exacerbated by weak penalties for non-compliance, have reinforced compliance challenges that affected performance of the regulatory system. (3) Whereas regulators like UNBS and URA have institutionalised and integrated routine monitoring and enforcement, NDA noted that the 2005 Food and Drugs (Food Fortification) Regulation mandates on fortificants/premixes do not align with the NDA Act, which focuses on drugs and not fortificants/premixes classified as a food, and this poses a barrier to enforcement, notably by food industries. (4) The multi-agency approach has also limited coherent information flow, which affects utilisation of electronic data due to a lack of a harmonised mechanism for anonymizing, reporting, and sharing data and use. For example, fortification-specific regulatory data exchange between regulators, coordinators, and policy actors was seldom reported across the program, and compliance trends were difficult to track outside of the legal purview of the UNBS. (5) Significant funding constraints and competing regulatory priorities curtailed the adequate execution of regulatory mandates across regulators. (6) Producers also reported financial pressures in compliance with conformity/regulatory requirements like testing and high costs of fortification inputs like premix (attracting 18 percent value-added tax).

The **recommendations** highlight the external, internal, import, and commercial monitoring or market surveillance actions for strengthening regulatory monitoring, including the legal and policy framework.

Legal and policy framework: Facilitating regulatory monitoring through policy action requires the appropriation of resources for adequate and effective regulatory monitoring, coupled with realistic regulatory monitoring frameworks that leverage best practice and prioritise sharing of evidence to inform the national program. While policy change takes a long time, the review has highlighted the need for utilisation of documented evidence to inform reviews and amendments to the existing food fortification regulation. These amendments can address ambiguities, harmonise institutional functions, and enable policy coherence for effective enforcement by regulatory bodies.

External, import, and commercial monitoring: There is a need for the development of a system-based monitoring program with clear oversight that avoids duplication of roles and optimises regulatory efficiencies in monitoring and enforcement. The focus should be placed on closing identified gaps in monitoring the quality of fortificants/premixes. Integration and system linkages are recommended to facilitate data collection, aggregation, and sharing for timely decision-making while leveraging available systems like the Uganda Electronic Single Window and FortifyMIS. Additionally, joint external monitoring by regulators is proposed to streamline external monitoring and enforcement mechanisms. Social audits can be explored to complement government regulatory monitoring systems and generate data to inform regulatory actions. Risk-based approaches can be explored to minimise costs for commercial monitoring.

Internal monitoring: Prudent execution of enforceable penalties is envisaged to motivate compliance. Relatedly, risk-based testing is recommended, coupled with training/mentorship to lower inherent costs, sustain investments, and promote best practices for both regulators and industry.

In **conclusion**, Uganda has made considerable progress in building a functional regulatory monitoring system across the food fortification value chain with key investments in systems and infrastructure to verify, promote, and improve compliance with national food fortification requirements. Despite the progress, Uganda's regulatory monitoring systems are still experiencing several challenges emanating from inherent gaps in the existing national regulations on food fortification. Key, among other issues, is the weakness in the organisation of the regulatory monitoring system to consistently and adequately verify the quality of fortificants along the value chain. To ensure sustainability and cost-effectiveness, this report recommends using simple and low-cost regulatory monitoring actions across MDA processes and systems, leveraging existing national systems and platforms to verify the quality of fortificants, building synergies among regulatory agencies to optimise regulatory capacities, and improving efficiency in enforcement and compliance.

1.0 Introduction

1.1 Micronutrient Status

Micronutrient malnutrition is one of the biggest global development challenges facing the world today, affecting both low middle-income countries and industrialised countries (USAID, 2022), and continues to be a public health concern in Uganda.

According to the Uganda National Panel Survey (UNPS; UBOS, 2020):

- One-quarter of children 6–59 months (23.9 percent) are stunted.
- Almost one-third (31.7 percent) are anaemic, of which 6.9 percent have iron deficiency anaemia and 13.7 percent have iron deficiency.
- Vitamin A deficiency among children 6–59 months is 5.4 percent using the modified relative dose response; vitamin B12 deficiency (serum B12 <203 pg/mL) and depletion (serum B12 <300 pg/mL) are 4.7 and 16.3 percent, respectively; and folate deficiency is 1.5 percent.
- Among nonpregnant women, prevalence of anaemia is 16.7 percent, of iron deficiency anaemia is 7 percent, and of iron deficiency is 16.7 percent.

Consequences of micronutrient deficiencies of iron, vitamin A, zinc, iodine, and folate include physical and cognitive effects on children, including impaired vision and cognitive development, growth retardation, and birth defects like spina bifida and hydrocephalus, as well as morbidity and mortality among nonpregnant and pregnant women (Allen et al., 2006). These undesired consequences can further lead to far-reaching implications and affect the human potential of individuals through reduced educational gains, work productivity, morbidity, and mortality (Stevens et al, 2022).

To address the micronutrient deficiencies in Uganda, the Government of Uganda (GOU) adopted high-impact interventions, including dietary diversification, industrial food fortification, micronutrient supplementation, and biofortification, among other food and nutrition security programs.

1.2 Uganda's Food Fortification Program

Food fortification programming in Uganda is supported by the Food and Drug Act, 1959; the Food and Drugs (Food Fortification) Regulations, 2005; the Food and Drugs (Food Fortification) (Amendment) Regulations, 2011, for wheat flour, maize flour, edible oils, and fats; and the Foods and Drugs (Control of Quality) (Iodated Salt) Regulations, 1997, for salt (MOH, 1997). Additional existing operational tools and guidelines for the ministries, departments, and agencies (MDA) include the national food fortification strategy and national standards. Uganda's food fortification program is implemented as a public-private partnership, with the coordination of the program being managed by the National Working Group on Food Fortification (NWGFF) under the leadership of the Ministry of Health (MOH). The NWGFF comprises representatives of the MDA, the private sector, nongovernmental agencies, civil society, and international partners. Regulatory monitoring is one of key functions of the food fortification program for effective enforcement and compliance with regulations and standards.

1.3 Regulatory Monitoring

In the context of food fortification, the term "monitoring" refers to the continuous collection, review, and use of information on program implementation activities (Allen et al., 2006). According to World Health Organization (WHO) guidelines, the scope of regulatory monitoring is prescribed to encompass internal monitoring, external monitoring, import monitoring, and commercial monitoring. The ideal monitoring system requires a set of established procedures, methodologies,

indicators, and reporting requirements to ensure continuous assessment coupled with an efficient feedback mechanism. This should be implemented consistently to ensure compliance with adequate fortification (i.e., fortified foods meet the nutrient, quality, and safety standards). Additionally, clear impact pathways are important to optimise operations and enable performance tracking along the regulatory continuum.

Fortification efforts started in Uganda with salt iodization in 1994, and in 1997 the country mandated that all imported salt be iodized. The Uganda fortification program also included voluntary fortification efforts by the private sector. The NWGFF facilitated the preparation and approval of fortification standards for oil, sugar, wheat flour, and maize flour in 2005. Since the introduction of the mandatory regulation for oils and fats and wheat and maize flours in 2011, considerable progress has been made regarding compliance with fortified foods. The *Fortification Assessment Coverage Tool (FACT) Survey in Uganda, 2015*, showed that vitamin A in edible oil and fats and iodized salt are on track. However, this has not been the case for cereal flours. A snapshot analysis showing trends in compliance with fortified foods is presented in Figure 1 (GAIN, 2017).

Figure 1. Fortification Quality/Adequacy of Percentage of Household Samples FACT 2015 and UNPS 2018[1]

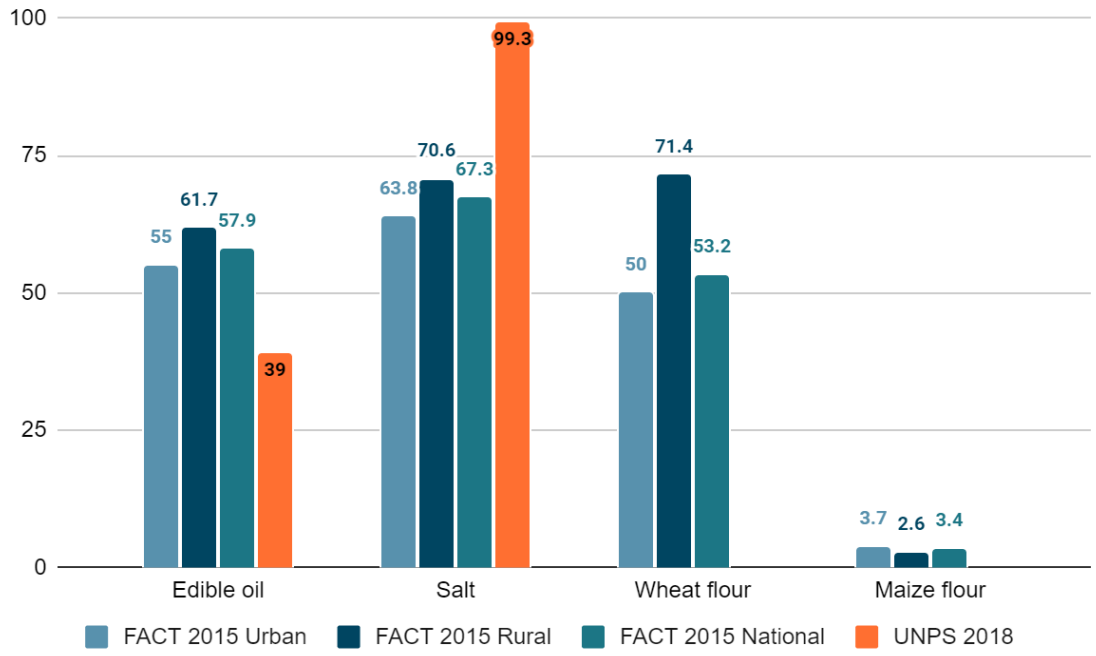


Figure 1 shows the adequacy or quality of fortified foods at the household level. The levels of compliance vary across food vehicles in both rural and urban settings. Except for maize flour, coverage and compliance for food grade salt, edible oils and fats, and wheat show good progress.

Furthermore, the UNPS national data on adequacy of fortification in salt samples collected at households showed 99.3 percent of the samples complied with iodine content of >15 mg/kg at households, which falls short of the minimum requirement of 20 mg/kg as per the national standards, which are applicable mainly at the production or factory level. UBOS 2020). However, this is considered adequate at the household level because some decay of the iodine may occur according

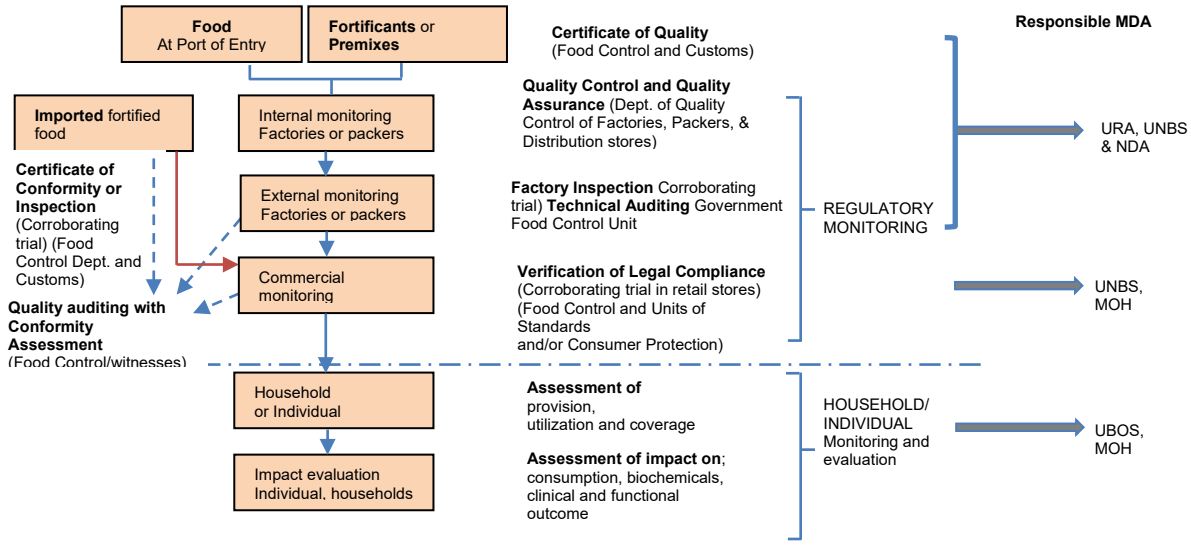
[1] For edible oil, although the retinol content found in samples at the household level was lower than the minimum content of **20 mg/kg** set for production/retail stores, these foods are the principal source of vitamin A for the population. At the household level, it is expected to find samples with half of the original content of vitamin A that they had at production.

to WHO. The mean iodine content was at 36.1 mg/kg. While 82.6 percent of the edible oil samples showed presence of vitamin A at the household level with a mean retinol content of 18.5 mg/kg, which means that most samples of oil were found as fortified, with amounts enough to satisfy the daily requirements of this vitamin A among the population. The UNPS also found that 45.9 percent of cooking fat was fortified with a mean retinol content of 13.2 mg/kg, and a median of <6.0 mg/kg. The limit of detection for evaluating retinol in edible oils and fats in this study was 6mg/kg. This means that more than half (54.1 percent) of the edible fat samples were either not fortified to begin with or no longer contained detectable concentrations of vitamin A by the time they reached the household. (UBOS 2020).

Despite the promising results on coverage and compliance of fortified foods, Uganda, like most countries, continues to grapple with challenges that hinder the actualization of regulatory monitoring protocols for fortified foods. The challenges are multidimensional and vary from the structure of regulatory monitoring frameworks to optimisation of activities, inputs, and systems central to sustain enforcement and impact. In a bid to strengthen the country's food fortification program, an exploration of regulatory processes and systems underpinning monitoring and enforcement of food fortification standards and regulations is imperative, and this provided the basis of this assessment.

Figure 2 shows the WHO monitoring framework for food fortification programs and further depicts how the Uganda regulatory monitoring framework is aligned with reference to the recommended WHO framework.

Figure 2. WHO Monitoring and Evaluation Conceptual Framework for Food Fortification Programs



***Adapted from**:* Allen et al. (2006)

From this background, USAID Advancing Nutrition, in support of the MOH and Ministry of Trade Industries and Cooperatives (MTIC), commissioned an assessment to map out the existing regulatory systems and processes to monitor fortification quality and food safety with the following objectives:

1. Document existing regulatory processes and systems to monitor food fortification quality and safety at different levels of program implementation across the food value chain.
2. Define and document information flow specific to regulatory monitoring for the food fortification program, as well as identify gaps and areas of redundant data collection.

3. Identify and document innovative or streamlined approaches and opportunities for collaboration, information sharing, and data utilisation to inform decision-making and track compliance with set standards and regulations so that timely corrective action can be taken.

The findings from this assessment are intended to inform strategic actions to strengthen regulatory monitoring and enforcement aimed at improving compliance with food fortification standards and regulations in Uganda.

It was beyond the scope of this review to undertake a detailed analysis of impact monitoring at the household level as the focus was on regulatory monitoring of fortified foods. However, during data collection, some key informants highlighted the existing data sources, including the following: the Uganda National Annual Panel Survey is conducted annually and includes a nutrition module that captures biomarker indicators and performance of fortified foods at the household level, and the UNPS is conducted every one to three years by the Uganda Bureau of Statistics (UBOS).

2.0 Approach Used in the Mapping Exercise

We employed a mixed method approach, conducting a desk review of the literature followed by key informant interviews with select members of the multi-sectoral NWGFF. The mapping exercise was carried out in 2022. The interview tool was designed to define monitoring and enforcement systems and information exchange across the subcomponents of regulatory monitoring, as recommended by the WHO (Allen et al., 2006). We reviewed nine reports and interviewed 29 respondents, including policymakers, regulators, and program managers from MDA, industries producing fortified foods, fortificants/premixes suppliers, research and laboratory actors, civil society, and academia.

Reports: The exercise gathered and reviewed relevant documents and technical reports to inform the framing of the report. These included national reports, regulations, and global reports referenced in the report. Specifically, the review process examined the actual flow of information from regulatory monitoring systems (legal framework and internal, external, and commercial monitoring) based on the WHO conceptual framework for regulatory monitoring shown in Figure 2.

Key respondents: In addition, we also conducted interviews with key stakeholders to obtain feedback on the enforcement progress and performance of the regulatory monitoring systems and processes for tracking compliance on the food fortification standards and regulations. The 29 interviews targeted stakeholders with specific roles and mandates in the food fortification regulatory system, as shown in **Annex 2**, and implementation, including regulatory bodies, NWGFF members, policymakers, program managers, academia and research institutions, private sector (including food industries), and civil society.

The analysis focused on identifying existing regulatory monitoring systems while identifying information pathways and gaps in a bid to inform recommended actions for strengthened enforcement and compliance of the food fortification regulations and standards.

3.0 Findings from the Mapping Exercise

The findings are presented by objective and discussed along the following topics:

- Stakeholders mapping in regulatory monitoring
- Legal and policy framework for regulatory monitoring
- External, internal, and commercial monitoring
- A strengths, weaknesses, opportunities, and threats (SWOT) analysis of the existing monitoring systems and information pathways

3.1 Stakeholders Mapping in Regulatory Monitoring

To foster understanding of the multiple stakeholders that operate and collaborate within the food fortification monitoring system, a stakeholder mapping of the various actors involved in the food fortification is illustrated in Figure 3.

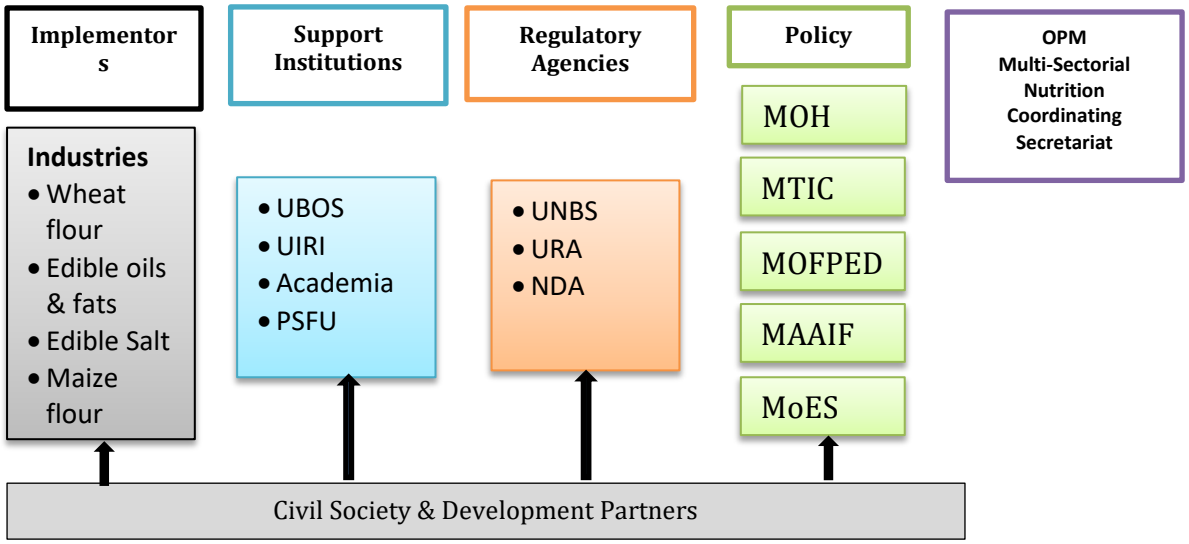
Policy Actors: The policy level has relevant line ministries, including the MOH, which is the NWGFF Secretariat and the custodian of the food fortification regulations; the MTIC, which coordinates the Scaling Up Nutrition (SUN) Business Network and supports industries and training of food industries on food fortification through a pool of trainers; the Ministry of Finance, Planning, and Economic Development (MOFPED), which provides tax incentives on fortificants/premixes and technology through Uganda Revenue Authority (URA); the Ministry of Education and Sports (MoES), which supports procurement and consumption of fortified foods in schools; and the Office of the Prime Minister (OPM), which provides strategic multi-sectoral nutrition coordination across the relevant sectors.

Regulatory Agencies: Uganda has a multi-agency regulatory system with shared mandates for control of fortified foods. The Uganda National Bureau of Standards (UNBS) is the custodian of national standards and provides conformity assessment services. The National Drug Authority (NDA) provides regulation of drugs and health care products. Although the regulation delegates NDA's role in fortificants/premixes regulation, it has not been achieved due to unclear supportive NDA laws on premix as a food ingredient. The URA is mandated to assess, collect, and account for central government tax revenues and advise the government on matters of policy relating to revenue. Relatedly, the country is in the process of realigning the legal and policy frameworks to strengthen food quality and safety through the Ministry of Agriculture, Animal Industry and Fisheries, which might call for alignment and streamlining institutional mandates and roles in regulatory monitoring of fortified foods and fortificants/premixes.

Implementers: The food industries are the producers and are governed by the regulations and standards to ensure compliance. These include food processors of wheat flour, maize flour, salt, and edible oils and fats. These are supported by other stakeholders that supply or produce inputs, including fortificants/premixes importers/suppliers, technology suppliers, and raw materials suppliers to enable fortification, among others.

Supportive Institutions: In addition to the regulatory bodies, supportive institutions interface with the regulatory system for fortified foods. UBOS supports surveys on household monitoring on the impact of health and nutrition interventions, including food fortification. The Private Sector Foundation Uganda (PSFU) advocates for a conducive and sustainable business environment for enterprise growth. The Uganda Industrial Research Institute (UIRI) champions innovations and translates applied research for the incubation of industry and academic institutions that conduct ongoing research to inform national development systems.

Figure 3. Key Stakeholders in Food Fortification



With the stakeholders mentioned in Figure 3, there is opportunity to collect data/information required in the monitoring and evaluation framework, including regulatory monitoring. There is a need to strengthen the data collection, synthesis, interpretation, and linkages across institutional data systems for effective monitoring, utilisation, and tracking of the food fortification program.

3.2 Legal and Policy Framework for Regulatory Monitoring

The legal framework specific to food fortification provides the basis for regulatory monitoring, ensuring product quality, safety, and the achievement of public health nutrition goals. (Luthringer et al., 2015).

The 1995 Constitution of the Republic of Uganda expresses the government's commitment to food security and nutrition and forms the supreme law for the enforcement of monitoring concerning the national fortification programs. Uganda is a signatory to global multilateral trade agreements under the World Trade Organization (WTO), which includes the Agreement on Technical Barriers to Trade and the Agreement on the Application of Sanitary and Phytosanitary (SPS) Measures. Uganda is also a signatory to several regional economic communities, including the East African Community (EAC), Common Market for Eastern and Southern Africa, the Tripartite Agreement, the African Continental Free Trade Agreement with SPS monitoring obligations, fragmented across several MDA. The food fortification regulations and standards for maize flour, wheat flour, salt, and edible oils and fats, are anchored under the food and drug law.

The Food and Drugs (Control of Quality) (Iodized Salt) Regulations, 1997: Issued at the historical onset of the national food fortification program, these enabled the implementation of the Universal Salt Iodisation strategy and are still enforceable to date to ensure that only iodized salt is recommended for human and animal consumption in the country (Onen, G., 2010).

The Food and Drugs (Food Fortification) (Amendment) Regulation, 2011: The Food and Drugs (Food Fortification) Regulations in 2005 and the amendments in 2011 provide the legal framework for mandatory fortification and monitoring of the food fortification program. (MOH, 2005, MOH, 2011). The regulation applies to industrial mills with a daily production capacity of 10 metric tons (MT) for edible cooking oil and fat and 20 MT for maize flour and all mills producing wheat flour. The regulation also requires the fortification of all imported maize flour, wheat flour, and edible fat and oil. The regulation has general guidance on fortification of foodstuffs, enforcement, and monitoring for effective compliance. Specifically, the regulation delegates monitoring and enforcement responsibilities to the NDA, tasked with ensuring quality control (QC) of premixes/fortificants, and the UNBS, assigned with quality assurance (QA) for the final fortified

products. Corresponding national standards have been developed by the UNBS to guide the implementation of the program by the food industries processing the four food vehicles.

National Industrial Food Fortification Strategy (2017–2022): From these regulations evolved the strategy that streamlined implementation roles and further revised a monitoring and evaluation framework for the food fortification program.

Coordination: The MOH provides coordination of the national fortification program as the custodian of the food fortification regulation in Uganda. This is coordinated through the established NWGFF, a multi-sectoral and multidisciplinary committee that oversees and guides the implementation of the food fortification program. As such, the NWGFF subcommittee on QA and QC is constituted of key regulatory agencies, including UNBS, NDA, URA, and other institutions tasked with conducting regular monitoring and support supervision to fortified food producers and implementers across the fortification value chain to promote and sustain compliance with national food fortification standards. This report provides the existing laws and policies used in the Ugandan food monitoring system.

3.3 External, Import, and Commercial Monitoring

External monitoring, including imports, and commercial/market monitoring are the procedures implemented by government entities responsible for food control to ensure compliance with fortification standards and regulations. Assessment of external regulatory monitoring systems was done based on regulatory monitoring components, subcomponents and indicators recommended by WHO and Centers for Disease Control and Prevention (CDC) to assess and track the progress of fortification monitoring. This section presents detailed findings related to the objectives identified from the key informant interviews and review of reports.

3.3.1 External Monitoring

This review established that Uganda employs a multi-agency system for regulatory control of fortified foods. The existing government mandates on external monitoring are shared between agencies of the MOH, MTIC, MOFPED, NDA, UNBS, and URA, respectively. The MOH delegated to UNBS the role of QA and regulatory monitoring of fortified foods. In the execution of this mandate, UNBS developed, regularly reviews, and enforces the food fortification standards.

The role of the NDA, as indicated in the regulatory framework, was intended to include inspection of fortificants/premixes and licensing of premix manufacturers, importation, and suppliers; however, this has not been institutionalised due to unclear supportive NDA legal frameworks because fortificants/premixes is classified as a food ingredient, not a drug, which is the mandate of NDA.

External regulatory monitoring activities include **audits** that verify that industry QA activities are performed according to plan and **inspections** that confirm that the fortified product complies with the food fortification standard. A key observation was that a single audit checklist that incorporates food quality, food safety, and food fortification was in use under the UNBS external audits scheme. It was established further that the UNBS certification scheme has fortification integrated, with the following reported as direct contributors to the effective administration of regulatory controls:

- Development and harmonisation of regionally applicable standards for fortified foods enforced by the mandatory fortification regulation (i.e., fortified food grade salt, fortified wheat flour, fortified milled maize products, and fortified edible fats and oils)
- Participation in regional harmonisation of inspection protocols for monitoring fortified and nutritious foods within East, Central and Southern Africa (ECSA) member states and adoption of standardised checklists for the ECSA region
- UNBS conducts biannual external monitoring control visits to fortifying industries, which is within the recommended regulatory monitoring practices by WHO/CDC. These include

inspections and technical audits where industry QA and QC protocols are examined, documentation is verified, and samples of fortified foods are drawn for compliance testing.

- Expansion of UNBS central testing facilities at the National Food Safety Reference Laboratories that are accredited by South African National Accreditation System (SANAS) under International Organization for Standardization (ISO) 17205 and Quality Management Systems
- Decentralisation of conformity assessment services like certification and testing services with established regional offices and laboratories in Gulu, Mbale, and Mbarara
- Coordination and participation in national proficiency testing scheme for strengthening laboratory capacity, competencies, and collaboration
- Expansion of the scope of testing service delivery through laboratory recognition schemes for external laboratories like UIRI analytical laboratories to shorten testing turnaround time

3.3.2 Import Monitoring

Uganda is implementing a fortification program that includes import monitoring. This is enforced under the Inspection and Clearance of Imports Regulation 2021. It ensures that all imported commodities compete under the same conditions as locally produced fortified products. Imported premixes/ fortificants are monitored under the same scheme for compliance with current national standards harmonised at the regional level. The existing government mandate on import monitoring was implemented by the URA in conjunction with the UNBS and the NDA.

Import monitoring and inspections are conducted jointly by border inspectors from UNBS and URA. The UNBS border inspectors clear the imports based on quality requirements and forward them to the customs department, where a team from URA checks for conformity to the custom requirements. The controls enforced at custom inspections are meant to verify that imported consignments are accompanied by a Certificate of Analysis for each batch as part of the clearing process. Additionally, there are existing secondary controls that include sampling of imported products for corroborating testing.

3.3.3 Internal Monitoring

Uganda has gazetted national standards that specify the desired characteristics of the fortified products that are currently enforced by the UNBS. As part of good manufacturing practices (GMPs) and prerequisite programs, internal monitoring is enforced and monitored by the UNBS to ensure consistent production of quality and safe fortified foods that meet national standard requirements. The established **internal monitoring** controls observed and reported from the industries included **QA** (i.e. activities that are undertaken during production to ensure that the products meet standards) and **QC** procedures and tests carried out by producers to document and prove that the process and end product meets standards.

It is significant to note that food producers have in place internal mechanisms of monitoring quality and food safety across the food value chain for fortified foods. All industry respondents interviewed indicated that they had in-house quality management systems and procedures for raw material control, process control, and final product control.

3.3.4 Commercial Monitoring or Market Surveillance

In the context of fortification, this is the process of collecting and analysing product samples and reviewing product packaging at retail stores and other food distribution sites to confirm that the product follows specifications, such as fortificant content and labelling requirements, as outlined in the fortification standards.

In Uganda, market monitoring of fortified foods is part of the strategy to assess industries' compliance with national standards. The surveillance occurs at retail points of sale and is designed to enhance consumer protection and promote fair trade. Although market surveillance takes place, it

has not been done regularly—largely because of limited resources. In circumstances where market surveillance happens, the scope is not focused on fortification to draw representative samples that would infer national compliance. Market surveillance of fortified foods has been partner supported.

Detailed descriptions of the existing elements of regulatory monitoring in Uganda, including external, import, commercial, and internal monitoring, are presented in **Annex 3**.

3.4 A SWOT Analysis of the Existing Monitoring Systems and Information Pathways

The information pathways for regulatory monitoring described by interviewees during the assessment indicated existing mechanisms of generating regulatory information and data. However, these information streams and mechanisms of collection and utilisation varied across regulators and other stakeholders in the fortification monitoring system. The analysis of existing regulatory monitoring systems and information flow pathways is presented as SWOT and discussed across three areas: policy and governance, external monitoring, and internal monitoring.

3.4.1 Overview of System Strengths

a) Policy and Governance

The regulatory monitoring system currently in place is logical and operates through multiple *agencies* across the four components of regulatory monitoring recommended by WHO. The roles and responsibilities of each of the applicable government departments in the development, enforcement, and monitoring of food fortification regulations and standards is elaborated in **Annex 1**.

At the governance level, there exists an established multi-sectoral nutrition coordination mechanism led by OPM, with communication pathways from the central to local government levels. These multi-sectoral coordination mechanisms provide essential cross-sectoral linkages with structures cascading down to the grassroots level. The SUN Business Network, for example, would be a great platform for the food industries to strengthen efforts in scaling up nutrition. The multi-sectoral platform provides an opportunity to accelerate implementation, linkages, and utilisation of the monitoring, evaluation, adaptation, and learning (MEAL) frameworks across the multidisciplinary data management systems.

Food fortification is integrated into relevant legal frameworks and key policy frameworks, including the Food and National Nutrition Policy of 2003, National Development Plan III, the Uganda Nutrition Action Plan II, the MEAL framework, and key MDA policies and strategies. This has facilitated mainstreaming of food fortification in government programs and provides for priority funding from government sector plans and budgets across the MDA.

The MOH, the coordinating entity, has existing information pathways and functions through the NWGFF, a multidisciplinary representation of stakeholders from public, private, civil society, academia, and development partners. The NWGFF formed the National Fortification Alliance as recommended by Allen et al., (2006). The working group structure included different subcommittees, including one on QA and QC that is charged with regulatory monitoring and enforcement to ensure quality and safety of fortified foods. This structure was mentioned by various stakeholders as a key platform for disseminating and sharing national regulatory monitoring information or data for use in policy and program decision-making. Although the stakeholders equally emphasised the need for strengthening the governance and coordination of the working group to sustain gains.

b) External Monitoring

The review showed that UNBS has institutionalised external monitoring and enforcement systems in key departments, including standards, certification, imports inspection, testing, and market surveillance. These institutional functions reported automated systems like the E-Portal for Imports Inspection, Certification Information Management System (CIMS), Laboratory Information

Management System (LIMS), and a Standards Web store under Standards departments to generate electronic data that tracks performance on regulatory monitoring and compliance.

Additionally, UNBS has secondary system controls that enable regulatory information audit and risk analysis (Internal Audit and Risk Management Department). Data within the legal scope (not violating confidentiality agreements) was disseminated on the official website and available to industry and other stakeholders for utilisation. From the key informant interviews, it was found that there exists an internal information sharing platform, the Human Resource Management Information System), within UNBS departments, although the need for system integration was also acknowledged as an emerging institutional priority.

In tandem with the WHO guidance on regulatory monitoring, the responsible government regulators, including UNBS, URA, NDA, and MOH, had existing structures that support external regulatory monitoring functions, including trained personnel, laboratories, and information management systems across the different government regulatory entities that can potentially facilitate efficient data generation, sharing, aggregation, and reporting.

Testing

UNBS has central testing facilities like the National Food Safety Reference Laboratories that are accredited by SANAS. Testing and other conformity assessment services have further been decentralised with established regional laboratories in Gulu, Mbale, and Mbarara, including other laboratories under the UNBS recognition scheme. Additionally, NDA and URA also have accredited testing laboratories.

Imports Inspection

Information flow was also reported between these UNBS departmental units and fortifying industries. The analysis further showed existing information pathways through the Automated System for Customs Data (ASYCUDA) World system between UNBS and URA customs, which were integrated via an interface for the imports inspection and customs clearance departments within URA and UNBS. In this communication system, the UNBS import inspectors and the URA customs officials shared regulatory and monitoring information about imported fortified foods and accompanying documentation like Certificate of Analysis provided by declarants (importers) through the interface of the UNBS E-Portal system and the URA's ASYCUDA World system. This system enables inspection teams present at all border points to conduct joint inspection of imported commodities, including fortified foods, which is followed by sampling and testing that is supported by the presence of rapid test kits for verification at border-stationed laboratories or further analysis at centrally located laboratories.

The UNBS, URA, and NDA all confirmed that they have dedicated staff stationed at border points for regulatory monitoring and enforcement activities. NDA, however, currently focuses only on clearance of drugs/medicines, not fortificants/premixes. This presents a gap in monitoring of fortificants/premixes at the import level.

A notable strength observed for monitoring imports was the Uganda Electronic Single Window (UESW). This is a single transactions portal that provides seamless sharing of regulatory data, enables joint regulatory monitoring and verification of traded commodities, and links various government MDA. TradeMark East Africa, with funding from the Danish International Development Agency, provided financial and technical assistance to the URA, as the lead implementing agency, and the MTIC, as the lead coordinating agency, to support the implementation of the UESW. The UESW has also ushered faster clearance and improved compliance through improved application of risk management protocols and joint profiling to improve enforcement, thus considerably reducing the number of declarations being selected for physical verification for UNBS, NDA, and other MDA.

The review indicated that the existing external monitoring has the recommended components to verify that internal monitoring, especially inspections including review of records, sampling framework and procedures, laboratory analysis and testing, and enforcement for non-compliance are institutionalised within the regulatory monitoring systems of UNBS.

The system allows for the development of compulsory food standards under existing acts like the UNBS Act, which can be passed by the National Standards Council mandated to gazette national standards. MTIC also reported housing a yet-to-be-rolled-out web-based fortification management information system, FortifyMIS, that can support compliance monitoring across key institutions, including fortifying industries.

Commercial Monitoring or Market Surveillance

Commercial monitoring or market surveillance of fortified foods forms part of the general products assessed for compliance with national standards at retail points of sale. At the moment, the UNBS undertakes surveillance within the context of general monitoring and, as such, this may not always be biased to fortified foods. The MOH, in collaboration with other regulators, has also integrated food fortification surveillance activities at market and import border points of entry monitoring, and routine activities would provide current data for real-time decision-making and effective monitoring. This assessment established that commercial monitoring has not been effectively rolled out in Uganda due to inadequate resources for regulatory monitoring and enforcement agencies and competing priorities that may hinder routine execution.

Under its mandate, the NDA, according to the provisions of the food fortification regulation, is delegated to undertake premix producer certification, monitoring imports of fortificants and their supply. From the analysis, the existing structure that supports this mandate is a management information system, National Drug Authority Management Information System (NDAMIS). Additionally, NDA had existing departmental structures that support regulatory monitoring, specifically a team of trained regulatory officers under the inspectorate and enforcement services, product assessment and registration, and product safety and laboratory services directorates. This monitoring structure, however, applied only to monitoring drugs, with fortificants monitoring challenged by ambiguities in the legal framework from the food fortification regulations. This limited the NDA's legal capacity to regulate manufacturers and suppliers of fortificants and the quality of fortificants.

c) Internal Monitoring

Industry respondents from this assessment had in place systems for conducting internal monitoring activities and generating internal quality reports. Specifically, they noted merit-based recruitment of staff in QA and QC departments. This, in combination with other practices, such as adherence to GMPs, was reported to contribute to product compliance and conformity to national standards. This finding was similar to what the Capacity Needs Assessment exercise by USAID Advancing Nutrition reported prior to conducting this exercise. The majority of food producers engaged in fortification activities had food quality systems in place based on GMPs and Hazard Analysis Critical Control Point (HACCP) plans aimed to monitor the process and quality of fortified foods. Large-scale oil and wheat flour processing industries had established internal QA systems as part of the requirements for certification by UNBS, while the majority of maize flour processors and salt processors had only recently obtained certification and, as such, needed to maintain a record of compliance.

3.4.2 Weaknesses or Challenges

The weaknesses or challenges in regulatory monitoring are largely attributed along policy and governance, external monitoring, and internal monitoring, as elaborated below.

a) Policy and Governance

Regulators like UNBS and URA have institutionalised regulatory monitoring activities for sustained and effective enforcement. NDA, on the other hand, noted that the Food and Drugs (Food Fortification) Regulation on fortificants/premixes regulation does not align with the NDA Act, which focuses on drugs and not fortificants/premixes classified as a food. This poses a barrier in enforcement to ensure quality of the fortificants/premixes supplies in the country, notably by the fortifying industries, which emphasised the need to have a regulatory body to monitor premix quality (MOH, 2005).

Funding constraints limited the execution of regulatory monitoring activities across the different MDA. This was cited as a significant impediment to the fortification program. Limited budget allocations coupled with significant human resource shortfalls resulted in the low execution of regulatory mandates and significant strains on key conformity assessment services like testing and taxing workloads for regulatory agency staff or analysts who must often prioritise food safety issues above those of quality and fortification. One key informant from regulatory body (*Laboratory Manager from UNBS)* noted, *"There is consistent pressure on the limited human resources, equipment, and laboratory consumables to allocate, among competing regulatory priorities."*

Occasional information pathways existed between line ministries and their agencies but were majorly generic, not limited to fortification. Information transfer specific to tracking compliance, although recommended, was not directly reported between regulators and the NWGFF Secretariat, the NWGFF members, and other policy actors, unless directly requested.

Similarly, a major finding from the assessment is that the coherent flow of information to stakeholders in the national food fortification program is obstructed by a lack of exchange interfaces of the electronic data or physical regulatory reports, challenging the seamless sharing and utilisation or feedback mechanisms for timely policy and program decision-making.

Industry players are expected to be active partners in this system but were largely excluded from the regulatory information flow and feedback. The industry characteristics, needs, and fortification status and compliance records were difficult to track outside of the legal purview of the UNBS, as noted by a stakeholder from a research institution, who said "... *Coherent information flow is challenged by a lack of interoperability and exchange of information across the National Food fortification program."*

b) External Monitoring

The current mandatory thresholds for the maize flour fortification program limit the potential for program scale. Additionally, the highly fragmented maize value chain presents challenges in routine monitoring and enforcement necessary for fortified maize flour compliance.

There is absence of a harmonised system for reporting and sharing data or information. Furthermore, producers were concerned with confidentiality at production levels, especially in scenarios where non-compliance is detected and reported for programmatic purposes.

Stakeholders highlighted that information was "locked" within different electronic and physical or manual systems, functioning in silos with results being obstructed information flow and limited utilisation of aggregated information to inform the program. There were industry complaints that when information is collected, reports or feedback is hardly shared. Relatedly, there was a paucity of data on fortified foods coverage and impact. Data collection is not routine, posing a challenge to periodic tracking and informed decision-making.

c) Internal Monitoring

Unlike industries in the oil and wheat flour processing sectors, producers in the maize milling sector had weak internal QA and QC systems. They lacked standardised or routine documentation in the form of QA and QC protocols and relevant food fortification monitoring data like premix reconciliation, which can provide a quick indication of successful fortification processes.

Furthermore, producers of fortified foods reported financial pressures in compliance with conformity requirements like testing and high costs of fortification inputs like premix (attracting 18 percent value-added tax). The cost of compliance testing was noted as challenging, citing multiple laboratory parameters with high associated testing costs coupled with delays in laboratory turnaround testing time that extended for months with no results.

Additionally, industry respondents indicated weak supervision and coordination of the overall food fortification program by MOH, but rather to engagement in oversight and coordination roles, in addition to housing the food fortification regulations. One of the critical areas was the quality of fortificants, which was noted as paramount to the success of the food fortification program, and the

MOH should closely monitor the performance by the delegated regulatory entities as per the regulation to sustain impact.

3.4.3 Opportunities

The following opportunities were identified with potential for leverage in strengthening regulatory monitoring for the national fortification program.

a) Policy and Governance

- The evolution of national reporting frameworks like the National Annual Performance Report (NAPR) under the ambit of the OPM. This presents an opportunity for national-level reporting on the performance of the overall fortification program and can inform pro-fortification strategic policy actions and reforms.
- The inclusion of food fortification in the National Development Plan III and the Uganda Nutrition Action Plan II underpins the mainstreaming of food fortification in government institution programs and provides an opportunity to attract ongoing financial and technical support for regulatory monitoring from government and donors.

b) External Monitoring

- Several information management systems exist across different government regulatory institutions. For example, URA has the ASYCUDA World System; UNBS runs the E-Portal, CIMS, LIMS, and Webstore; NDA runs NDAMIS; and MOH runs the Health Management Information System. This provides an opportunity for system linkages that can potentially facilitate efficient data and information aggregation, synthesis, reporting, and sharing for evidence-based regulatory strategic actions. The National Information Technology Authority under the Ministry of Information and Communication Technologies and National Guidance is mandated to coordinate, promote, and monitor information technology developments in Uganda within the context of national social and economic development, which may support in linking the systems within these government institutions to share reports on compliance and performance trends.
- A standards development process consistent with the ISO International Electrotechnical Commission Directives Parts 1 and 2 aimed at standardisation currently implemented by UNBS is inclusive of industry and takes into consideration the concerns of fortifying food industries in revision of standards through participation in technical committees.
- The UESW single transactions portal run by URA that provides seamless sharing of regulatory data, which enables joint verification of traded commodities, is an opportunity for sharing compliance information trends and data on regulatory monitoring and compliance with potential to link 22 government MDA.
- Participation of Uganda in the regional and bilateral harmonisation processes at EAC, African Organisation for Standardisation, ISO, and Codex Alimentarius through UNBS provides the opportunity for sharing new international and regional developments and best practices in regulatory monitoring and enforcement for adoption in the national system.
- FortifyMIS, housed under MTIC, could be leveraged to support compliance monitoring of the national fortification program (via internal and external monitoring at producer and import levels), and performance measurement and surveillance (via inspections at markets).
- Uganda, through UNBS, was reappointed Coordinator for the Food and Agriculture Organisation of the United Nations/WHO Coordinating Committee for Africa for 2022 to 2024, which presents opportunities to strengthen national regulatory monitoring practices aligned to regional and international priorities.

3.4.4 Threats

The following threats that necessitate action were identified in regulatory monitoring and enforcement for fortified foods and the overall national fortification program.

a) Policy and Governance

The *multi-agency* approach employed for regulatory monitoring of the food fortification program in Uganda presents inefficiency in coordination, enforcement of the regulation and standards, and coherence, which threatens regulatory monitoring systems. Regulatory monitoring that falls under multiple regulations and regulators often results in fragmented implementation that threatens continuous and efficient enforcement.

Weak penalties in the 2005 Food and Drugs (Food Fortification) Regulation for non-compliant industries, coupled with a lack of a rewards framework, were noted to be demotivating for the compliant industries. There was consensus among industry respondents regarding considerable financial pressure related to fortification and that this status quo promulgates compliance gaps.

4.0 Recommendations and Actions

The recommendations presented are derived from the analysis of the literature on regulatory monitoring and the opinions gathered from key informants, including strategic actions following engagement meetings with regulatory bodies. The actions are presented according to specific components of regulatory monitoring, including external, internal, import, and commercial monitoring or market surveillance.

4.1 External Monitoring

Develop a system-based monitoring program that avoids duplication of roles. While there are regulatory processes and systems in the different entities with key mandates, there is a need to come up with a harmonised version owned by all regulators, with MOH playing an effective role in program oversight. The system-based approach for monitoring can be effectively rolled out and may include the integration of existing information systems envisioned to make the process of data collection, collation, analysis, interpretation, and utilisation more efficient.

Establish a centralised data repository to facilitate data sharing across the relevant stakeholders. Information from monitoring activities should be shared regularly with relevant sectors, especially the industries engaged in the food fortification program. Feedback should include the sharing of information by the coordinator and the NWGFF about successes and any necessary course corrections.

Regular supervision of delegated entities by MOH is recommended to address gaps in the regulatory monitoring of fortificants. In the interim, it is further proposed that UNBS support the MOH to sample and test fortificants/premixes for quality verification against national standards using a risk-based approach for cost-effectiveness.

Provision of incentives to industries is recommended to encourage industries to comply with the standards. Incentives like tax waivers on fortification inputs may gain great reception by the industry from a practical standpoint. Economic incentives equally communicate that the national government is willing to share in the rewards and risks of the food fortification program.

Joint monitoring visits by regulators were proposed to optimise efficiencies in the national monitoring program and further promote realistic, efficient, and transparent government inspection and enforcement mechanisms. This approach would create synergies and solve current capacity limitations faced by respective regulatory agencies and is perceived as less disruptive to industry business operations.

Development of relevant technical guidelines is envisaged to ease the implementation of existing food fortification standards and minimise costs, such as testing randomised indicator micronutrients to support low-cost fortification compliance assessment as current specified test parameters have been deemed very "prescriptive." To further address testing-related resource challenges, decreased emphasis should be placed on quantitative testing and shifts made towards risk-based testing to lessen the burden on laboratories and lower related costs. This approach emphasises the need for technical audits of industries producing fortified foods and imported consignments while leveraging the industry's internal monitoring activities.

Food fortification regulators should execute enforceable penalties that drive consistent compliance among food processors. The performance of a food fortification program is hindered by non-compliance. This may be remedied by strengthening enforcement through commensurate and timely penalties based on the severity of the violation.

Personnel responsible for regulatory monitoring should be given adequate training periodically in the management of all aspects of the food control system, including inspection, sampling, and laboratory analysis.

Lastly, to address confidentiality concerns at production levels, especially in sharing compliance reports, coding is recommended to anonymize monitoring data and maintain confidentiality, where necessary.

4.2 Internal Monitoring

Training on internal monitoring protocols is a key recommendation to address capacity gaps among industry personnel and strengthen compliance with national fortification standards. Such training can be supported through government and implementing partners and may be focused on standardised documentation for QA and QC protocols and relevant food fortification monitoring data like premix reconciliation, which provides a quick indication of successful fortification processes. This data may prove useful for tracking performance and is easy to apply in industrial settings as a verification step.

4.3 Commercial Monitoring

Considering the budgetary resource requirements needed for comprehensive commercial monitoring activities, there is a need to explore complementary approaches, such as social audits that would generate data to inform regulatory actions. Risk-based sampling approaches can be explored to minimise costs for commercial monitoring. Additionally, adoption of innovative technologies for real-time data capture and rapid testing may be adopted to improve efficiency in routine commercial monitoring activities.

Furthermore, implementation of a realistic rewards framework to appreciate, recognize, and motivate industry players that have done exceptionally well in terms of compliance with national standards is envisaged to motivate and sustain compliance among producers. This may be in the form of existing rewards frameworks like the annual BUBU Expo (MTIC) or the Private Sector Development Enterprise Award. Award status may cover a specified period and recognition coverage may be in print and electronic media.

4.4 Legal and Policy Framework

Policy actors must encourage the integration of regulatory monitoring activities into sector work plans and budgets and implement realistic regulatory monitoring frameworks that balance best practices with the available resources. Specifically, this report recommends that government agencies delineate responsibilities to avoid duplication of effort, create linkages, and facilitate sharing of data and evidence to inform the evolution of regulatory mechanisms within the national program.

Advocacy platforms should be explored to lobby for financial budget allocations to address resource shortfalls in the regulatory response of mandated government entities, including engaging partners to supplement funding gaps and technical assistance for effective regulatory monitoring for the food fortification program. Non-traditional actors like civil society groups, academia and research institutions, and consumer protection agencies each have an important role to play and should be included in food fortification engagements to guide their contributions to the program.

Evaluate cost-benefit ratios to establish the feasibility of maize flour fortification to address limitations to mandatory thresholds for the maize flour fortification program and guide stakeholders (policymakers and food processors) on the best course of action (e.g., exploring targeted fortification as opposed to mandatory fortification).

Identify suitable indicators and harmonise reporting tools for integration into existing national regulatory monitoring systems that feed into policy-level national nutrition reporting frameworks like the NAPR under the OPM for overall tracking of milestones.

Lastly, evidence-informed reviews and amendments to existing food fortification regulations to address ambiguities are recommended as paramount to harmonise institutional functions and enable coherence with other statutory instruments for effective enforcement by regulatory bodies.

5.0. Conclusion

Uganda has made considerable progress in building a functional regulatory monitoring system across the food fortification value chain with key investments in systems and infrastructure to verify, promote, and improve compliance with national food fortification requirements. The enactment of the mandatory regulation and the development of corresponding national standards laid a foundation to strengthen food fortification regulatory monitoring systems in the country. Integration of food fortification into the internal monitoring processes has ensured the quality and compliance of centrally processed fortified foods at the industry level. Mainstreaming of food fortification into routine monitoring processes of regulatory agencies particularly UNBS, URA, and MOH demonstrates a commitment to sustainability.

Despite the progress, Uganda's regulatory monitoring system is still experiencing several critical challenges emanating from inherent gaps in the existing national regulations on food fortification. Key among other issues is the weak regulatory monitoring system to consistently and adequately verify the quality of fortificants/premixes along the value chain. Taking into consideration the principles of large-scale food fortification on sustainability and cost-effectiveness, this report recommends simple and low-cost regulatory monitoring actions across MDA processes and systems, including leveraging existing monitoring protocols like inspection or audit schemes applied for product certification by UNBS, using the imports clearance scheme to perform joint verification and enforcement for fortificants and fortified foods, and using risk-based testing to monitor the quality of fortificants for effective regulatory monitoring across the existing systems.

6.0 References

Allen, Lindsay, Bruno de Benoist, Omar Dary, and Richard Hurrell, eds. 2006. *Guidelines on Food Fortification with Micronutrients*. Geneva: World Health Organization. https://www.who.int/publications/i/item/9241594012.

GAIN (Global Alliance for Improved Nutrition), Makerere University, and Centers for Disease Control and Prevention. 2017. *Fortification Assessment Coverage Tool (FACT) Survey in Uganda, 2015.* Geneva: Global Alliance for Improved Nutrition.

Luthringer, Corey L., Laura A. Rowe, Marieke Vossenaar, and Greg S. Garrett. 2015. "Regulatory Monitoring of Fortified Foods: Identifying Barriers and Good Practices." *Global Health: Science and Practice* 3 (3): 446–61. http://dx.doi.org/10.9745/GHSP-D-15-00171.

MOH (Ministry of Health). 1997. *The Food and Drugs (Control of Quality) (Iodated Salt) Regulations, 1997.* Kampala: Ministry of Health.

MOH (Ministry of Health). 2005. *The Food and Drugs (Food Fortification) Regulations, 2005.* Kampala: Ministry of Health.

MOH (Ministry of Health). 2011. *The Food and Drugs (Food Fortification) (Amendment) Regulations, 2011.* Kampala: Ministry of Health.

Onen, G. 2010. *Revision of the Salt Iodisation Regulations and Standards for Iodised Salt in Uganda.* Kampala: Uganda National Bureau of Standards. http://library.health.go.ug/download/file/fid/1466

Stevens, Gretchen A., Ty Beal, Mduduzi N. N. Mbuya, Hanqi Luo, Lynnette M. Neufeld, and Global Micronutrient Deficiencies Research Group. 2022. "Micronutrient Deficiencies Among Preschool-Aged Children and Women of Reproductive Age Worldwide: A Pooled Analysis of Individual-Level Data from Population-Representative Surveys. *Lancet Glob Health* 10 (11): e1590–99.

UBOS (Uganda Bureau of Statistics). 2020. *The Uganda National Panel Survey 2018/19, Wave VII Report.* Kampala: Uganda Bureau of Statistics. https://www.ubos.org/wpcontent/uploads/publications/11_202110_2021UNPS_Report_wave7_report.pdf

USAID (U.S. Agency for International Development). 2022. Large-Scale Food Fortification Programming Guide: Supporting Food Fortification at a Country Level and on a Global Scale. Washington, DC: USAID. https://agrilinks.org/post/usaid-large-scale-food-fortification-programming-guide-supporting-food-fortification-country.

Annex 1: Matrix of Institutional Roles in Implementation of the Mandatory Food Fortification

Institution	Department	Role
MOH	Nutrition Division, Food Fortification Secretariat	Provide policy, oversight, and coordination for the food fortification program.
NDA	Inspectorate Department	Enforce regulations on the manufacturing, procurement, distribution, storage, and utilisation of fortificants and premixes. Conduct site inspections to verify adherence to GMPs by premix manufacturers and dealers.
Food Industries (Producers)	Maize and wheat millers, oil processors, dealers in fortificants and premixes, salt packers, importers	Implement the food fortification regulations. Submit samples for compliance testing.
OPM	Department of Policy Analysis	Coordinate the multi-sectoral framework for nutrition. Integrate food fortification into government MDA planning frameworks and development plans (e.g., National Development Plan, Uganda Nutrition Action Plan).
	Department of Disasters Preparedness	Integrate food fortification into disaster preparedness and emergencies in OPM. Verify compliance of relief supplies to national standards and regulations. Engage with humanitarian agencies to comply with national standards and regulations.
MOFPED	MOFPED	Allocate resources for food fortification across different sectors. Provide tax incentives for fortification inputs (premixes and equipment).

Institution	Department	Role
	URA	Ensure regulation and facilitate clearance of compliant fortified products and fortification inputs (premixes and equipment). Provide tax-related guidance. Provide reports on the volume and source of fortified products and inputs.
MTIC	Micro, Small and Medium-Scale Enterprises Division	Provide overall policy direction to the fortifying industries. Ensure a transparent, motivating, and enabling regulatory environment for the food industry. Provide supportive supervision on food fortification to micro, small, and medium-scale enterprises. Verify production levels of fortifiable food manufacturers. Profile industries producing fortifiable food vehicles.
	International Trade	Implement WTO trade notifications (new) and publications (revised) of regulations related to food fortification.
UNBS	Food and Nutrition Standards Division	Develop and promote food fortification standards. Update and harmonise food fortification standards. Provide updates to relevant stakeholders on the development of food fortification standards.
	Certification Division	Provide compliance reports from certification schemes of fortified foods.
	Testing Division	Test and report compliance of fortified foods against national standards.
	Inspection (market and border posts surveillance)	Surveil fortified foods against national standards at markets.
PSFU	PSFU	Advocate for a conducive and sustainable business environment for enterprise growth. Support members to build their competitiveness capacity at the national, regional, and global levels.
UIRI	UIRI	Research and development Test and research products related to food fortification for the NWGFF for action.

Institution	Department	Role
		Provide technical advisory services, technical backstopping, and food fortification technology transfer to industries.
MoES	Learning Institutions	Promote knowledge on good nutrition practices and consumption of fortified foods in schools, colleges, and training institutions.
	Higher Institutions of Learning	Participate in food fortification research (development of research protocols, ethical approvals, implementation, development of policy briefs, and dissemination).
Academia	Makerere University	Build capacity for food fortification research. Develop strategy for food fortification research and dissemination of research findings.
UBOS	UBOS	Coordinate the National Statistical System and provide quality statistics and statistical services that support development processes.

Annex 2: Interview Respondents by Stakeholders Category

Category	No. of Respondents
Policymakers and Implementers	8
Regulators	5
Industries Producing Fortified Foods	10
Premix/Fortificant Suppliers	3
Research and Laboratory Actors	1
Civil Society Organizations	2
Academia	3

Annex 3: Regulatory Monitoring Activities and Frequency of Data Collection in the Food Fortification Program

Enforcement Agency	Component	Subcomponent	Purpose	Key GOU Indicators collected by Regulatory Entity	Frequency /Timing	Current Practice
UNBS	1. External monitoring	1.1 Quality Assurance Audit	Verify that industry QA activities are performed according to plan.	QA & QC procedures/protocols in place for the industry	Scheduled at least every 3–6 months (frequency increased for non-compliance)	UNBS conducts biannual industry visits to check compliance with standard requirements.
UNBS		1.2 Quality Control Inspection	Confirm that the fortified product complies with the fortification standard.	Samples of fortified products meet standard specifications	Scheduled at least every 3-6 months (frequency increased for non-compliance)	UNBS conducts biannual industry visits to check compliance with standard requirements.
NDA		1.3 Quality Assurance Audit Premix	Verify that QA activities are performed according to GMP guidelines by manufacturers of premix/food fortificants.	QA & QC procedures/protocols in place for premix manufacturers	Conducted once every 3 years, though not done regularly (Past NDA engagement in premix audits was partner supported.)	The NDA Drug Act is not explicit on the institutional mandate for inspection of fortificant because it is not a drug.
NDA		1.4 Quality Control Inspection Industry	Confirm that premix complies with the fortification standard and GMP guidelines.	Samples of fortificants/ premix meet standard specifications	Not currently done	QC is not integrated into the NDA monitoring framework. The Food and Drugs (Food Fortification) regulation of 2005 does indicate the role of NDA in premix inspection; however, the NDA Drug Act is not explicit on the institutional mandate to monitor the quality of fortificants.

URA and UNBS (Joint Mandate)	2. Imports monitoring	2.1 QA Audit 2.2 QC Inspection/testing	Confirm that the country import products and premix are fortified in the country of origin and comply with fortification standards.	Certificate of Conformity for imported fortified products and premix samples of fortified products and premix tested meet fortification specifications	Each time a product or premix consignment lot enters the country	UNBS/URA joint custom verification is done for all incoming lots. Under the pre-export verification of conformity/destination Inspection and release under seal protocol clearance process, URA only clears fortified or any related products like fortificants/premix after UNBS clearance based on compliance to standards. Premix is currently not tagged for intervention, hence presenting compliance gaps.
UNBS and MOH/UBOS	3. Commercial Monitoring	Market Surveillance	Confirm that products available to the consumer in the marketplace comply with quality, packaging, labelling, and fortification content as required by the standard.	Retail & market samples of imported fortified products and premix tested meet fortification specifications	Market surveillance biased to food fortification is conducted if partner funded through the institutions named	UNBS, MOH, MTIC, and UBOS conduct routine surveillance. The nutrition module is integrated into the Uganda annual household panel survey.
Production, QC Personnel, and Procurement and Storage Personnel	4. Internal monitoring	4.1 Quality assurance	Implement procedures to manufacture fortified products that comply with national fortification standards.	Implement quality assurance protocols and checklists according to standard requirements for Dosing rate, Certificate of Analysis of fortificants/premix, Storage and other good manufacturing practices	Daily or according to production schedules or QA protocols and checklists	Follow established standard operating procedures (SOPs), GMP/good hygiene practices (GHP) manuals, and HACCP plans.
		4.2 Quality Control	Confirm that fortified products comply with national standards.	Quality control protocols and checklists A sampling of products according to internal monitoring protocols Calibration of dozers	Daily or according to production schedules or QC protocols and checklists	Conduct qualitative tests (e.g., the iron-spot test to verify QC).