OECD Regulatory Policy Working Papers No. 21

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https://dx.doi.org/10.1787/b1e00dfb-en

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Regulatory governance of large-scale food fortification

By Vaia Karapanou, Christiane Arndt-Bascle, Fatima Toktosunova

This document presents a comprehensive framework for solid regulatory governance of large-scale food fortification (LSFF), a key strategy to addressing micronutrient deficiencies. It identifies six core pillars that are critical for the effective design and implementation of LSFF initiatives across diverse country contexts: collecting data and scientific evidence to identify the problem and policy options, designing policies and regulations, ensuring adequate authorisation processes, implementing supervision and enforcement measures, building capacity for continuous improvement and incentivising stakeholder performances. It builds on the recommendations and principles on regulatory policy developed by the OECD Regulatory Policy Committee (RPC) as well as case studies. The framework aims to assist policymakers and regulators in evaluating their legal frameworks and offers insights on how to improve regulatory practices and outcomes. It also explores how the implementation of each of these pillars could be assessed through the development of indicators and presents findings from selected pilot country studies.

Acknowledgements

This paper was prepared by the OECD Public Governance Directorate (GOV), under the leadership of Elsa Pilichowski, Director, and the direction of Anna Pietikäinen, Head of the Regulatory Policy Division. The authoring team was led by Christiane Arndt-Bascle, head of the Regulatory Governance of Food Fortification Programme, and comprised of Vaia Karapanou, Fatima Toktosunova and Christiane Arndt-Bascle. The authors thank Emilie Balbirnie, Florentin Blanc, Omar Dary, Paul Davidson, Aishani Gupta, Soneath Hor, Gourangi Kumar, Alexis Kyander, Emily LaRose, Naïl Lazrak, Penjani Mkambula, Edefe Ojomo, Anahita Pathak, Claudia Pazlopez, Gordana Ristic, Sina Smid, Kumiko Takanashi and Leonie Vierck for their substantive input to the paper. The team also thanks the OECD officials who provided invaluable comments and advice, including Jens Arnold, Michele Cecchini, Koen Deconinck, Gillian Dorner, Marianna Karttunen, Paulo Magina, Anna Pietikäinen, Adriana Garcia Vargas, Cristiana Vitale and Sabine Vuik. The authors would also like to thank the Harvard Law School Food Law and Policy Clinic team under the leadership of Emily Broad Leib, who undertook literature research as the basis of this work. The paper was prepared for publication by Jennifer Stein, with editorial support from Andrea Uhrhammer.

The team extends their gratitude to the delegates of the Regulatory Policy Committee for their support and invaluable input, and in particular to members of the Steering Group on Measuring Regulatory Performance chaired by Canada for sharing their extremely helpful ideas and insights.

Special thanks are extended to the Advisory Group on Regulatory Governance of Food Fortification, comprised of experts from academia, international organisations and NGOs, for their extremely helpful guidance and insights.

The team is grateful to the representatives of governmental authorities from the countries covered for their co-operation and for sharing their experiences and good practices. The OECD Secretariat is grateful for a financial contribution from the Bill and Melinda Gates Foundation to the project.

JEL Classification:

Key words: Regulatory governance, large-scale food fortification, OECD, micronutrient deficiency

* OECD, France

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1 Introduction

Background

Micronutrient-related malnutrition, also known as micronutrient deficiency, refers to the lack of essential vitamins and minerals necessary for normal human development and function. It is a pressing global issue, affecting millions of people worldwide. While OECD and high-income countries are also affected, women and children in low- and middle-income countries are particularly at risk, with the prevalence of micronutrient deficiency reaching 48% in women of reproductive age and 45% in children (Stevens et al., 2022[1]).

Micronutrient deficiencies have long been a concern, as they can lead to severe health problems and hinder economic development. From the existing strategies to address micronutrient deficiency, *Large-Scale Food Fortification (LSFF)* is a cost-effective strategy that can reach large populations by adding essential micronutrients during processing to commonly consumed foods such as flour, oils, rice and salt (UNICEF, Bill and Melinda Gates Foundation and USAID, 2021[2]). LSFF helps fill the micronutrient intake gaps in existing daily diets across a wide population. By adding micronutrients or premixes, i.e. a blend of vitamins and/or minerals into specific staple foods during processing, nutritional benefits can reach a broad segment of the population.

LSFF is a complement to, not a substitute for, a healthy diet. It is usually embedded in a wider nutrition strategy including improving the diversity and quality of diets, nutrition education, other fortification interventions, micronutrient supplementation such as iron and/ or folic acid tablet provision, hand and food hygiene, and infectious disease control measures such as deworming (WHO and FAO-UN, 2006[3]). An impact assessment of the costs and benefits of food fortification compared to other policy interventions can help governments decide whether it is needed as part of the policy mix to reduce micronutrient deficiency. The assessment requires data and scientific evidence on malnutrition prevalence, affected populations, consumption patterns, food market structure, and other relevant factors.

LSFF has been implemented in high, middle- and low-income countries for over a century because it safely and effectively prevents micronutrient deficiencies and is very cost-effective. Every USD 1 of investment is estimated to generate USD 27 of economic return through disease prevention, improved earnings, and enhanced productivity (UNICEF, Bill and Melinda Gates Foundation and USAID, 2021[4]). The cost-effectiveness, in combination with health and productivity benefits of LSFF, supports the call for a stronger global commitment to food fortification. This is particularly emphasised by the 2023 World Health Assembly resolution that calls on Member States to develop policies on food fortification with micronutrients and/or supplementation and encourages strengthening of fortification financing and monitoring mechanisms (World Health Assembly, 2023[5]).

Governments typically mandate LSFF to ensure broad segments of the population receive essential nutrients. As of 2023, more than 100 countries mandate salt iodisation, and about half of the countries worldwide require wheat flour fortification. Several countries also mandate the fortification of edible oil, maize flour and a few mandate rice fortification. Mandatory food fortification requires food producers to add specified amounts of essential vitamins and minerals to certain food categories. This approach is appropriate in contexts with widespread micronutrient deficiencies and is recommended where such

deficiencies pose serious public health risks (Codex Alimentarius Commission, 1987[6]). Voluntary food fortification on the other hand involves the addition of vitamins and minerals to certain food categories or food products by food producers on a voluntary basis. Despite the absence of a legal obligation, many countries regulate voluntary food fortification.

Certain requirements exist under both mandatory and voluntary regimes, to ensure that fortified food products are safe for human consumption and that labelling information and advertisements are accurate and not misleading to consumers. In particular, consumers should not be induced to buy unhealthy food because it is fortified (Giner, Rodriguez and Elasri, 2023[7]). Examples include breakfast cereals high in sugar or unhealthy snacks for children.

LSFF is delivered through the food system and/or social protection programmes and is considered a medium- to long-term preventive measure for addressing micronutrient deficiencies across the broader population (Osendarp et al., 2018[8]). Notwithstanding the considerable progress that has been achieved in food fortification over the past decades, challenges persist especially in low- and middle-income countries, that make access to fortified staple foods such as flour, rice or oil difficult. For example, introducing fortification requirements does not necessarily imply that businesses will start fortifying staple foods. Where governments have decided to introduce food fortification, it is important to investigate whether there are barriers to achieving the desired outcomes due to potential weaknesses in the institutional arrangements and regulatory framework for LSFF.

Improvements to regulatory governance can play a pivotal role in ensuring the sustained success of LSFF programmes. It is important to understand what constitutes regulatory governance before delving into more specific inquiries on: *What are the key elements of the regulatory governance of LSFF? What factors contribute to the success of LSFF initiatives, beyond regulation and standards development?*

Regulatory governance encompasses a set of regulatory mechanisms and structures including i) core policies i.e. government statements defining the orientation for regulating and governing; ii) actors, institutions, and capacities responsible for implementing, monitoring and enforcing regulations; and iii) systems, processes and tools ensuring regulatory delivery through specific practices (OECD, 2014[9]). Specifically, for LSFF, regulatory governance entails:

- Collecting data and scientific evidence to identify the extent of micronutrient deficiency, establishing national objectives related to its prevention, and considering different policy options.
- Designing LSFF policies and regulations based on evidence. Assessing the impact of different policy options including regulatory and non-regulatory options. If regulation is identified as the best course of action, enacting regulation specifying food fortification requirements, including which foods to fortify and with which fortificants, based on scientific evidence reflecting the current micronutrient status of the population.
- Stipulating the responsibilities of public agencies for food fortification and their interaction, emphasising co-ordination and information-sharing between authorities.
- Specifying the requirements and obligations for private sector players involved in food fortification, including importers, producers, distributors, and retailers. The rules may include authorisation and labelling requirements to import, produce and trade fortified food and premixes.
- Implementing tools, processes and practices shaping the way that public agencies operate, including co-ordination, information exchange, and capacities to oversee compliance and enforcement.

The OECD Regulatory Policy Division has launched this project to develop a measurement framework for regulatory food fortification indicators that can serve as a diagnostic tool to identify policy, regulatory and institutional gaps as well as priority areas for reform. The LSFF Regulatory Measurement Framework builds on the *OECD Recommendation of the Council on Regulatory Policy and Governance* (OECD, 2012[10]) and on subsequent OECD publications to promote sound regulatory practices. More specifically

the measurement framework is based on the *OECD Best Practice Principles on Regulatory Enforcement and Inspections* (OECD, 2014[11]) which seeks to build an overarching framework to support initiatives on improving regulatory enforcement through inspections, and on the *OECD Regulatory Enforcement and Inspections Toolkit* (OECD, 2018[12]) which proposes a checklist of 12 criteria that help officials, regulators, stakeholders, and experts to assess the level of development of the inspection and enforcement system of a particular institution or structure, to identify strengths and weaknesses and potential areas for improvement.

The development of the measurement framework has been based on a combination of theoretical and practical approaches. A literature review focused on trends, issues, and challenges in LSFF programmes' implementation worldwide, particularly where micronutrient deficiencies are most prevalent, with the aim of consolidating the key regulatory and institutional factors required for LSFF. Pilot country studies delved into the policies and practices looking for gaps and shortcomings as well as good practices in the regulatory systems, to enable identification of elements most conducive to the success of LSFF programmes. Lessons from the literature review and the pilot country studies contributed to formulating the normative foundation of the measurement framework for LSFF regulation.

The analysis has helped to identify an array of bottlenecks and gaps in regulatory systems that negatively affect LSFF outcomes. These include insufficient budget allocation for food fortification activities, burdensome licensing and import requirements, unclear responsibilities of public sector agencies, lack of supervision co-ordination mechanisms, an absence of inspection tools, and a lack of enforcement measures.

The measurement framework is designed to provide a systematic approach to identify key regulatory elements essential for the effective design and implementation of LSFF initiatives across diverse country contexts. It aims to assist policymakers and regulators in evaluating the presence or absence of these critical elements within their legal frameworks and to offer insights on how to improve regulatory outcomes.

Objectives

This LSFF regulatory measurement framework is a methodological document that intends to be relevant for all country contexts. The objectives of the framework are threefold:

1. *Analyse the existing framework:* The LSFF measurement framework involves a comprehensive and systematic analysis of the regulatory environment enabling LSFF, where needed. It takes into account all relevant aspects of food fortification regulations and utilises a structured approach to analyse them. This process aims to identify key elements that are essential for the effectiveness of a regulatory framework for LSFF, where governments decide to regulate.
2. *Identify missing elements*: The measurement framework identifies any missing core regulatory elements that might be lacking in the current LSFF regulatory landscape of different countries. Therefore, it fills in gaps in the existing knowledge on how to achieve an enabling regulatory environment for LSFF and, as a result, informs which interventions are better suited to attain maximum impact in a given country context.
3. *Operationalise measurement:* The framework provides a checklist of key regulatory elements that enhance the design and implementation of LSFF regulations and serves as a reference point for benchmarking LSFF regulatory performance across different geographies.

Scope

Staple food regulation coverage

The measurement framework explores the regulatory landscape for LSFF; therefore, it focuses on regulating and overseeing the fortification of commonly consumed staple foods and condiments, rather than composite foods such as breakfast cereals or breastmilk substitutes. Staple foods including flour and rice, and condiments such as salt and oils are essential parts of everyday diets across all socioeconomic levels, making them effective vehicles for delivering essential micronutrients to large segments of the population. In contrast, composite food products such as breakfast cereals and breastmilk substitutes are considered value-added products and are not universally consumed. The emphasis therefore lies in understanding the regulatory mechanisms that govern the fortification processes for the most commonly consumed food items, contributing to a comprehensive examination of the broader regulatory framework surrounding LSFF.

LSFF regulatory cycle

The overarching intention is to address the entire regulatory system covering all phases of the regulatory cycle that underpin LSFF. This includes the formulation of regulations, their implementation, monitoring, and performance assessment. While analysing the regulatory system holistically, the measurement framework puts particular emphasis on actual implementation of LSFF on the ground, focusing on areas where the major gaps and issues have been identified.

Regulatory diagnostic and measurement tool

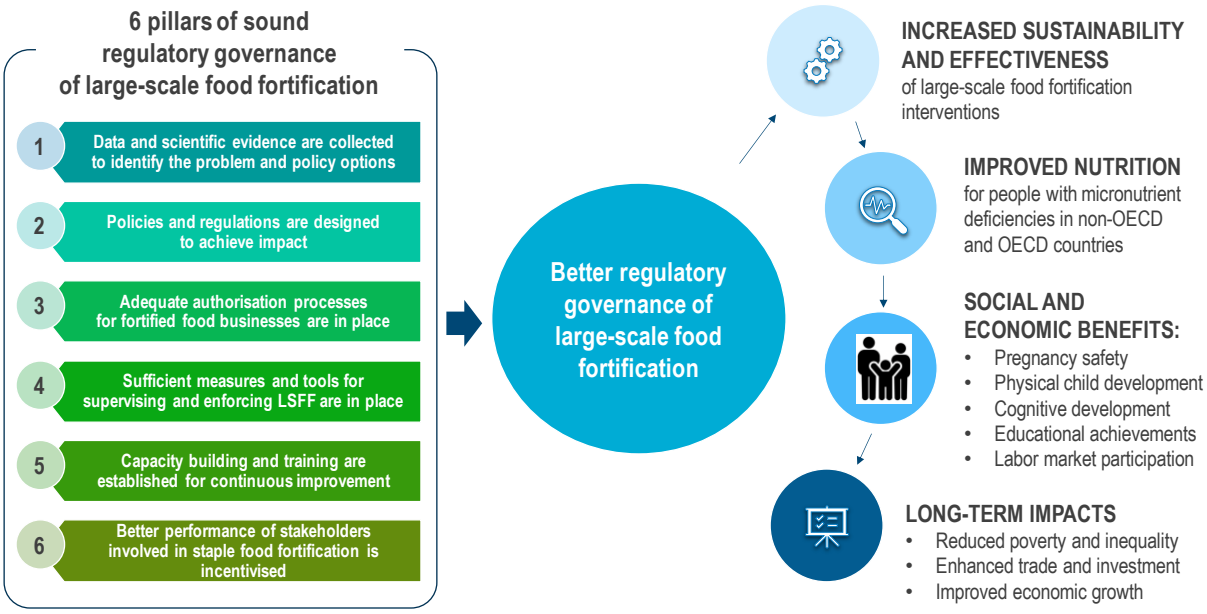
The LSFF measurement framework provides a comprehensive *checklist of essential regulatory elements* for the design and delivery of LSFF. It is intended for use in diverse countries, serving as *a reference for benchmarking* of LSFF regulatory performance across different geographies. The measurement framework provides a set of criteria against which countries can assess their regulatory systems and identify areas for improvement. By fostering an informed process of LSFF regulation development and implementation, the framework can be used in a variety of ways as part of national and regional strategies, self-evaluation, peer reviews, and regional and multilateral discussions for co-ordinated efforts on the ground.

2 Structure of the framework

The analysis performed so far has brought to light the most frequently encountered bottlenecks and challenges along with good practices. Reviewing the commonalities observed in regulatory and institutional landscapes related to LSFF has led to the identification of six core pillars (Figure 2.1). The measurement framework is structured on the basis of these regulatory pillars which are intertwined, and each pillar plays a significant role in the design, development, implementation, control, and sustainability of LSFF. They are the following:

- **Pillar 1 – Data and scientific evidence are collected to identify the problem and policy options:** This includes scientific evidence and data to identify the prevalence of micronutrient malnutrition, the foods most commonly consumed and the micronutrients which are deficient in the daily diets. Relevant data and scientific evidence help to identify policy options, select the right food vehicles and fortificants where needed, and enable periodic review and update of policies and regulations.
- **Pillar 2 - Policies and regulations are designed to achieve impact:** Policies and regulations are designed and reviewed based on evidence. This includes an assessment of the impact of different policy options. If the decision to regulate is made, the regulatory framework for LSFF is established in the appropriate legal form and legal hierarchy to ensure implementation, it is underpinned by policy objectives related to preventing micronutrient deficiency, including the definition of outcomes to be achieved, while at the same time clearly delineating responsibilities for food fortification. Legal documents should include explicit reference to specific food fortification standards. Additionally, LSFF should be effectively incorporated into existing food law frameworks.
- **Pillar 3 – Adequate authorisation processes for fortified food businesses are in place:** Includes well-defined requirements that are not burdensome for businesses, transparent procedures and clearly defined mandate of regulatory authorities responsible for authorising business operators prior to starting the operation. Additionally, it involves labelling requirements that must be met for the trade of fortified foods.
- **Pillar 4 – Sufficient measures and tools for supervising and enforcing LSFF are in place:** Focuses on enforcement and inspection arrangements to ensure compliance with LSFF requirements. This includes establishing co-ordination and communication channels among authorities; implementing risk-based and evidence-based interventions to address food fortifications risks; determining optimal points for enforcement and inspections; and applying appropriate and proportionate enforcement measures.
- **Pillar 5 – Capacity building and training are established for continuous improvement:** Involves continuously improving LSFF implementation through activities designed for the specific needs of stakeholder groups, including government authorities, businesses, and consumers.
- **Pillar 6 – Better performance of stakeholders involved in staple food fortification is incentivised:** Centres on government support for LSFF programmes through allocating appropriate budgets for the implementation of adopted measures, removal of market distortions for greater policy coherence, incentives offered to the industry through various available means where needed, as well as the inclusion of fortified foods in social safety net programs.

Figure 2.1. Core pillars of good regulatory delivery in food fortification



Source: Own visualisation

Within each pillar, there are specific elements, to be used as criteria for evaluation. These pillars along with their elements establish a comprehensive framework for designing and evaluating the effectiveness of LSFF regulatory systems. The identified regulatory elements are relevant both in legal systems where it is mandatory to fortify selected foods and where food fortification requirements are voluntary. Depending on the existing setup, some of the identified elements will be more important than others e.g., food labelling will be particularly important in systems where food fortification is voluntary, while enforcement measures will play a more significant role when food fortification is mandatory.

The six sections in the paper are dedicated to the six core regulatory pillars. The open questions presented under each section aim to assess qualitatively the implementation of each of the pillars. Annex A explores how some selected questions could be transformed into more closed questions with the aim of obtaining comparable information across countries that could be presented in the form of scorecards and, where feasible, also be aggregated into several composite indicators. In the context of LSFF, indicators can serve to benchmark country performance, offer incentives for improvement by identifying bottlenecks and highlighting areas that require attention and allow tracking changes in countries' regulatory systems and monitoring progress. Annex B presents findings from selected pilot country studies that investigated the policies and practices related to LSFF. The Annex contains five country fact sheets for Burkina Faso, India, Indonesia, Nigeria and Viet Nam. Each country fact sheet provides an overview regarding micronutrient deficiencies in the country and the nutritional landscape, relevant legislative and institutional framework, regulations identifying food fortification standards for staple foods and premixes, regulations ensuring industry compliance, measures and tools enforcing LSFF and incentivising key stakeholders. Each country fact sheet also includes a list of regulations that were reviewed during the pilot country studies.

3 Pillar 1: Data and scientific evidence are collected to identify the problem and policy options

A clear and evidence-based understanding of the prevalence of micronutrient malnutrition allows policymakers to assess the scope of the problem and prioritise interventions accordingly. Scientific evidence on which micronutrients are deficient and which foods are most commonly consumed by the population are critical to enable informed decision-making when identifying and evaluating different policy options. Whether the selected policy option involves food fortification, dietary supplementation or other interventions, having adequate scientific data ensures that policies are targeted and effective for addressing the micronutrient deficiency. Ongoing data collection also supports periodic reviews of the policies, ensuring they remain responsive to nutritional needs.

Where LSFF is selected as a possible policy intervention, interventions begin with the identification of the prevalence of micronutrient deficiencies in the population and the selection of appropriate micronutrients (fortificants) to be added to specific foods, commonly referred to as food vehicles.

Micronutrients to be added address deficiencies of the population verified based on scientific evidence

Scientific evidence of deficiencies in the population should drive the process of determining which micronutrients should be added to foods. This approach enables the targeting of specific micronutrient deficiencies and the selection of appropriate fortificants to address these deficiencies. This evidence should cover the prevalence and severity of micronutrient deficiencies in different population groups, dietary patterns, and common sources of nutrient intake (WHO and FAO-UN, 2006[3]).

Typically, evidence about nutritional deficiencies is available through national health surveys, specifically on demographic health, micronutrients, and food intake, as well as through nutrition and health surveillance data, and clinical data. Public health officials should therefore establish a set of metrics to determine: i) whether a micronutrient deficiency or inadequacy is observed in the population and requires attention, and ii) whether this deficiency is widespread enough to warrant fortification as an appropriate solution (Institute of Medicine (US) Committee on Use of Dietary Reference Intakes in Nutrition Labeling, 2003, p. 124[13]). Furthermore, when evaluating existing food fortification programmes, national surveys can help assess if current fortification levels are sufficient to address deficiencies or inadequate intake without leading to excess micronutrient intake.

Organisations specialising in public health or nutrition, including international organisations and non-governmental organisations (NGOs), can help design, carry out and/or interpret survey results and provide insights and advice, especially when government capacity in this area is limited. Also, sufficient funding is

necessary to conduct nutritional surveys periodically to monitor and evaluate the micronutrient status in the population over time.

The selection of appropriate fortificants (micronutrient compounds and chemical form) should be based on technical parameters, in particular, stability and bioavailability of fortificants when added to the selected food vehicles. Certain micronutrients are not stable when exposed to heat, light, and oxygen. Therefore, the conditions of food processing, packaging materials and cooking practices should be considered when selecting fortificants. Additionally, it is essential to consider how well the body can absorb and utilise the added micronutrients, which is known as bioavailability. The rate of absorption can vary based on the chemical forms of micronutrients, the presence of nutrients and other substances that may enhance or inhibit their absorption, and the interactions between added micronutrients.

Food vehicles are the most commonly consumed food of the population

Scientific evidence should drive the selection of the appropriate food vehicle(s). To ensure that food fortification reaches a broad part of the population, the food vehicle(s) should be frequently consumed by the population (staple food and condiments). Selected food vehicles should be those that can be purchased by people from every section of the society, are affordable, and can be fortified at the point of manufacture (Chadare et al., 2019[14]).

This selection should be based on data of food consumption patterns, which enable identifying appropriate food vehicles (candidates for fortification). Additionally, the selection should consider consumer preferences, along with intended use and preparation methods, changes in sensory properties such as colour, smell and taste potentially caused by micronutrients added to a staple food, along with any cost increase (WHO and FAO-UN, 2006, p. 96[3]).

The selection of food vehicle(s) should aim at ensuring that fortification is socially acceptable, does not lead to any change in dietary habits, and safely generates nutritional benefits to targeted population groups (WHO and FAO-UN, 2006, p. xix[3]).

Indicative questions

1. Are specific micronutrient deficiencies identified in the country?
2. What are the methods utilised to determine the prevalence of micronutrient deficiencies of the population? Is this information verified through a nationwide nutrition survey?
3. Is the evidence on micronutrient deficiencies, whether obtained from national nutrition survey or other sources, used to inform LSFF measures adopted in the country?
4. Is scientific evidence on micronutrient deficiencies, obtained through national nutrition survey or other means, used to define the selection of which micronutrients (fortificants) should be added to foods?
5. Are periodical nutritional surveys conducted to assess the level of micronutrient deficiencies in the population? Are changes in LSFF measures based on these?
6. Is the level of micronutrient addition sufficient to address the target deficiency or inadequacy without resulting in excess?
7. Are the chosen food vehicles for fortification determined based on the most consumed food products (staple food) in the country, taking into consideration consumer preferences, intended use, and preparation methods?
8. Do the fortificants meet the technical requirements (stability and bioavailability) to ensure reliable and adequate delivery of the intended micronutrients to the targeted population?

4 Pillar 2: Policies and regulations are designed to achieve impact

The regulatory framework governing LSFF is rooted in national policies and strategic plans. These documents establish a general framework for fortification efforts, outlining objectives and strategies within the context of national priorities. This strategic approach ensures that LSFF interventions are integrated into a broader national agenda, thereby enhancing their effectiveness and impact in addressing micronutrient deficiencies and promoting public health. Achieving the identified objectives necessitates the allocation of an appropriate budget. By aligning budget allocations with LSFF objectives, resources can be directed towards priority areas, maximising the impact of LSFF programmes on public health outcomes.

Furthermore, the regulatory framework for LSFF is structured in a hierarchical manner, comprising different levels of legal instruments. At the top level are the primary legislative documents, established by the legislature, which provide the overarching legal framework for LSFF regulation. Under them are subordinate regulations, adopted by the executive government, which provide details on LSFF implementation. Subsequently, there are the technical standards for food fortification, which detail the specific requirements and guidelines for fortifying foods with micronutrients.

During the development or revision of the LSFF regulatory framework, stakeholder engagement plays a pivotal role in improving regulatory quality and implementation. Central to regulatory policy, it guides decision-making processes from public policy formulation to the evaluation of regulatory outcomes. By gathering diverse input and opinions, governments generate evidence for their decisions, thereby improving the quality and efficiency of the regulatory framework. Notably, engaging stakeholders develops a sense of ownership and accountability and promotes compliance.

National objectives aimed at preventing micronutrient deficiencies are established. Public policy and strategic plans set a fundamental basis, framework, and direction for national food fortification initiatives

Experience shows that the absence of national objectives related to the prevention of micronutrient deficiency are a barrier to food fortification programmes (Tarini et al., 2021[15]). Public policy and strategic plans set general foundation, framework, and guidance for national food fortification initiatives. A well-developed national policy that includes LSFF as a strategy to address micronutrient deficiency, accompanied by strategic plans, signals government engagement and commitment to support food fortification programmes. It could also constitute the pre-condition that is needed to trigger further government action, like the introduction of legislations, regulations and standards.

Generally, LSFF is integrated in an overarching national policy on public health, food and nutrition security, or agricultural policy. Recognising the potential socioeconomic impact of micronutrient malnutrition, including factors such as reduced income, productivity, and increased healthcare expenses on an entire

generation (Darnton-Hill et al., 2005[16]), LSFF may be also included in economic policy documents addressing economic resilience and recovery.

Typically, the policy, serving as an overarching multiannual document, is to be followed by a more detailed government action plan. The action plan proposes a series of specific actions, defines responsibilities of public authorities and the roles of other stakeholders involved in LSFF, allocated resources and sets specific timeframes for implementation. The action plan can be realised through annual operation plans which specify required actions, responsibilities and resources (human, financial, physical, IT, other) on an annual basis.

The policy should be grounded on scientific evidence and data from national health (nutrition) surveys to establish the reference point of micronutrient malnutrition. It should define specific, measurable, attainable, relevant, and timely (SMART) objectives, along with performance indicators, means and programmes for achievement of the set objectives. This, also, involves specifying the public institutions responsible for the policy implementation, evaluation and review and outlining the roles of the private sector.

The policy should also include provisions on systematically collecting data and feedback to enable policy makers to assess the impact of the policy, make informed adjustments as needed and enable policy review. Monitoring and evaluation will enable tracking the progress of food fortification programmes towards the policy objectives of reducing micronutrient malnutrition, identify areas of success and pinpoint areas requiring improvement. The policy should finally identify the instruments to be used, such as regulations, standards, and guides to achieve the set objectives.

Food fortification is a part of evidence-based interventions designed to address micronutrient malnutrition. Before adopting food fortification measures, governments should evaluate scientific evidence regarding the prevalence and severity of micronutrient deficiencies, its distribution across the population, whether food fortification alone or in combination with other measures constitutes the most effective intervention for addressing micronutrient malnutrition. Particularly, it is crucial for governments to determine if the target population will benefit from fortification efforts. Vulnerable and difficult-to-reach populations, such as rural communities that may not participate in traditional market systems, must be considered. These groups may be deficient in essential nutrients but might not have access to fortified foods through market-based commercial channels. Ensuring that food fortification programming and measures also address these populations efficiently is vital to achieve adequate and equitable coverage. Strategies might include engaging local millers or broader distribution of fortified foods to reach these underserved groups effectively. Analysing market dynamics, size and structure help in understanding the potential coverage and scalability of fortification programmes.

Evaluating different policy options is typically conducted through a regulatory impact assessment (RIA) which serves several key functions. Firstly, RIAs should clearly establish the problem, including its magnitude and whether it is temporary or permanent in nature, and should be based on the best reasonably obtainable evidence and scientific expertise. It should then clearly state the objectives sought, which are not the means to achieve them. It should consider all feasible options, including nutrition education, micronutrient supplementation, and other nutrition interventions, as well as different approaches such as mandatory versus voluntary fortification, and also assess the effects of “doing nothing” as a point of comparison. Additionally, it should explore the scope of regulation, considering elements such as fortification level, food categories, the use of fortified foods such as flour and oil in the production of all or limited processed foods, etc. It should also ascertain various industry characteristics including market structure and the state of the domestic and international markets, as well as the potential inclusion or exemption of small-scale producers. Moreover, the RIA should include a cost-benefit analysis of the different options to ensure that the preferred approach is effective, efficient and sustainable, considering its impact on public authorities, citizens and businesses. The assessment should also address distributional effects, evaluating how the selected intervention can potentially affect different population groups including vulnerable groups and types of businesses, along with broader implications for market

participants, international trade and overall well-being. Stakeholder engagement is essential throughout the evaluation process to ensure diverse perspectives are considered in developing any policy. The development of enforcement and compliance strategies including forecasting the probability of compliance among businesses, should also be an integral part of the evaluation process. Monitoring and evaluating the policy, including the development of success indicators and data collection strategies are integral to ensuring the policy's continued success, and need including from the outset (OECD, 2020[17]).

Adequate and sustainable budget allocations for implementation of adopted LSFF measures are secured

National budget allocations serve as the primary funding source for the effective implementation of regulatory measures in LSFF programmes. To remain successful, food fortification requires continuous commitment and investment by governments (Osendarp et al., 2018[8]). This includes allocating sufficient and sustainable budgets to ensure adequate implementation capacity. Ideally, a costed plan will be used to advocate and secure budgetary allocations. This can be informed by regulatory capabilities across vital areas such as inspection and verification services including sample collection and laboratory analysis, technical advice, communication with the industry and consumers. Lack of stable funding and unpredictable budgets adversely affect the efficacy of LSFF efforts and pose challenges, including in adequately compensating regulatory staff and providing essential professional training, potentially compromising the effectiveness of LSFF efforts (Luthringer et al., 2015[18]).

Moreover, sufficient budgetary support is vital to alleviate the burden on regulatory agency staff and prevent such situations where limited resources, both human and material, are allocated among competing regulatory priorities. For instance, when regulatory agency staff face challenging workloads and must prioritise food safety issues over those of food quality and fortification (Luthringer et al., 2015[18]).

In the process of allocating national budget for LSFF measures, it is essential to establish a mechanism to align funding volume with performance of government agencies responsible for implementing LSFF measures. This ensures that financial resources are distributed in a manner that reflects effectiveness and efficiency of these agencies in achieving the objectives of the food fortification programme. Such approach promotes accountability and optimal performance.

Appropriate level of regulation, which mandates LSFF, is established and integrated into the existing regulatory framework

The regulatory framework for LSFF is considered in the below sections across three tiers:

1. Primary legislative documents mandating food fortification provisions, adopted by the legislature;
2. Technical food fortification standards; and
3. Subordinate regulations specifying details for LSFF implementation, adopted by the executive government.

Determination of the level of LSFF regulation for mandating food fortification rests on legal and administrative factors

The choice of the level of regulation mandating fortification relies on legal and administrative considerations, including the hierarchy of laws, separation of powers and division of responsibilities, and the practicality of implementation.

LSFF is not generally characterised by a standalone law dedicated solely to food fortification, but rather relevant legal provisions are incorporated into the primary legal document often referred to as *food law*, adopted by a legislature. These legal provisions commonly aim at addressing nutrition-related and food sustainability concerns of a nation and set a legal foundation for subsequent LSFF measures. Subordinate regulations, known as *implementing regulations* are adopted by the executive government with the aim to provide specific details on how the law is to be implemented and enforced. This organisational structure gives a flexibility within the LSFF regulatory framework, as amending laws is more challenging and time-consuming than revising regulations. Prompt revision of regulations may become necessary due to advancements in scientific knowledge, innovative food processing technologies, or emergencies that require quick actions to safeguard public health.

In a number of countries, fortification is mandated directly by primary legislation, adopted by the legislature (Parliament). This trend is more pronounced in salt iodisation legislation, which for most developing countries occurred earlier compared to fortification of other food vehicles.

LSFF regulation should be integrated into existing food law frameworks

The regulations governing food fortification should be integrated into existing food law frameworks wherever feasible (Dijkhuizen et al., 2013[19]). Food law and related regulations regarding food safety and quality, along with the broader food safety and quality control system are the primary tools that are available to governments for establishing an appropriate level of oversight over food fortification practices. Food fortification regulation and food safety regulation are therefore inextricably linked and interdependent.

Accordingly, requirements applied to food safety and quality domain automatically extend to the food fortification, following the same principles, encompassing the entire food fortification chain, involving risk assessment, management (inspection, sampling, and laboratory testing) and risk communication.

Food fortification standards: ensuring comprehensive and clear directions in LSFF regulation

The technical fortification standards are established by the government for fortification of specific products. Food fortification standards should leave no room for ambiguity and be carefully worded to avoid confusion for producers. They should contain specific information on the following:

- *Identification of fortified food*: Clearly define the range of foods or food categories that are subject to fortification
- *Micronutrient names*: Specify the names of micronutrients
- *Micronutrient levels*: Specify minimum and maximum levels of micronutrients to be added to the food
- Micronutrient compounds: Detail the permitted micronutrient compounds that can be used for fortification

In the development of food fortification standards, it is essential to consider and align with general principles, regional standards and guidelines where possible (Codex Alimentarius Commission, 1987[6]) (WHO, 2014[20]) (WHO, 2016[21]) (WHO, 2018[22]) (WHO, 2022[23]). It is also necessary to ensure that food fortification standards and regulations are in accordance with international agreements on trade and more specifically the WTO Technical Barriers to Trade (TBT) Agreement (World Trade Organization, 1995[24]) and the WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) (World Trade Organization, 1994[25]) which promote standard harmonisation to reduce barriers to trade. Under these WTO agreements countries may adopt trade-restricting measures to improve human health but they are encouraged to comply with international standards such as the ones developed by the Codex Alimentarius Commission, to help reduce trade barriers (OECD/WTO, 2019[26]). These globally recognised

benchmarks play a fundamental role in establishing appropriate food fortification standards, promoting harmonisation of food fortification requirements globally and regionally, and facilitating a trade across borders. In addition, the development of food fortification standards needs to ensure that standards are technically sound and meet the needs of local population.

Comprehensive scope of LSFF regulation is ensured via the appropriate selection of food vehicle and nutrients, full supply chain application, clarity in requirements, and reference to food fortification standards, and explicitly stating exemptions if applicable

The scope of the regulation mandating LSFF incorporates several key aspects:

1. **Selection of food vehicle and nutrients**: LSFF regulation outlines which foods to fortify and the specific nutrient(s) to be added. This selection should be based on scientific evidence and taking into account the current micronutrient status of the population and their consumption patterns.
2. **Specification of technical standards**: LSFF regulation makes explicit reference to specific technical food fortification standards.
3. **Comprehensive coverage**: LSFF regulation should apply to all stages of food fortification supply chain. It should be aligned with the legal provisions governing the broader food chain. Safety and quality of fortified food is to be ensured throughout the entire production and distribution process.
4. **Definition of the role of participants**: The LSFF regulation should provide certain and unambiguous requirements, so that all parties involved, including producers, importers and exporters, transporters and retailers are clear on their respective responsibilities, and subsequent penalties for deviance from their obligations. Distinct delineation of responsibilities among government authorities, is crucial to avoid ambiguity, prevent overlaps or gaps, and enable institutions to effectively implement the regulation within their purview.
5. **Clarification of exemptions:** In cases when certain elements are exempted, such as exported foods, the regulation should explicitly specify these exclusions and provide justification, ensuring it does not create discrimination between national and imported products.

Stakeholders' involvement in the development of LSFF policy, standards and regulations governing LSFF

The implementation of LSFF programmes involves various stakeholders across the value chain and includes government authorities at both central and regional levels; industry partners, who are key collaborators; NGOs, which often play an active role on the ground in implementation; and academia, represented by scientific councils providing specific advice on fortification. Consumer associations and other public organisations also play a crucial role in ensuring that the interests and needs of the general public are considered. By advocating for consumer rights, providing feedback on fortification programmes, and raising public awareness, they help ensure transparency, accountability, and public trust in the fortification process.

Stakeholder engagement is a fundamental pillar of regulatory policy across various stages, including the development of public policy and choice of regulatory instruments; design of new regulation (or review of the existing one); implementation of regulation; and monitoring and evaluation of its effects (OECD, 2011[27]). It allows governments to gather evidence as a basis for their decisions, improving the quality of rule-making process by getting more diverse inputs and opinions from those that will be affected by government's decisions. Engaging stakeholders fosters a sense of ownership and promotes compliance.

Stakeholder engagement should not be restricted to draft laws or regulations, but extend upstream – initiating proposals, and downstream – monitoring and evaluation, throughout the regulatory governance

cycle (OECD, 2015, p. 69 sqq.[28]) (OECD, 2021, p. 54 sqq.[29]). Establishing a systematic and targeted approach to stakeholder consultation from the LSFF programme's onset and throughout its lifespan is essential. Stakeholder engagement must be integrated in the planning of public agencies' work to ensure that stakeholders' consultations are not rushed at the end of the process only to comply with the requirements (OECD, 2015[28]).

Transparency in the consultation process is vital. All stakeholders should be adequately informed in advance about the opportunity to participate and provided with sufficient time to familiarise themselves with the LSFF programme details to provide meaningful feedback.

Governments should offer clear and transparent feedback on stakeholders' inputs in the decision-making process, ensuring stakeholders are informed about the impact of their contributions. While not all inputs may be accepted, policymakers should set out openly and transparently the reasons for rejecting the inputs and maintain accountability for their decision (OECD, 2015[28]).

Stakeholder engagement mechanisms, including digital methods, should attract, empower, and manage public expectations. Digital engagement, while valuable, should complement conventional practices, such as working groups, advisory committees, public hearings, reaching out directly to vulnerable and minority groups etc. Successful digital engagement requires optimal design tailored to both policymakers and the public's needs, along with resource investment.

The adoption of policies promoting plain language in laws and regulations is essential for fostering stakeholder engagement. By using clear and straightforward language, governments enhance accessibility and comprehension among diverse stakeholders.

Indicative questions

1. Is LSFF integrated in the existing national policy or strategy – on public health, food and nutrition security, food safety and quality, agricultural and economic policy etc?
2. Does the process of development of the national policy/strategy related to LSFF involve stakeholders' consultation?
3. Is there a monitoring and evaluation system to track progress and impact of LSFF programme?
4. Do the policy and/or government action plan set specific objectives, measurable targets, aimed at tackling of specific micronutrients deficiency issues through LSFF?
5. Is there a multiannual government action plan to implement the national objectives set by the policy, specifying LSFF programmes?
6. Is the governmental body/are governmental bodies clearly defined to implement the policy/action plan?
7. Are human, physical, IT resources for implementing the action plan envisaged and annually secured?
8. Is LSFF regulated? What is the level/hierarchy of LSFF regulation(s)?
9. Did the government conduct a regulatory impact assessment (RIA)? If yes, what policy options were analysed? How were costs and benefits assessed?
10. Is the budget for LSFF action plan allocated by government annually?
11. What is the process used to develop LSFF standards domestically?
12. Does the development of domestic LSFF standards take into account relevant international standards (Codex general principles, WHO guidelines)?
13. Are LSFF standards adapted to specific products and ways of preparation that are typical for the country?
14. Does LSFF regulation make explicit reference to specific food fortification standards?

15. Is LSFF regulation integrated into existing food safety regulatory frameworks?
16. Are the LSFF requirements clear and comprehensive? With avoidance of ambiguity and gaps (e.g., when roles and responsibilities of authorities are not formulated clearly and thus creating potentially a lack and/or overlapping of control; nutrient(s)' level might not be clear; nutrient compounds are not defined etc.)?
17. What is the scope of LSFF regulation in terms of:
    a. which food products are to be fortified, with which nutrient(s), at which minimum-maximum levels?
    b. what industry types and sizes are to produce fortified food?
    c. whether fortified food is to be domestically produced or imported?
    d. whether imported food should/can be fortified?
18. Does regulation or other legal document provide guidance on how to implement LSFF measures?
19. Does LSFF regulatory framework provide specific mandates to public authorities regarding food regulation and food control in general and LSFF more specifically?
20. Does the process for adoption of LSFF regulation and food fortification standards requirements involve stakeholders' consultation? If yes, which stakeholders are invited for consultation?
21. Is the stakeholder consultation process transparent, i.e., do all affected parties have the possibility to participate in consultations, are they informed sufficiently about the possibility to consult, are there minimum periods for providing a reply?

5 Pillar 3: Adequate authorisation processes for fortified food businesses are in place

The process of authorisation entails any approval or decision by the relevant public authority or authorities that is a precondition for producing fortified food and premixes at a specific location or facility. *Authorisation extends to registration or notification, and licensing of businesses*. *Ex ante* (prior to operation) inspections by the competent public authorities, when appropriate, may also be part of authorisation, ensuring compliance. The authorisation processes should be accessible, transparent, time-bound, and clear to enable businesses to start their operations without hindrance and avoid authorisation processes becoming an obstacle to trade (Moïsé and Sorescu, 2021[30]) (OECD, 2019[31]).

Authorisation processes include well-defined requirements, transparent procedures, clearly defined responsible regulatory authority(-ties) and adequate tools

The LSFF authorisation process is considered in terms of i) integration of LSFF authorisation within the overall food business authorisation system, ii) clarity of authorisation requirements, procedures and authorising institutions for businesses to apply and obtain the authorisation prior to starting fortified food and/or premix production, and iii) tools to facilitate the overall authorisation process. LSFF authorisation is integrated within the overall food business authorisation system.

Existing licensing and registration systems should be expanded to include fortified food production import and export (when applicable), thereby minimising the need for multiple concurrent systems (Nathan, 1999[32]). This extension should cover relevant components of the food fortification chain, such as:

1. the production of fortified food and premixes;
2. the import of fortified food (ready-to-use) or food to be processed and fortified, along with the import of ingredients for premixes;
3. the export of fortified food and premixes (when applicable).

Requirements, processes, and institutions for the authorisation are well-defined and transparent

The requirements and procedures to produce, import, export and trade fortified foods as well as fortificants should be well-defined, as well as freely and publicly available. The regulatory authorities responsible for authorisation should be explicitly outlined. This transparency provides businesses with clarity and predictability, enabling them to adequately prepare for operation, allocate resources and plan activities. Furthermore, it minimises the risk of arbitrary decision-making by licensing and registration authorities.

Authorisation requirements and processes should strike a balance, ensuring they are reasonable and not overly restrictive (stringent), to avoid any discouraging effect on industry participation or non-compliance by industry.

Tools to facilitate the authorisation and to enable LSFF enforcement are operational

The application of online licensing and registration systems streamlines the authorisation process, offering easy access to requirements and guidelines. Simultaneously, it supports maintaining and updating an electronic register or database of businesses involved with fortified food production, import and export and assists regulatory bodies to keep track of businesses operating within their jurisdiction, thereby streamlining the enforcement of LSFF regulations. This register should provide crucial information, including business location, ownership details, and the nature of operations. Such comprehensive data enables regulators to identify and target potential risks and to optimise inspections and enforcement efforts for greater effectiveness and efficiency. In this context, the interconnection between digital platforms for authorisation, inspection and enforcement activities holds significant importance in LSFF implementation.

Labelling requirements are a prerequisite for the trade of fortified food

According to the World Trade Organization (WTO) Technical Barriers to Trade (TBT) agreement, labelling requirements should be applied equally to both domestic and imported products, without discrimination between domestic and imported products nor create barriers to trade (Giner, Rodriguez and Elasri, 2023[7]) (Moïsé and Sorescu, 2021[30]). Additionally, WTO Sanitary and Phytosanitary Measures (SPS) Agreement primarily aim to ensure food safety and protect public health. This includes ensuring that food labelling related to health claims, ingredients, and nutritional information is based on scientific principles, thereby ensuring that international trade is not unnecessarily restricted.

When it comes to domestic trade, the role of labelling is multifaceted and viewed from three perspectives: i) being a prerequisite for market placement of fortified food, ii) enhancing consumer awareness, and iii) supporting traceability which is crucial for the enforcement of LSFF regulations.

To facilitate a market access for fortified food

Meeting specific labelling requirements is imperative for both wholesale and retail trade of fortified food. The label should include essential information indicating that the food product is fortified and added micronutrient content (Nathan, 1999[32]).

To enhance consumer awareness

Labels must be accurate and free from any misleading health claims (Nathan, 1999[32]), ensuring that consumers make informed decisions based on reliable information. Additionally, incorporating a readily identifiable logo on the label serves to easily differentiate fortified products from non-fortified products (Turk and Spohrer, 2016[33]).

The logo enhances consumer awareness of food fortification and contributes to informed choices about dietary intake. Logos, especially in voluntary systems, serve as powerful visual cues that indicate the presence of fortification in food. Complemented by targeted education initiatives and dietary guidance along with effective communication strategies that emphasise the importance of fortified staple foods, these labelling practices play a vital role in ensuring consumers understand the benefits of fortified food. However, it is worth noting that the logos or health claims should be used to promote the average consumption of fortified food products. Overconsumption of food vehicles such as salt, oils and sugar has been alerted due to the increased risk of diet-related diseases (e.g., excess salt intake leads to higher

blood pressure, and excess vegetable oil intake leads to higher lipid/fat concentrations in body/overweight). Thus, logos and health claims need to be carefully designed to tackle both the optimisation of micronutrient intake and the balanced consumption of food vehicles with potential diet-related health risks (World Health Organization, 2022[34]).

To support enforcement of LSFF regulations

Labelling is especially important for enforcement bodies as it enables traceability. It allows government authorities to trace noncompliant foods back to their sources (Nathan, 1999[32]). To fulfil the traceability requirements, labels should include at least information such as the name and contacts of a food business operator (manufacturer, importer, distributer, etc.), expiry date/best before date and preferably lot or batch number. Labels may, also, contain other elements facilitating product identification and tracking. Alignment with international guidance, such as the Codex General Standard for the Labelling of Prepackaged Foods (Codex Alimentarius Commission, 1985[35]) and other relevant international standards and guidelines, is important to harmonise labelling requirements.

Labelling is crucial as it serves as the initial step, allowing enforcement bodies to identify noncompliant products. Testing further ensures whether foods meet the required fortification levels stipulated by regulations.

Certain trading scenarios, where products are sold without standard packaging, in bulk or where consumers provide their own containers, pose challenges for effective labelling and traceability. In these scenarios, traders should employ innovative means of labelling if possible, or offer alternatives, such as documentation proving the origin of bulk products sourced directly from producers or distributors.

Indicative questions

1. Is registration required for businesses involved in the production, import and export of fortified food and production/import/export of premixes?
2. Is licensing required for the production, import, export of fortified food and the production/import/export of premixes?
3. Are there available defined prerequisites for registration that the businesses must meet before commencing the production, import and export of fortified food and the production/import/export of premixes?
4. Is the process of registration perceived as easy or complex?
5. Are there available clear (well-defined) requirements and procedures on licensing that the businesses should meet before starting the production, import and export of fortified food and the production/import/export of premixes?
6. Is the license awarded to the owner for all of his/her facilities or does each facility need to be separately licensed?
7. Is the process to obtain a license, including providing the required supporting documents that the business (facility/facilities) needs to submit when applying for a license, the cost of the license, longevity of the process, and validity of the license, perceived as easy or complex?
8. How is the validation of the production/manufacturing process conducted? (e.g., with submission of documentation, through an inspection etc.). Is an inspection performed as part of the licensing process?
9. Is the license for production of fortified food permanent or renewable? If renewable is clear information provided about the requirements for the renewal?
10. Is information on the licensing of facilities stored in a digitally accessible database?
11. Is there a register or database of facilities that:

   a. produce, import, and export fortified food
   b. produce/import/export premixes

12. Is there a shared platform connecting the licensing and registration systems with inspection and enforcement activities? Are there other means to provide connection and compatibility of the licensing and registration systems with inspection and enforcement activities?
13. Are labelling requirements clearly outlined for fortified food as a prerequisite for wholesale and retail trade of fortified food?
14. Are there provisions in food regulatory framework governing nutritional claims?
15. Is traceability legally binding? Are there clear requirements about which information needs to be displayed on the label to secure traceability?
16. Are businesses required to keep track of all raw materials and ingredients used in production and about all products dispatched to the buyer?
17. Is there a logo or quality mark associated with the labelling of fortified products?

6 Pillar 4: Sufficient measures and tools for supervising and enforcing LSFF are in place

The regulatory framework governing LSFF extends beyond regulations and standards, encompassing their practical implementation. The supervision and enforcement of LSFF play a vital role in ensuring effective implementation. Evidence suggests, in many instances, shortcomings in supervision and enforcement significantly impact the success of LSFF programmes. To ensure the proper implementation of LSFF regulations and standards, the regulatory authorities should employ appropriate measures and tools for effective and efficient oversight and enforcement.

Adequate co-ordination and communication mechanisms among public authorities engaged in LSFF are operational

Depending on how public administration is organised in each country, the supervision of LSFF implementation may fall under the responsibility of a single authority or of multiple authorities such as various line ministries, food authorities, central and local authorities, in-land and border inspection agencies, market surveillance agencies etc. The co-ordination is approached from two perspectives: horizontally among multiple sectoral authorities, and vertically, between central and local government levels.

Establishing a co-ordination mechanism within multi-authority system for effective LSFF governance

To ensure effective supervision of LSFF, it is imperative to establish a co-ordinated approach, given the involvement of various agencies in areas such as food safety, food security, trade, agriculture, health, industry, import, export, and standards. A structured co-ordination framework among these agencies is required to mitigate challenges, addressing potential overlaps and conflicts in mandates.

Establishing a central-local co-ordination mechanism for effective LSFF governance under decentralised system

Within a decentralised governance system, a well-defined organisational framework is essential for optimal implementation of LSFF measures. This framework should best outline a central-level authority and delegation of practical responsibilities to regional and local levels and requires providing standardised procedures. Regional and local authorities, responsible for enforcing food fortification standards, should establish and adhere to a formalised vertical reporting line to the central authority. This structured reporting mechanism ensures a systematic flow of information, enhances accountability and promotes a unified

approach to LSFF governance. The establishment and formalisation of this vertical reporting chain are fundamental to keep central authorities, including line ministries, consistently informed and actively engaged in overseeing LSFF at all levels (World Bank, 2016[36]) (Dijkhuizen et al., 2013[19]).

LSFF co-ordination is strengthened through adoption of appropriate legal and administrative arrangements

It is imperative that the involved authorities co-ordinate to leverage resources effectively. A lack of co-ordination and collaboration impedes the implementation and success of LSFF programmes. Introducing legal provisions on the co-ordination of the workstreams of the institutions involved, is a valid way to enable collaboration, avoid duplication of efforts and ensure that resources are allocated appropriately. These provisions delineate the responsibilities of relevant government authorities, designating a primary authority for food fortification and mandating inter-authority reporting.

Another approach involves establishing administrative arrangements, such as signing a multi-authority memorandum of understanding (MoU) (Global Alliance for Improved Nutrition (GAIN) et al., 2018[37]). The MoU can formalise decision-making procedures, promote information sharing and streamline authorisation, enforcement and inspection processes among public agencies. Further means to enhance collaboration and facilitate the information sharing include forming a LSFF taskforce, multi-ministerial working groups, cross-sectoral bodies, and other co-ordination entities.

Regulatory enforcement and inspections to ensure compliance with LSFF requirements are arranged

Regulation mandates the authorities for enforcement and inspection

The regulation should identify the authority(ies) responsible for supervision, delineate their mission and role, along with specifying the roles of all other institutions involved in LSFF supervision. Supervision is ensured through the exercise of regulatory enforcement and inspections, granting the designated authorities the power to oversee compliance with LSFF requirements. This includes the authority to inspect and enforce in case of a non-compliance. Effective implementation of these provisions is crucial to ensure compliance with LSFF requirements.

LSFF is effectively integrated and balanced within the food safety system for optimal oversight

Similarly with integrating food fortification requirements into the existing food safety regulatory framework, the controls and monitoring protocols for fortified food should be integrated into existing food safety controls (Neufeld et al., 2017[38]). If separate systems are in place, this can divert attention away from food fortification because staff may prioritise food safety issues over food fortification as these issues generally pose a higher and more immediate risk (e.g. microbiological and/or chemical contaminants) than concerns about sub-standard quality of fortified foods (Neufeld et al., 2017[38]). The enhancement of food fortification inspections will benefit the overall strengthening of existing food safety systems.

Risk-based and evidence-based interventions to target food safety and fortification risks are employed

The regulations underpinning food safety and quality, that encompasses LSFF, should provide for a risk-based planning and targeting of inspections. Authorities should adopt a risk-based approach as the

underlying foundation of all inspection and enforcement activities. A risk-based approach to supervision entails establishing a methodology to prioritise inspections and assign inspection frequency based on the risk rating of the business (OECD, 2018[12]). Inspections should therefore be planned and targeted based on the level of risk posed. At the same time, inspections should be proactive and a base level of frequency of inspections may be required to maintain supervision credibility. This strategy optimises the use of limited resources, such as time, budget, manpower and professional experience, by directing them to high-risk activities and operators and investing in addressing key problems. The approach ensures that resources are allocated to tackle significant risks rather than being spread thinly across all supervised objects. This approach, supported by existing empirical evidence, has been proven to lead to more effective enforcement outcomes (da Cunha et al., 2016[39]) (Unnevehr, 2015[40]) (Blanc, 2018[41]).

Applying risk-based tactics in food safety advances fortification efforts. While the risk-based approach inherent in food control measures is essential for preventing immediate harm and mitigating risk associated with food safety, food fortification primarily pertains to enhancing the quality of food by adding essential nutrients and dealing with rather long-term health effects. Nevertheless, implementing risk-based planning and targeting of inspection and enforcement activities in the domain of food safety enables adequate oversight in the integrated segment of food fortification. This approach is instrumental for the regulatory governance in LSFF. Application of the overall risk-based approach along the entire food fortification chain ensures the fortified food meets the established requirements and minimises risks associated with fortified products.

While developing a risk-based plan of inspections, certain risk criteria should be considered, which are grouped into two categories:

i) Static risk criteria: they remain constant over time and are easily identifiable and include: the type of business/product, the size of the business, and the volume of operations (e.g., domestic or exporting business), whether an establishment produces a food product to be fortified or adds fortified ingredients during food processing. Static risk criteria provide a basic understanding of the business environment, helping with the initial assessment of risk and regulatory compliance.

ii) Dynamic risk criteria: these criteria are subject to change based on inspection results (e.g., under- and over-fortification) and encompass factors such as the inspection track record of the business and information about its past business attitude. Dynamic risk criteria are essential for adjusting risk assessment over time, allowing for more detailed and refined evaluation that reflects the changing compliance and performance of the business.

Having a risk-based system requires having in place a standardised system of assessing risk. Further, the risk management system should be communicated to all stakeholders to improve awareness of potential risks and raise levels of compliance (Blanc, 2018[41]). When supervision and enforcement are guided by an evidence-based assessment of risk, this demonstrates a rational and objective approach, creating trust and fostering a culture of compliance.

The points for enforcement and conducting inspection are appropriately defined to ensure safety and quality along the food fortification chain

To ensure safety and quality throughout the chain, effective control at the most strategically important points for enforcement and inspection is crucial. The key enforcement and inspection points are i) the point of entry for imports of fortified foods and premixes, ii) the production site, iii) the trade site. These points of control enable more cost-effective inspections, optimising the use of scarce resources and capturing more representative conditions. This approach optimises the often challenging and time-consuming task of tracing fortified food to its source for enforcement and corrective action (Luthringer et al., 2015, p. 452[18]) (UNICEF and Food Fortification Initiative, 2014[42]).

This proactive and preventive approach stands in contrast with the prevailing practice where official control tends to be very reliant on sampling and testing of final products e.g. at grocery stores and local food markets with its considerable expenses and unavoidably of a high variability and margin of error (World Health Organization, 2013[43]) (UNICEF and Food Fortification Initiative, 2014[42]).

Appropriate, proportionate and responsive enforcement measures are in place to deter noncompliance.

Responsive enforcement strategy to be employed to back up LSFF implementation

Enforcement should adhere to the principles of responsive (differentiated) regulation, which implies that response of the regulatory authority should depend on the business profile, past behaviour, business attitude towards compliance and the risk posed by the infraction (OECD, 2018[12]). Enforcers should have a toolbox of differentiated and targeted approaches to enforcement and avoid generic 'one-size-fits-all' approaches that will not be appropriate for every situation (Baldwin, 1990[44]).

Enforcement authorities should be vested with an appropriate framework of discretion (within limits) to vary their enforcement actions, depending on the context and the risk level posed (OECD, 2018[12]). The legislation should also make clear the decision-making processes and powers of inspectors along with the rights and obligations of inspectors and regulated subjects (OECD, 2018[12]). At the same time, it is crucial that enforcement against non-compliance is carried out consistently. The lack of enforcement and motivation to enforce at all levels greatly impairs the implementation and potential for impact of adopted LSFF initiatives (Dijkhuizen et al., 2013[19]). Evidence suggests regulatory agencies could demonstrate a lack of willingness to impose penalties or penalties being not severe enough to encourage adequate fortification.

Risk-based and proportionate enforcement actions

Similarly, the severity of the enforcement action taken should be dependent on the level of risk posed. It is important that sanctions and other compliance measures are proportional to the risk level presented by a specific violation, ensuring a deterrent effect for severe infractions, while minimising the burden to businesses for minor infractions. A proportionate response to violations fosters a sense of fairness and encourages a proactive attitude towards meeting regulatory requirements.

Progressive enforcement: providing a gradual approach to sanctions for LSFF compliance

A progressive application of sanctions is essential. First-time offenders may receive a warning letter along with the guidance of the inspector on how to remedy the shortcoming with a short follow-up for a specified remedy period (Global Alliance for Improved Nutrition (GAIN) et al., 2018[37]). Concurrent offences warrant heavier sanctions, such as larger fines, temporary closures or revocation of licenses (Global Alliance for Improved Nutrition (GAIN) et al., 2018[37]). The severity of the fine should be based on the risk posed and the business attitude towards compliance. This gradation of sanctions allows for the necessary escalation of sanctions by the enforcer if needed to create a credible threat and deterrence (OECD, 2018[12]). Sanctions must be sufficiently dissuasive without being excessively punitive, ensuring effectiveness while also making the fine imposed more costly than the expense of fortifying (Ebata et al., 2021[45]).

Information regarding regulatory enforcement and inspections results is shared between regulatory authorities involved in overseeing food fortification through digital tools

Results of inspections and enforcement activities should be stored in a digital database and shared with relevant agencies. The digital storage of results allows for rapid data collection and analysis (Global Alliance for Improved Nutrition (GAIN) et al., 2018[37]). Information management systems support the storage of results from various sources, including food production facilities, import sites, and laboratories, enabling the quick generation of reports and graphs to identify trends (Global Alliance for Improved Nutrition (GAIN) et al., 2018[37]).

Furthermore, the sharing of information and inspection results among the relevant government bodies enhances co-ordination and prevent duplicative supervisory activities. Data management systems promptly alert relevant authorities to potential regulatory monitoring issues, facilitating faster remediation (Global Alliance for Improved Nutrition (GAIN) et al., 2018[37]). At a broader level, the digital collection of inspection activities results provides invaluable information on LSFF programme performance. Aggregating such data allows tracking trends and issues, informing programme performance and evaluation, and guiding necessary changes to LSFF policy (Hwalla et al., 2017[46]).

Accredited laboratories with capacity to test for fortification exist

Testing the fortified food is a crucial part of assuring the presence of micronutrients, and for this purpose independent, accredited laboratories are necessary to carry out control measures (Bhagwat et al., 2014[47]). These laboratories need to be adequately resourced, employing internationally recommended methods, having adequate supplies and equipment and appropriately trained staff to ensure accuracy of the testing process, testing results and interpretation of the results. These guarantee that businesses and inspectors receive accurate information about the levels of fortificants, allowing them to act upon results quickly (Luthringer et al., 2015[48]). Furthermore, laboratories, whether government or privately-owned, should have sufficient capacity to meet effectively testing demands.

Accredited laboratories operate under rigorous quality standards and protocols, following requirements of ISO/IEC 17025 (ISO, 2017[49]), a global standard for entities performing laboratory activities. Adherence to ISO/IEC 17025 ensures that laboratories produce reliable and accurate test results, which is crucial for verifying that fortified foods meet regulatory standards and deliver the intended nutritional benefits (GAIN, 2021[50]).

In lower-income countries with potential shortage of accredited laboratories specialising in micronutrient testing, it will be necessary to allow some level of flexibility and to involve non-accredited laboratories. While these non-accredited laboratories may be in a transitional phase and not yet fully comply with the global standard requirements in terms of technical and staff capacity, they should seek approval from public authorities in order to be able to conduct micronutrient testing in fortified foods.

The information on both accredited and approved laboratories specialising in micronutrient analysis should be publicly available. This enables businesses and authorities to easily identify recognised laboratories for submitting their samples for testing.

Ensuring the adequacy of test results begins with the proper sampling of the food product. This necessitates the establishment of a specialised sampling protocol and trained and authorised personnel to conduct the sampling. The sampling protocol should be based on globally recognised standards and best practices, ensuring consistency, reliability, and accuracy. This includes guidelines on sample collection, handling, storage, and transportation to maintain the integrity of the samples (Codex Alimentarius Commission, 2023[51]) (Codex Alimentarius Commission, 2023[52]). Enforcement authorities

need to be aware of the expected margin of error and range of variation in laboratory results, which can occur among others due to for example different sampling methods, the variability inherent in chemical testing methodologies and in measuring very small amounts of micronutrients (Global Alliance for Improved Nutrition (GAIN) et al., 2018[53]). Authorities need to be able to interpret the results accordingly to determine the appropriate enforcement measures.

Exploring the use of rapid testing methods is valuable, particularly in settings where resources and accredited laboratory capacity are limited (Theriault et al., 2022[54]). Businesses can use these methods for self-assessment and public authorities can endorse them for official use in the supervision of food fortification. Rapid testing provides an initial screening to detect the presence of micronutrients, allowing non-accredited laboratories to participate and thereby expand the overall testing capacity with quick results. Additionally, the portability of rapid testing kits enables public authorities to perform on-site testing, even at remote production facilities. Before integrating rapid testing as a supplement to laboratory capacity, authorities should consider the feasibility of domestic manufacturing of these devices and the local sourcing of vials and reagents (Mkambula et al., 2020[55]). Evaluating cost-efficiency is crucial to ensure that rapid testing methods are sustainable and accessible.

Indicative questions

1. In case of a single authority in charge of LSFF (e.g., food safety and quality), are there co-ordination mechanisms with other relevant agencies in place?
2. In case multiple authorities are involved in LSFF supervision, do they co-ordinate with each other?
3. Are there established co-ordination and communication mechanisms or channels among these public authorities?
4. Are there provisions specifying co-ordination among LSFF authorities in the legislation?
5. Are the roles and responsibilities of the public authorities involved in regulatory enforcement and inspections regarding LSFF well defined? Is there a legal document or documents for specifying their mandates for enforcing and inspecting LSFF requirements?
6. Are regulatory enforcement and inspections specific to fortification? Are there any inspection protocols for fortified foods? Or is fortification one of the items controlled in a broader inspection protocol, such as on food safety and on food quality?
7. Do (annual/multiannual) inspection plans exist specifically to control food fortification?
8. Is the planning and conducting of inspections based on risk criteria or the level of risk of the facility/operator of the facility? Is fortification taken into account in the risk assessment?
9. Do field officers use inspection tools, such checklists when performing inspection in food processing, storage, transportation, and trade? Do checklists include fortification-related questions?
10. What are the primary locations/points for LSFF enforcement and inspections?
    a. production sites
    b. points of entry for importation of fortified foods and premixes
    c. wholesale and retail (market control)
11. Is fortification controlled during import control of products?
    a. is there a specific import protocol to control fortification?
    b. is fortification controlled as one of the items in a broader import/export inspection protocol?
12. When performing an inspection, do officers verify the traceability of staple foods, material/premixes/and raw material?

13. Does applicable legislation/regulation allow for differentiated (responsive) enforcement? This implies that the enforcer/regulator's response should accord with the profile of the business, its past behaviour, attitudes towards compliance and the risk posed by the infraction.
14. Does applicable legislation/regulation allow for differentiation in enforcement response, such as though progressive application of sanctions: issuing warning letters for first-time offenders; and for concurrent offences - more heavy sanctions, such as, larger fines, temporary closures, or revocation of licenses.
15. Is regulatory enforcement and inspections as currently conducted adequate to effectively monitor LSFF?
16. Is there observed a lack of willingness to impose penalties, or are penalties not stringent enough to ensure adequate fortification?
17. Are there reporting procedures for field officers following an inspection?
18. Are inspections results (including noncompliance) stored in a digitally accessible database?
19. Does regulation allow government officers to provide compliance guidance to food business operators?
20. Do laboratories have the capacity (enough and trained human resources, infrastructure and equipment, material) to test samples for fortification?
21. Is information on accredited and/or approved laboratories are available?
22. Do laboratories have the capacity (enough and trained human resources, infrastructure and equipment, material) to test premixes?
23. Is there a sample collection protocol in place including guidance on when and how to take samples in order to ensure that they are representative and instructions on how to treat samples?
24. Are rapid methods used for testing food samples?

7 Pillar 5: Capacity building and training are established for continuous improvement

Effective implementation of LSFF measures relies on the collaborative efforts and capacities of various stakeholders: i) Government agencies hold the mandate for establishing and enforcing LSFF regulations that involve setting standards for nutrient levels, compliance monitoring and ensuring safety of fortified foods. The government's capacity extends to inspection and enforcement capabilities, and the creation of awareness and education for both the public and businesses; ii) Food production and processing businesses bear responsibility to adhere to food fortification standards and maintain consistent production practices for ensuring fortified food meet regulatory requirements; iii) Ultimately, consumers' acceptance and awareness are critical for the success of LSFF. Their capacity refers to the willingness to embrace fortified foods and effectiveness of public awareness and communication strategies in conveying the benefits of LSFF and encouraging consumer engagement. Each stakeholder's capacity to fulfil its role in this process is an imperative for ensuring that fortified foods meet regulatory requirements and standards, are consistently available, and accepted by the population.

Capacity building for food fortification implementation is an ongoing effort and it is achieved through various methods tailored to the specific stakeholder group

Strengthening the government's capacity for LSFF: incentivising regulatory personnel, providing guidelines, technical training support and resources

Lack of adequately trained staff remains a key obstacle to overseeing fortified foods (Sight and Life and Global Alliance for Improving Nutrition (GAIN), 2015[56]). In low- and medium-income countries, the lack of well-trained inspectors is cited as a key challenge to creating a legal and regulatory environment conducive to compliance (Luthringer et al., 2015[48]).

To ensure regulatory effectiveness, a core team of trained and incentivised inspectors is crucial. This requires incentives and motivational elements such as availability of travel budgets for conducting on-site inspections in different locations, recognition of timely performance results, appropriate professional training, and a strong emphasis on professional integrity and effective communication with the industry (Luthringer et al., 2015[18]). Additionally, having knowledgeable and trained individuals who can function in a stewardship role is essential. These leaders guide the system by ensuring adequate data supports food fortification initiatives, fostering collaboration and advocating for necessary budgets.

To enhance transparency and consistency it is essential to develop official LSFF implementation guidelines. These guidelines should include the latest food fortification regulatory requirements and provide

inspectors with instructions on how to verify their compliance, detailed explanation on the use of checklists, guidance on the appropriate use of enforcement powers to help inspectors determine the appropriate response to non-compliance considering the seriousness of the violation, the history of non-compliance and the available enforcement options and corrective measures. These guidelines enable education of inspectors, including less experienced or trainee inspectors and align inspection practices, making the process clearer and fairer.

In addition to food fortification guidelines, equipping inspectors with essential tools, such as *checklists*, is crucial for effective oversight. The checklist is a structured tool used by inspectors to systematically review and ensure business compliance with regulatory requirements. It serves as a guide during inspections outlining key points that need to be checked or verified. Inspectors use checklists to gather detailed information, serving as a foundation for decisions on enforcement actions and measures to be imposed. By consolidating all key requirements into a single document, checklists simplify and improve the inspection process. This not only expedites inspections but also ensures uniformity and consistency as inspectors focus on the requirements included in the checklist.

Capacity building is directly associated with providing regulatory agency staff a range of *training sessions* on food fortification regulations. Regulatory agencies with a core team of trained professionals/inspectors are better equipped to succeed in their performance goals. The training for regulatory personnel should include sessions on LSFF objectives, scope, implementation and enforcement intricacies. The training also should aim to cover advancements in scientific knowledge, technological innovations, regulatory changes and emerging trends related to food fortification. This includes evolving knowledge on nutrient interactions, improved fortification technologies, updated standards and innovations in monitoring and assessment tools.

Enhancing the ability of public authorities to collect relevant data is a vital element. Continuous collection and aggregation of data related to food fortification are essential to ensure that a programme is achieving its goals. A critical weakness in many lower-income countries, despite the widespread practice of LSFF, is the failure to generate, access or utilise data during programme design and implementation (Aaron et al., 2017[57]). Data collection serves for various aspects of a food fortification programme: gathering evidence to define micronutrient deficiencies; collecting data for regulatory supervision and enforcement, and reporting, monitoring and evaluation of the adopted food fortification programmes. It entails the need to establish standardised procedures and methodologies to facilitate the on-going and systematic collection and aggregation of data, ensuring that the gathered information is reliable and actionable and enabling public authorities to develop the capacity to effectively manage the data collection process. There is an increasing recognition of data's crucial role in shaping and informing public sector activities. A truly data-driven public sector recognises data as a key strategic asset. This approach applies data to transform the design, delivery and monitoring of public policies and services. Data-driven regulatory governance contributes to establishing a common vision, enhancing coherent implementation and co-ordination and strengthening institutional, regulatory, capacity and technical frameworks (OECD, 2019[58]).

In addition, adequate laboratory capacity and expertise are an essential addition to the implementation capacity of the regulatory agencies. Adequately equipped laboratories enable agencies to conduct comprehensive and timely testing, allowing them to respond promptly to non-compliance issues, making informed decisions and follow-up actions (Luthringer et al., 2015[48]).

Enhancing the capacity of food business operators for LSFF: providing guidelines and training

Similar to government agencies, *guidance documents* should also be developed to assist businesses to comply with regulatory requirements. Regulated businesses need guidance, advice and information. Effectively addressing potential questions from businesses is essential to increase compliance. Providing guidance for the fortification process is essential. It enables the production of properly fortified food items

and encourages producers to adhere to fortification regulations. The guidance and information documents should be accessible, offering clear explanations of the regulatory requirements for food fortification and providing practical guidance on compliance in a manner understandable by businesses. In addition to guidance and information documents, making checklists available to businesses in advance significantly promotes compliance because it enables them to understand the legal requirements and be aware of the crucial inspection points.

In addressing *training*, businesses require comprehensive training in both general good manufacturing practices in food production and, more specifically in the intricacies of food fortification. This targeted training ensures businesses meet broader food manufacturing standards and acquire specialised knowledge for effective and compliant food fortification practices.

Tailored guidance and training are required for small businesses in LSFF, addressing their unique challenges and needs. This builds their capacity, enabling them to navigate the requirements and challenges of food fortification, promoting compliance and contributing positively to the broader fortification goals.

Fostering consumer awareness and acceptance of fortified foods through education and communication programmes

Consumer education can enhance the impacts of food fortification programmes (Chadare et al., 2019[14]). It plays a key role in generating consumer demand for fortified staple products. Studies highlight the connection between nutritional education and improved nutritional outcomes, specifically the direct impact of the parents' nutritional education on nutritional status of their children (Lowe et al., 2021[59]).

In various contexts, mass media, advertising and promotional campaigns have proven effective in elevating consumer awareness and fostering demand for fortified staple foods. Effective advertising involves providing sufficient information to consumers, making advertisements easy to recognise, designing them carefully with appropriate wording including accurate health claims and ensuring that advertisements do not mislead consumers (OECD, 2019[60]). Additionally, alongside setting clear labelling requirements, it is important to establish measures to restrict the advertisement of unhealthy food and prevent over-claiming or misleading statements in order to maintain healthy eating (OECD, 2021[61]).

When informing consumers about fortified staple foods, it is important to emphasise the need for a balanced, healthy diet and the consumption of micronutrient-rich foods, rather than focusing solely on the role and benefits of fortified staple foods. The information of fortified foods should be presented in a clear and concise manner focusing on the key characteristics of the product. The goal is to empower consumers to make informed decisions by providing them with accurate and easy-to-digest information about the food products they are considering purchasing without being misled by exaggerated health claims.

Governments can play a crucial role by supporting consumer awareness and education programmes. Collaborating with other LSFF stakeholders, governments can establish effective programmes reaching diverse demographics, ensuring widespread understanding of the nutritional benefits of fortified staple food. A commitment to sustainability in these initiatives ensures their long-term impact for LSFF.

Indicative questions

1. Are government authorities, state officials and field officers aware of LSFF requirements? How are they informed?
2. Are there established guidelines for the LSFF implementation and control for state officials and field officers?
3. Are these guidelines adopted and executed by the government authorities?

4. Do field officers use inspection tools such as checklists when performing inspection of food processing, storage and trade? Do checklists include fortification-related questions?
5. Is financial support stipulated or provided to authorities for additional tasks added to their scope of work specifically to oversee and ensure compliance with LSFF requirements?
6. Are technical training sessions on food fortification control offered for the authorities in this field?
7. How is data utilised by public officials across different aspects of food fortification programmes? Is data effectively used by public officials in gathering evidence on micronutrient deficiencies, to support enforcement and inspection activities, monitoring and evaluation of food fortification programmes?
8. Are there guidelines specifically on LSFF implementation for food business operators?
9. In the business landscape where small and micro-businesses (household level) prevail, are technical and advisory support initiatives offered for these businesses? For instance, is there a manual on good manufacturing practice in food fortification?
10. Are there any education programmes in place for LSFF to target various groups of stakeholders and the general population? Are these programmes available for the population in rural and remote areas?
11. Are consumers aware of ongoing LSFF arrangements? How are they informed?
12. Are LSFF regulation and standards publicly available? Can consumers and producers access the regulation and standards?

8 Pillar 6: Better performance of stakeholders involved in staple food fortification is incentivised

If governments mandate food fortification to increase the supply of fortified staple food in the market, they may additionally need to create incentives for stakeholders in fostering LSFF implementation, in particular in low-income countries. In any event, governments should consider removing policies that create unnecessary market distortions such as domestic taxes or import tariffs for premixes, machinery or fortified staples to reduce overall fortified food costs and price and for greater policy coherence.

(Dis-)incentives for stakeholders are analysed and where necessary adjusted to increase supply of fortified staples

The cost of food fortification of staple foods can potentially be significant for businesses depending on the type of food vehicles selected, the micronutrients to be added, the existing production process and the corresponding market structure. The incremental cost of food fortification cannot always be absorbed by industry without passing it on to the consumer, or easily absorbed by consumers themselves. Furthermore, solvency issues can arise from delays between premix purchases and eventual receipts of customer payment. This challenge is particularly pronounced during the initiation and early phases of staple food fortification programmes owing to the need to invest in specialised equipment and premix stock. These added expenses pose a distinct challenge especially for smaller producers, potentially concentrating the market, and leading to a bifurcated market through deliberate avoidance or under-fortification. Adjusting the level or eliminating value added taxes (VAT) on fortified food products, as well as VAT and import duties on fortification equipment and premixes, can reduce such market entry costs (WFP and GAIN, 2022[62]). The latter is particularly important in the case where premixes or fortification equipment are not produced in the country itself.

If governments want to increase the amount of fortified staple food in the market, they need to ensure that no unnecessary restriction to entry and competition are caused by existing policies. Unnecessary regulatory barriers, such as overly complex business registration requirements, unduly restrictive planning rules, difficulties in accessing finance and overly restrictive importer rules, all increase business costs and are detrimental to supply. Non-tariff barriers such as delays in treating premixes or fortified products at the border can also decrease the supply and quality, given that some vitamins such as vitamin A degrade over time, in particular in suboptimal storage conditions. Governments can work towards reducing barriers while ensuring safety at the same time.

A second step is to consider providing financial and in-kind subsidies (e.g. specialised equipment) at the outset of LSFF programmes. Particularly in emerging markets, targeted financial incentives for small businesses are expected to encourage participation in fortification and compliance with fortification

requirements (Osendarp et al., 2018[8]). Given the prevalence of small-scale, cottage or artisanal firms producing staple foods (salt, rice, oil, maize flour, occasionally wheat flour), often constrained by limited financial resources and low levels of technical skills required to consistently comply with fortification standards (Mkambula et al., 2020[55]), governments can consider implementing grant programmes to support the fortification efforts of these enterprises. Direct subsidies can help cover expenses related to the purchase of fortification equipment, the procurement of premixes and testing and monitoring costs. Direct subsidies including providing free or partially covering premix costs, have been utilised to build new initiatives and encourage industry participation (Garrett, Luthringer and Mkambula, 2016[63]).

However, while subsidies can be effective in establishing the programme, it is important to stress that they should be targeted to the firms that really need them to get off the ground and should be provided on a time-limited basis to prevent industry dependence.

When considering any form of financial support, government should ensure that these interventions are carefully designed to ensure that the expected benefits outweigh the costs and that potential negative externalities are taken into account (IMF et al., 2022[64]). Effective government support should be proportional to the problem it aims to solve, time-limited, targeted to those most in need, non-discriminatory and transparent (OECD, 2023[65]). Furthermore, it is essential that interventions are the least distortionary in terms of competition and trade, in order to achieve their objectives (OECD, 2023[65]).

Social safety net programmes generate demand and encourage business entry

Social safety net programmes that are implemented and supported by governments, entail the distribution of food to vulnerable populations such as low-income households, schoolchildren and pregnant or lactating women. By including fortified food staples in social safety net programmes, vulnerable populations are supported, and a consistent market demand is created for these specific items, motivating food industries to produce fortified food in accordance with the programme requirements. Given the substantial scale of food distribution in such programmes, this enhances firms' economic viability to produce fortified food.

Social safety net programmes often involve distributing food packages or vouchers to redeem fortified food items at designated locations. School feeding programmes can help target micronutrient malnutrition amongst children by providing nutritious meals to students. Workforce feeding programmes designed to support individuals in low-income areas have also been included. The programmes provide nutritious meals in the workplace or to participants in job training, skills development, and employment placement services.

Social safety net programmes use public procurement mechanisms. Effective public procurement enhances public trust and is increasingly used to achieve broader policy objectives (OECD, 2019[66]). It also helps engage suppliers early on, to help achieve broader policy objectives, including ensuring sustainability of food systems. Market engagement with relevant stakeholders contributes in building consensus and ensuring a shared understanding of benefits (OECD, 2021[67]). Public food procurement (PFP), also known as institutional food procurement, leverages government purchasing power and consistent food demand. A key feature of PFP is its ability, through its policy and regulatory framework, to determine the types of food to be purchased (e.g. local, culturally appropriate, healthy, nutritious and including fortified), the sources (e.g. local farmers, SMEs, women, youth and other vulnerable producer groups) and the production systems (e.g. environmentally sustainable, climate resilient and biodiversity-conserving agricultural productions). Local, regional and national governments can tailor PFP to various policy objectives, including the necessity for fortified foods. Accordingly, PFP has considerable potential to influence norms around food, consumption and production patterns, providing numerous social, economic and environmental benefits (Swensson et al., 2021[68]) (OECD, 2023[69]).

Indicative questions

1. Has the government recently analysed and eliminated unnecessary market distortions that reduce the supply of fortified staples?
2. Is the government approving budget allocations specifically for LSFF initiatives? Do these allocations provide resources to the authorities to implement LSFF efforts?
   a. are these budget allocations aligned with the LSFF performance indicators, if such indicators are stipulated by relevant policies or regulation?
   b. will there be adjustments to the budget allocations if poor performance is attributed to the government authorities involved in LSFF?
3. Do LSFF regulations offer incentives, such as subsidies, credit with low interest rates, tax exemptions, small cash support, equipment or other measures, to encourage producers engaging in food fortification and to ensure continuous compliance with fortification initiatives? Has the government analysed whether their support follows international rules and good practices and that the expected benefits outweigh the costs?
4. Adopted food fortification measures can pose challenges for small and micro- food businesses to meet compliance with LSFF requirements. Are there any programmes or services designed to specifically assist these businesses?
5. Does documentation exist indicating whether existing social safety net programs include the provision of fortified staple food, either for free or at a reduced cost, to specific population groups based on household income?

Annex A. Methodology for assessing countries' regulatory systems for LSFF

The previous sections presented, in the form of normative statements, the regulatory pillars that are crucial for the design, development, implementation, control and sustainability of LSFF. The pillars are of broad applicability to any country to be included in the assessment. Each pillar is further broken down into regulatory components and subcomponents with observable elements that can be used to assess what already works and what can be improved.

Development of indicators

Based on the observable elements elaborated for each pillar, we plan to develop indicators and scorecards on regulatory systems for LSFF to enable country assessments. Indicators have proven useful in the context of policy analysis, in comparing policies across countries, identifying trends and drawing attention to particular issues (OECD/European Union/EC-JRC, 2008[70]).By defining indicators and scorecards, we will be able to summarise more detailed information on food fortification regulation in an visual and simplified way that is easy for policy makers and the general public to understand, aiding in decision-making processes. The indicators can also provide countries with incentives for improvement in the context of LSFF. They can identify bottlenecks and highlight areas that require attention. Using indicators will also enable keeping track of the changes countries make to their regulatory system and monitor progress.

When considering the overall relevance of the indicators that will be defined for the LSFF framework, we will ensure, throughout the project, that the data is generated first and foremost with users in mind. The Handbook on Governance Statistics (Praia City Group, 2020[71]) highlights that the production of statistics "is not an end in itself, rather, it must serve those who put the data to use for better policy and better outcomes." When elaborating the indicators, we will apply best practices to ensure their quality, ensuring that they are relevant, credible, timely, measurable and accessible (OECD, 2011[72])..

We will focus on the most important regulatory (sub)elements of the identified pillars to develop indicators. These are core areas where bottlenecks and gaps in countries' regulatory systems are observed, where it is meaningful to create incentives for improvement. The indicators we develop are based on a selection of normative statements from each pillar. They do not aim to measure everything but what they measure matters.

We will construct indicators so that they are meaningful, relevant and valid across all countries to be assessed not just for a particular country or group of countries. This requires a nuanced understanding of policy implementation and outcomes across a wide range of countries and contexts.

Development of composite indicators

It is planned to construct some composite indicators to present the information in a more digestible format that is attractive to a wide audience including high-level policy makers.

Composite indicators aggregate multi-dimensional processes into simplified concepts. These indicators can facilitate cross-country comparable analysis. The main benefit of composite indicators is to provide simple comparisons and tools for identifying trends in wide-ranging policy areas. The strength of composite indicators lies in their ability to summarise complex and multidimensional issues to show the 'bigger picture'. For this reason, they are useful for benchmarking exercises and to gauge performance over time in complex policy areas. However, aggregate measurements come at the cost of detail and risk causing simplistic policy conclusions. If poorly constructed, they can send misleading or false messages.

We will develop the composite indicators based on the main steps outlined in the OECD & JRC *Handbook on Constructing Composite Indicators* (OECD/European Union/EC-JRC, 2008[70]). The degree of aggregation will be decided once all the sub-indicators are selected and have been tested practically in their feasibility.

For this project, it will also be important to publish comparable indicators and scorecards together with qualitative information to put the information into context and report on country specific elements that matter but that are not measured or measurable. By definition, cross-country comparable indicators are not context specific, yet context does matter. This is why it is planned to publish country profiles combining both qualitative, more context specific assessments and cross-country comparable indicators. Even when marrying both methods it will not be possible to cover everything, so prioritisation of selected pillar elements to analyse more in depth in each country will be of utmost importance.

The degree of aggregation of sub-indicators will be decided once all the sub-indicators are selected and have been tested practically for their feasibility. In some cases, it might be more meaningful to collect qualitative information or present information in a more disaggregated way.

Challenges in creating cross-country comparable policy indicators

When developing cross-country comparable policy indicators for this project, it is necessary to highlight the challenges that can exist:

1. **The lack of consistent and reliable data and information**: Different countries have different data collection methods, and the quality of the data and information may vary. In some countries documentation of regulatory systems is more readily available than in others. This makes it difficult to ensure that the indicators are measuring the same thing across all countries. Moreover, data may be lacking altogether for certain countries or policies, limiting the ability to create a comprehensive picture of policy outcomes across countries.
2. **The interpretation of information can vary** (Kahneman, Sibony and Sunstein, 2022[73]): This can arise due to a number of different factors:
    a. Terminology may have different meanings depending on the country and even for different experts depending on their background (Maestas, 2016[74]).
    b. Each country has a different national context which means that measures that may work effectively in one country do not work as effectively in another.
    c. Reference points for interpreting information in terms of the performance of a system might differ from one country and one respondent to another as expectations differ.
    d. Regulations and regulatory systems are sometimes open to interpretation with a clear answer to specific questions being difficult to achieve.
3. **Regulation and its implementation may vary across the country:** The organisation of regulatory systems is likely to vary between countries, in particular if competencies are decentralised across regions and municipalities. Some regions might have different regulations in place than others and some municipalities might be very strong in inspections and others do not

at all inspect fortified food. It will not be possible to collect information on e.g., inspections and enforcement systems in all regions, so it might be necessary to choose a representative region instead. Future work on operationalising the indicators will explore how to address scoping issues such as regional variations in regulations and/or their implementation and applicability.

4. **The structure of the staple food industry is different in every country**: this implies a different scope of application of regulations and its implementation, making it more difficult to develop cross-country comparable policy measures.

Development of an Expert Survey to collect quantitative and qualitative information in countries

To collect the necessary information required, an Expert Survey shall be developed in accordance with OECD best practices (OECD, 2012[75]). Expert Surveys rely on the knowledge of subject experts to measure complex concepts that would otherwise be difficult to measure (Maestas, 2016[74]). We will use country experts with the necessary knowledge, expertise and objectivity to help us collect information and to answer the questions. This shall address some of the challenges identified above in creating cross-country comparable policy indicators and will ensure that we collect information that is relevant and context specific. Experts on the subject matter will provide more accurate answers and be able to synthesise vast amounts of information compared to a single researcher (Maestas, 2015[76]).

Using expert assessments allows us to develop indicators that consist, on the one hand, of factual questions that require fact-based answers (e.g., the existence of a legal document, a report, an institutional structure) which are verified with the submission of relevant documentation and, on the other hand, perception questions that will enable conveying what works or doesn't work in LSFF regulatory frameworks and will be influenced by contextual elements. Perceptions are shaped by many factors. Perceptions of the quality of regulations can be influenced by trust in government, experience with front-line service etc (OECD, 2012[77]). Studies have found that responses to perception-based questions vary according to the level of knowledge and personal experience with regulations. Experts having significant experience with regulations exhibit a more balanced view of regulation, acknowledging costs and benefits (OECD, 2012[77]). Perception questions do not need to be entirely subjective. For the planned survey on the regulatory governance of food fortification, experts will need to base their answers to perception-based questions on concrete experiences and information.

Like other types of surveys, expert responses are prone to both systematic and random error. The degree of error associated with responses by experts will depend on (i) whether experts have incomplete information about targets leading them to guess incorrectly (ii) whether experts rely on heuristics to simplify complex information (iii) whether experts adopt bias views based on their perspectives.

Several actions can be taken to reduce response bias and errors through the expert survey we will deploy:

1. **Clear Questions** will be drafted. All questions developed in the Survey shall follow OECD Guidance on questionnaire design to obtain comparable measures from responses to the Survey.
2. **Guidelines for Experts** will be developed. Experts will need to assess each country in the same way to allow for fair comparisons. For this reason, we will be developing a guideline for experts that will enable experts to understand questions in the same way to allow for meaningful country comparisons. These will need to ensure that the same benchmark is used across countries, that terminologies are understood in the same way everywhere and that there is no room for interpretation of the question-and-answer categories. Moreover, guidelines will be provided to support the experts in understanding what types of data collection tools can be used to support their response to questions (e.g., type of documentation to be reviewed, interviews). Question design to assess regulatory systems across countries is very complex, hence the importance of

not trying to measure everything but to measure the most important elements that matter everywhere.

3. **Survey Measures will be included to evaluate expertise.** Mechanisms will be included within the Survey to assess the quality of responses received from Experts. Questions can be asked to Experts to express their level of certainty about their assessment.

4. **Questions will be pretested.** We will run the survey on a smaller scale before launching the expert survey to all countries. This piloting will enable us to identify how experts are likely to interpret and reach to the questions in the survey. By piloting the Survey, we will be in a position to respond to the following key questions: (i) Are questions consistently understood across experts (ii) Do the answers accurately describe what the experts have to say? (iii) Do the answers provide valid measures of what the question is designed to measure? (iv) Do experts have the information required to respond to the question (Fowler, 2009[78]) or do they need to advise with external sources (e.g. public officials, stakeholder representatives)?

Framework development for expert survey

We have started developing indicators for expert assessments for some elements pertaining to the supervision and enforcement of LSFF which have been highlighted through our work so far as being particularly challenging for countries to successfully implement. The tables below include very preliminary indicators on:

1. LSFF oversight and co-ordination
2. Legal authorisation for enforcement and inspections
3. Risk-based inspections

Please note that none of these are complete measurements of these items and that suggested indicators and scoring are very preliminary. They mainly serve at this stage as an illustration of the type of methodology we plan to employ. We will need to further refine the questions, indicators and scoring scheme building on comments of regulatory governance and food fortification experts as to obtain meaningful measurements.

Table 8.1. Table on Indicator 4. Measures and tools for overseeing, inspecting and enforcing LSFF

Preliminary sub-indicator 4.2 Legal framework for regulatory enforcement and inspections	
Short name	Legal background for enforcement and inspections
Relevant sub-principle(s)	To ensure compliance with quality requirements along the entire food fortification chain, regulatory enforcement and inspections by government agencies should be regulated by legal documents and integrated within food safety and quality.
List of Criteria	1. Legal provisions regulate enforcement of food fortification standards 2. Legal provisions regulate inspection of food fortification 3. Responsibilities of governmental institutions for inspection of food safety are described in regulatory documents 4. Responsibilities of governmental institutions for inspection of food fortification are described in regulatory documents 5. Food fortification and food safety control are integrated 6. Government inspectors are allowed to access the food management system documentation of businesses involved in food fortification
Approach	Q1) There is a legal provision which gives mandate for enforcement of food fortification to a government institution(s). Potential responses (choose only one): a) Yes (1 point) b) No (0 points)

	Q1a) If yes, please provide a scan/copy of the provision (and translation into English, if appropriate). Q2) There is a legal provision which gives mandate for inspection of food fortification to a government institution(s). Potential responses (choose only one): a) Yes (1 point) b) No (0 point) Q2a) If yes, please provide a scan/copy of the provision (and translation into English, if appropriate). Q3) There is a legal provision which gives mandate for enforcement of food safety to a government institution(s). Potential responses (choose only one): a) Yes (1 point) b) No (0 points) Q3a) If yes, please provide a scan/copy of the provision (and translation into English, if appropriate). Q4) There is a legal provision which gives mandate for inspection of food safety to a government institution(s). Potential responses (choose only one): a) Yes (1 point) b) No (0 point) Q4a) If yes, please provide a scan/copy of the provision (and translation into English, if appropriate). Q5) The responsibilities of government authorities are clearly defined in terms of food fortification-related inspections and enforcement. Potential responses (choose only one): a) Yes, without overlap. (1 point) b) Yes, with some overlaps. (0.5 points) c) No, responsibilities are not clearly defined and there is a lot of overlap. (0 points) Q6) The enforcement and inspection of food fortification is integrated within the enforcement and inspection of food safety. Potential responses (choose only one): a) Yes (1 point) b) No (0 point) Q7) There is a legal provision which allows inspectors to access food management system documentation of the business. Potential responses (choose only one): a) Yes (1 point) b) No (0 point) Q7a) If yes, please provide a scan/copy of the provision (and translation into English, if appropriate).
Sampling logic	No sampling
Data source(s)	Legal documents
Limits and bias of data Sensitivity to changes over time	X
Data validation and quality assurance	Country experts will collect evidence documents and verify the relevance and validity of the evidence documents. OECD will provide guidelines to experts to standardise experts' responses and ensure key terms are understood in the same way.
Comparability	New
Reference period/year	Not applicable
Periodicity of data and time of data release by government	Since the year 2000, but the published year of the legal documents should be identified.
Preliminary sub-indicator 4.3 Risk-based inspections are employed	
Short name	Risk-based inspections
Relevant sub-principle(s)	The legislation underlying the LSFF programme should enable risk-based targeting of inspections.
List of criteria	1. Legal provisions require that inspections to control food businesses are risk-based. 2. Government authorities in charge of food-related inspections classify food

	businesses according to their risk level (to determine the frequency of inspections). 3. Government authorities in charge of food-related inspections have access to sufficient data to determine the risk level of food businesses.
Approach	Q1) There is a legal provision to perform risk-based inspections in the food sector. Potential responses (choose only one): a) Yes, a risk-based approach is mandatory (1 point) b) Yes, a risk-based approach is allowed (0.5 point) c) No (0 point) Q2) This legal provision applies to food fortification. Potential responses (choose only one): a) Yes (1 point) b) No (0 point) Q2a) If yes to Q2: When was this provision was last updated? Q2b) If yes to Q2, please provide a scanned copy of the procedure (and translation in English, if applicable)? Q3) Government authorities in charge of food-related inspections effectively classify food businesses according to their risk level. Potential responses (choose only one): a) Yes, government authorities fully implement a risk-based approach (1 point) b) Yes, but only some risk criteria are being taken into consideration (0.5 point) c) No (0 point) Q3a) If yes, do authorities take into account food fortification when classifying food businesses according to their risk level? Potential responses (choose only one): a) Yes b) No Q3b) If yes, is this classification used to determine frequency of inspections? Potential responses (choose only one): a) Yes (1 point) b) No (0 point) Q5) Do authorities have data available to assess the risk level of food business? Potential responses (choose only one): a) Yes, sufficiently (1 point) b) Yes, some data but not sufficient (0.50 points) c) No (0 point) Q5a) If yes, please describe the type of data that is available and any shortcomings. Q6) Do authorities have the capacity to assess the risk level of food business based their track record or history of compliance? Potential responses (choose only one): a) Yes (1 point) b) Yes, partially (0.50 points) c) No (0 point) Q7) Do authorities use data to assess the risk level of food businesses based on data? Potential responses (choose only one): a) Yes (1 point) b) Yes, partially (0.50 points) c) No (0 point)
Sampling logic	No sampling
Data source(s)	Legal documents, inspection procedures, inspection plans
Limits and bias of data Sensitivity to changes over time	X
Data validation and quality assurance	Country experts will collect evidence documents and verify the relevance and validity of the evidence documents. OECD will provide guidelines to experts to standardise experts' responses and ensure key terms are understood in the same way.
Comparability	New
Reference period/year	One year
Periodicity of data and time of data release by government	Annually

Preliminary sub-indicator 4.4 Regulatory control is performed at appropriate points in food chain	
Short name	Points of control
Relevant sub-principle(s)	Inspections are performed at critical sites to ensure that food businesses comply with food fortification regulations.
List of Criteria	1. Legal provisions require that food fortification is controlled at the levels of production/processing, trade and import. 2. Inspection tools are in place to control food businesses. 3. Inspection tools indicate how food fortification is to be controlled at the level of production/processing, trade and import. 4. Inspections conducted at the levels of production/processing, trade and import are adequate to control compliance with food fortification regulation.
Approach	Q1) Legal documents specify that food-related inspections must take place at a universal level, at the levels of production/processing, trade and import. Possible responses (choose only one): a) Yes, all three levels/ yes, the legal provision requires universal food-related inspections. (1 point) b) Yes, only two levels. (0.75 point) c) Yes, only one level (0.25 point) d) No, legal documents do not specify at which level inspections should take place. (0 point) Q1a) If yes, please tick all that apply: a) At the level of production/processing b) At the level of trade c) At the level of import d) Universal inspections Q1b) If yes, please provide the legal document and the paragraph/page number this is to be found. Q2) Government authorities provide inspectors with inspection tools (e.g. inspections protocol, manual, checklist etc.) to control food businesses. Potential responses (choose only one): a) Yes. (1 point) b) No. (0 point) Q2a) If yes, inspection tools enable inspectors to verify compliance with food fortification regulations. Potential responses (choose only one): a) Yes, fully. (1 point) b) Yes, partially: these tools only apply to some regulations, and/or only some food categories. (0.5 point) c) No, these tools do not enable inspectors to control food fortification. (0 points) Q2b) If yes, please provide a scanned copy of the inspection tools which inspectors use to control food fortification, and a translation into English (if applicable). Q3. Inspections conducted at the production/processing level are adequate to control compliance with food fortification regulation. Potential responses (choose only one)*: a) Strongly agree (1 point) b) Agree (0.75 points) c) Neutral (0.50 points) d) Disagree (0.25 points) e) Strongly disagree (0 points) Q4. Inspections conducted at the trade level are adequate to control compliance with food fortification regulation. Potential responses (choose only one)*: a) Strongly agree (1 point) b) Agree (0.75 points) c) Neutral (0.50 points) d) Disagree (0.25 points) e) Strongly disagree (0 points) Q5. Inspections conducted at the import level are adequate to control compliance with food fortification regulation. Potential responses (choose only one)*:

	a) Strongly agree (1 point) b) Agree (0.75 points) c) Neutral (0.50 points) d) Disagree (0.25 points) e) Strongly disagree (0 points)
Sampling logic	No sampling
Data source(s)	Legal documents, inspection procedures, checklists/instructions for inspectors, reports, decisions, inspection plans, laboratory results
Limits and bias of data Sensitivity to changes over time	X
Data validation and quality assurance	Country experts will collect evidence documents and verify the relevance and validity of the evidence documents. OECD will provide guidelines to experts to standardise experts' responses and ensure key terms are understood in the same way. *Guidance will be provided for each question to ensure comparability.
Comparability	New
Reference period/year	One year
Periodicity of data and time of data release by government	Annually

Source: Own elaboration.

Annex B. Summaries of pilot country studies

Annex B presents findings from selected pilot country studies that investigated the policies and practices related to LSFF. The Annex contains five country fact sheets for Burkina Faso, India, Indonesia, Nigeria and Viet Nam. Each country fact sheet provides an overview regarding micronutrient deficiencies in the country and the nutritional landscape, relevant legislative and institutional framework, regulations identifying food fortification standards for staple foods and premixes, regulations ensuring industry compliance, measures and tools enforcing LSFF and incentivising key stakeholders. Each country fact sheet also includes a list of regulations that were reviewed during the pilot country studies.

Burkina Faso

Overview and nutritional landscape

Burkina Faso is a low-income, food-deficit West African country with a population of 22.7 million (World Bank, 2024[79]), of which more than 40% live below the poverty line. The country's economy mainly relies on agriculture and limited natural resources, including the recent development of gold mining. Recent terrorist attacks resulted in political instability, and significant population displacement in certain areas.

Micronutrient malnutrition is high and a 2021 survey (INSD and ICF, 2022[80]) found that 23% of children under five are stunted or chronically malnourished, while 7% of children have severe growth retardation. Stunting is disproportionately more prevalent in rural areas (26%) than in urban areas (14%), which remain very affected. Wasting affects 11% of children, including 2% severely wasted, while 18% of children under five are underweight, with 4% being severely underweight. Over half of women of reproductive age and children under the age of two are anaemic. An earlier dataset from 2010 found vitamin A and zinc deficiencies in more than 50% of children under five and 17% of women. In 2014, only 23% of households consumed adequately iodised salt. Salt is mostly imported from Ghana and Senegal and weak import controls as well as unofficial importations purportedly caused a decline in household consumption of iodised salt in recent years.

Until 2023, the country was an active member of the West African Economic and Monetary Union (WAEMU), from which it was suspended due to political reasons, and of the Economic Community of West African States (ECOWAS), from which it withdrew in early 2024. The latter supports free trade between member countries through the adoption of regional standards based on international recommendations. Burkina Faso's edible oils producers and the biggest millers belong to the professional ECOWAS associations which are committed to food fortification under WAEMU's health policy. The National Multisectoral Nutrition Policy (PNMN) 2020–29 and the Multisectoral Strategic Nutrition Plan 2020-24, aim at addressing micronutrient deficiencies and anaemia in children, as well as strengthening maternal nutrition and nutrition governance.

Legislative and institutional framework

Several ministries and official control agencies oversee food fortification. These include:

- the Ministry of Agriculture through the Directorate of Plant Protection and Packaging (DPVC);
- the Ministry of Trade and Industry through the Burkinabè Agency for Standardisations, Metrology and Quality (ABNORM);
- the Ministry of Health through the National Agency for Environmental, Food, Labour, and Health Product Safety (ANSSEAT, formerly the National Public Health Laboratory); and
- the Ministry of Economy and Finance through the General Directorate of Customs (DGD).

At the production level, ANSSEAT is responsible for inspecting manufacturing facilities and for sampling finished products, both of which lead to issuing Sanitary Quality Certificate to the premises. ABNORM also carries out on-site inspections and sampling of food products for laboratory testing, in order to grant authorisation for distribution. Commercial control is performed by ABNORM and by the Mobile Brigade of Economic Control and Fraud Repression (BMCRF). At the import level, DPVC controls iodised salt and is responsible for phytosanitary controls, while ANSSEAT controls other food categories. Customs procedures and clearance are performed by DGD. In case of suspected fraud, BMCRF can carry out independent controls and impose measures, at all three levels (production, commercial and import).

Rising crisis and insecurity in recent years presented serious challenges to official controls and led to their suspension in the most dangerous parts of the country. In addition, budget lines for official control missions have been severely reduced, while human capacities remain limited across official control agencies. Testing laboratories of ABNORM and ANSSEAT have insufficient equipment, testing kits, human capacities and training. Rapid testing of wheat flour for iron fortification is suspended due to shortage of testing kits.

The National Fortification Alliance was established in 2014 to foster collaboration and information sharing between public and private stakeholders. It is presided by the Ministry of Health with the Ministry of Commerce and Industry serving as vice-chairs.

Regulations identifying fortification standards: Staple foods and premixes

The government adopted food fortification standards in 2010, following regional standards issued by WAEMU and aligned with WHO guidelines for salt iodisation and the fortification of wheat flour and vegetable oil. National standards for wheat flour and vegetable oil were adjusted to individual adult consumption. Food fortification is essentially regulated by two joint ministerial decrees:

1. The decree 2012-0232/MICA/MS/MEF/MAH mandates fortification of refined vegetable oils with vitamin A and wheat flour with iron and folic acid. In addition to regulating fortification, it defines quality assurance procedures through laboratory testing and control.
2. The decree 2013-1033/MS/MASA/MEF/MIC regulates the importation, commercialisation, and consumption of iodised salt.

The decrees require imported products to meet national standards for fortified wheat flour, salt, and edible oils. They also provide for the possibility to voluntary fortify wheat flour with other B-group vitamins and zinc. Regional standards for labelling and accreditation of laboratories have been adopted in Burkina Faso, to support free import/export of food. The use of the regional “ENRICHI” logo is also recommended.

Ensuring industry compliance

Regional guidance exists to support industry compliance with fortification requirements and government officials in conducting respective controls, however it is not utilised. There currently exist no government led incentives to support producer compliance with fortification standards in particular: i) the risk level of businesses is not taken into account in determining the frequency of inspections; ii) local supply of micronutrient premixes is irregular, and manufacturers must purchase them individually, mostly from

Europe, leading to logistical difficulties and higher costs reflected in product price; iii) premixes are subject to import tax; iv) no subsidies or loans are offered for the purchase of fortification equipment.

Measures and tools for enforcing LSFF

The Ministry of Health has adopted a checklist covering food quality, safety and fortification, to serve as a reference for ABNORM agents when performing official inspections. The current enforcement framework outlines the necessity for regular inspection visits, although in practice, controls are sporadic and primarily conducted upon request. Control procedures are not harmonised among official control agencies, leading to duplications and discrepancies in regulating various aspects such as food hygiene, handling and fortification practices. Similarly, sanctions are mandated by different legal documents and are hence lacking consistency. This lack of cohesion allows for the possibility of sanctioning the same non-compliance multiple times, as results are not communicated among control agencies. Moreover, sanctions do not appear to be sufficiently coercive and consistently applied.

Way forward: Incentivising key stakeholders

Improvements in regulatory inspections can help the government better address challenges faced by food fortification initiatives. Opportunities for improvement include:

- reducing duplications in official controls,
- implementing risk-based, regular controls by trained inspectors, equipped with tools for rapid testing,
- and rolling-out a common approach to control food safety, quality, and fortification by official control agencies.

Well-targeted inspections, along with an evidence-based sampling plan, could reduce the costs of official control. Regular access to rapid testing may reduce the need for sampling and lab testing. Building capacities in official testing laboratories could increase accuracy of results. Sanctions, if applied in line with risk level, can help promote compliance. Additional incentives, such as access to knowledge on fortification processes and government incentives to lower operational costs, can further contribute to improving the compliance of businesses with existing regulations.

List of regulations reviewed

1.	Law No. 22-2005 on the Public Health Code.
2.	Joint Order N° 128/MS/MCPEA/MEFM.Agri./MATD of April 26, 2002, on the creation and responsibilities of the Steering Committee for micronutrient fortification programmes and projects.
3.	Joint Decree No 2003-189/MS/MAHRH/MATD/SECU/MFB/MPCE of August 18, 2003, on the regulation of the importation, marketing, and use of salt.
4.	Law No. 011-2007/AN on the establishment of a national system of standardisation, certification, accreditation and promotion of quality, promotion of quality.
5.	Order No 2010-102/MCPEA/SG/ONAC of July 1, 2010, on the approval of standards for refined vegetable oils fortified with vitamin A, and soft wheat flour fortified with iron and folic acid.
6.	Regulation No. 03/2010/CM/UEMOA of June 21, 2010, on the harmonisation scheme for accreditation, certification, standardisation, and metrology activities in the WAEMU.
7.	Decree N°2011- 0264/MICA/MEF/MS/MEDD/MFPTSS on the regulation of vegetable oil production industries establishment.
8.	Joint decree N°2011- 0265/MICA/MEF/MS on the characteristics of vegetable oils.
9.	Inter-ministerial decree No 2012-0232/MICA/MS/MEF/MAH of October 30, 2012, on compulsory fortification of refined vegetable oils with vitamin A, and soft wheat flour fortified with iron and folic acid.
10.	Inter-ministerial order No 2013 -1033/MS/MASA/MEF/MICA of September 27, 2013 regulating the import, marketing, and use of salt.

11.	Decree No. 2018-0860-PRES-PM-MCIA-MINEFID establishing the list of products subject to special import and export authorisation (edible oils, wheat flour, sugar, etc.).
12.	Decree N° 2014/597/MS/MICA/MEF/MASA of June 24, 2014, on the creation, attributions, organisation, composition and functioning of the National Alliance for Food Fortification (ANF-BF).
13.	Inter-ministerial order No. 2023-00636/MDICAPME/MSHP/MEFP, defining the features and conditions of the distribution and marketing of edible oils for consumption in Burkina Faso.
14.	Inter-ministerial order no. 2023-00638/MDICAPME/MSHP/MEFP/MEEA/MFPTPS on the installation and operation of edible oil production units in Burkina Faso

India

Overview and nutritional landscape

India is one of the fastest growing economies globally, with real GDP for the financial year 2022-23 estimated at 6.9% (World Bank, 2024[81]). Micronutrient deficiencies pose a major challenge for its population of over 1.4 billion, the world's largest (Ministry of Health and Family Welfare of India, 2021[82]). Country-wide surveys conducted under the Ministry of Health and Family Welfare of India, highlight improvements over the past decade in nutritional indicators like children under 5 years who are stunted, or wasted or underweight etc. However, the latest information on the nutritional status of India shows that there are 25 of the 36 States and Union Territories where prevalence of anaemia among women is more than 50% while for 29 of the 36 States and Union Territories the prevalence is more than 50% among children (Ministry of Health and Family Welfare of India, 2021[82]). One of the ways in which India addresses nutritional inadequacies is by fortification of staple foods. Food fortification in India is not mandatory, except for fortification of salt with iodine and iron. For other staple foods, standards for fortification exist, thus making India a country with voluntary regulated system for fortification of identified food vehicles. The Government of India has taken stock of the nutritional requirements of the demography and emphasised the need for fortified foods to be distributed across all government led safety-net programmes by 2024.

Legislative and institutional framework

In 2006, the Indian government created one consolidated legislation addressing food safety, the Food Safety and Standards Act, establishing the Food Safety and Standards Authority of India (FSSAI) to regulate the sector. The FSSAI, as per the recommendations and scientific opinions of its expert panels, sets standards for food safety, including standards for the addition of micronutrients to foods and further, ensures that food business operators comply with these standards. In 2017, the FSSAI constituted a scientific panel on food fortification and nutrition, to identify nutritional gaps in the general Indian diet, and specific target groups. As of 2021-22, there are Scientific Panels dedicated to Nutrition and Fortification as well as for Methods of Sampling and Analysis (Food Safety and Standards Authority of India, 2022, p. 23[83]), which started formulating methods to test for compliance to these standards. The FSSAI also provides licences and registration to all food business operators (FBOs), as required by the Food Safety and Standards Act, 2006. The law governing the licensing and registration procedures for food safety and standards in India is the Food Safety and Standards (Licensing and Registration of Food Businesses), Regulations, 2011.

Regulations identifying fortification standards: Staple foods and premixes

In 2016, the FSSAI operationalised the Food Safety and Standards (Fortification of Foods) Regulations. In April 2022, further amendments relaxed minimum micronutrient requirements. These regulations specify standards for fortification of staple food articles, namely wheat flour and rice (with iron, vitamin B12 and folic acid), milk and edible oil (with vitamins A and D) and salt (with iodine and iron). While it is not mandatory to fortify foods, all FBOs are required to adhere to these standards if they choose to fortify their

food products. Salt is an exception and has been mandatorily fortified with iodine since the 1950s. A detailed regime for regulating premixes is in the stages of development. As of now, only standards for vitamins and mineral premixes for manufacturing fortified rice kernels (FRK) have been issued by the Bureau of Indian Standards (BIS). The FSSAI has adopted standards for vitamin and mineral premix used to manufacture fortified rice kernels in the context of the national fortification programmes (FSSAI, 2023[84]).

Ensuring industry compliance

The enforcement of the regulations pertaining to standards for fortification of staples is undertaken by the FSSAI and State Food Safety Authorities. It includes implementation of regulations which specify the processes and documentation required to obtain and maintain a license. Upon acquiring a license, the manufacturer can endorse and display the logo for identification of fortified foods, i.e., '+F' on its labels which must follow the requirements as specified by law (FSSAI, 2020[85]).

In September 2021, the FSSAI digitised all food enforcement activities under the platform – Food Safety Compliance System (FoSCoS). Details of all enforcement related activities, including adjudication and penalties, audit management systems, annual returns of food business operators are now on the FoSCoS. The system also assists FBOs to apply for license/registration certificate and track their applications. The samples are tested in laboratories recognised by the FSSAI. If a sample is found to be non-compliant, then sanctions are imposed as per the law. Appeals against such sanctions lie in the food safety appellate tribunals and further high courts of the country (Ministry of Law and Justice of India, 2006[86]). The enforcement machinery of FSSAI and State Food Authorities oversees compliance with the standards outlined in the Food Safety and Standards (Fortification of Foods) Regulations, 2018, through routine inspections and sampling. Further, as a preventive measure to mitigate risks, the manufacturing of food under the category of Fortified Rice Kernel is included in the high-risk category of the risk-based inspection schedules, thereby enabling authorities to prioritise inspections of premises belonging to Food Business Operators (FBOs) involved in high-risk food categories. Pre-license inspections are mandatory before the issuance of a license under this category, ensuring thorough scrutiny and adherence to regulatory compliances.

Measures and tools for enforcing LSFF

The Constitution of India mentions the duty of the government to raise the level of nutrition, but until 2013, there was no justiciable right to food flowing from any legislation. There has been a welfare system for distribution of food grains at affordable prices in place since the independence of India, the Public Distribution System (PDS). The National Food Security Act came into effect in 2013, specifying "life-cycle approach" as one of its guiding principles, wherein special provisions have been made for pregnant women and lactating mothers and children in the age group of 6 months to 14 years. They can receive nutritious meal free of cost through a widespread network of centres, called *Anganwadi* Centres. Moreover, the *Pradhan Mantri Poshan Shakti Nirman* (PM POSHAN), a centrally sponsored scheme launched in March 2018, lays emphasis on the nutritional status of children from the ages 0 to 6 years, adolescent girls, pregnant and lactating women. To further support voluntary fortification, nutrition-centric annual community gatherings, called *Jan Andolans*, have been organised under the PM POSHAN, while the months of September and March have been dedicated to raising awareness on nutrition and are celebrated as *Rashtriya Poshan Maah* (National Nutrition Month) and as *Poshan Pakhwada* (Nutrition Fortnight) respectively.

Way forward: Incentivising key stakeholders

Thus far, the adoption of the practice of fortifying staples has been on a voluntary basis. Financial incentives, including for instance tax incentives or business subsidies which may incentivise food business operators to engage in fortification have not been put in place until now. Moreover, setting up manufacturing units for

fortification of certain staples, like rice, is a capital-intensive business and this acts as a barrier to entry for smaller-scaled food business operators. Under the country's national nutrition mission, field workers are given certain targets for home visits to beneficiaries, growth monitoring, sensitisation on nutritional value of foods etc. On meeting such targets, they become eligible for incentives as specified by the Ministry of Women and Child Development (Ministry of Women and Child Development of India, 2022[87]), including cash awards ranging between EUR 445 to EUR 556 (Ministry of Women and Child Development of India, 2022[88]). Monetary awards are also available for villages on reaching certain milestones, such as becoming '*Kuposhan Mukt'* villages, i.e., becoming villages without malnutrition. A sum of EUR 1 111 580 per annum has been allotted for such awards and villages which qualify as free from malnutrition are awarded EUR 1 111 each from the sum allotted for such awards.

Established players in the market are gradually taking up the practice of fortifying staples since there is a demand from the government. In fact, the government has announced that by 2024, all its safety net programmes will mandatorily distribute only fortified staples, which has acted as a soft incentive for those FBOs having significant capital and capacity to take up the practice of food fortification.

List of regulations reviewed

	Legislations
1.	Food Safety and Standards Act, 2006
2.	Food Safety and Standards (Licensing and Registration of Food Business) Regulations, 2011
3.	Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011
4.	Food Safety and Standards (Packaging and Labelling) Regulation, 2011 *Superseded by the Food Safety and Standards (Labelling and Display) Regulations, 2020
5.	Food Safety and Standards (Laboratory and Sampling Analysis) Regulation. 2011
6.	Food Safety and Standards (Fortification of Foods) Regulation, 2016 *Replaced by the Food Safety and Standards (Fortification of Food) Regulation, 2018 as applicable, after amendment by Food Safety and Standards (Fortification of Foods) First Amendment Regulations, 2021 and Food Safety and Standards (Fortification of Foods) Second Amendment Regulations, 2021
7.	Food Safety and Standards (Food Recall Procedure) Regulation, 2017
8.	Food Safety and Standards (Food Safety Auditing) Regulation, 2018
9.	Food Safety and Standards (Recognition and Notification of Laboratories) Regulation, 2018
10.	Food Safety and Standards (Prohibition and Restriction of Sales) Regulation, 2011
11.	Food Safety and Standards (Contaminants, Toxins and Residues) Regulation, 2011
12.	Food Safety and Standards (Health Supplements, Nutraceuticals, Food for Special Dietary Use, Food for Special Medical Purpose, Functional Food and Novel Food) Regulations, 2016
13.	Food Safety and Standards (Food Recall Procedure) Regulation, 2017
14.	Food Safety and Standards (Import) Regulation, 2017
15.	Food Safety and Standards (Approval for Non-Specific Food and Food Ingredients) Regulation, 2017
16.	Food Safety and Standards (Safe food and balanced diets for children in school) Regulations, 2020
17.	FSSAI (Transaction of Business at its Meetings) Regulations, 2010
18.	FSSAI (Procedure for Transaction of Business of the Central Advisory Committee) Regulations, 2010
19.	FSSAI (Salary, Allowances and Other Conditions of Service of Officers and Employees) Regulations, 2013
20.	FSSAI (Transaction of Business and Procedure for the Scientific Committee and Scientific Panel) Regulations, 2016
21.	FSSAI (Recruitment and Appointment) Regulations, 2018
22.	FSSAI (Financial) Regulations, 2023
23.	Food Categorization Code, 2012
24.	Bureau of Indian Standards Act, 2016
25.	The Bureau of Indian Standards Rules, 2018
26.	Food Safety and Standards Act, 2006

Government Notifications/Orders/Letters

1.	Operationalisation of Food Safety and Standards (Fortification of Foods) Regulations, 2016, relating to standards for fortification of food, File No. 11/03/Reg/Fortification/2014 dated 17 November 2016
2.	Operationalisation of Food Safety and Standards (Fortification of Foods) Regulations, 2016, relating to standards for fortification of food, File No. 11/03/Reg/Fortification/2014(pt.1) dated 19 May 2017
3.	Directions regarding 'Health Claims' permitted under the Food Safety and Standards (Fortification of Foods) Regulations, 2016, File No. Standards/SP (Fortified & Enriched Foods)-02/FSSAI-2017 (Part File-1), dated 22 December 2017
4.	Direction regarding permission for use of stickers/stamping of fortification logo on the labels, File No. REG-17/Fortification-stickers/FSSAI-2017, dated 19 January 2018
5.	Direction regarding operationalisation of Food Safety and Standards (Fortification of Foods) Regulations, 2018 relating to standards for fortification of food, File No. 11/03/Reg/Fortification/2014 (pt. III), dated 10 May 2018
6.	Order on Endorsement for +F logo within the FLRS –reg., File No. F.29014/FSSAI/FICS-FLRS/WORK IN I&T/2016, dated 21 August 2018
7.	Letter on Licensing/Registration of Premix under FSS Act, 2006 – reg., File No. 12(12)2018/Fortification/RCD/FSSAI, dated 17 September 2018
8.	Direction regarding operationalisation of the Food Safety and Standards (Food Products Standards and Food Additive) Amendment Regulations, 2020, relating to standards for fortified atta, fortified maida, iodised salt and iron fortified iodised salt, dated June 2020
9.	Exclusion of Food Category "13" (Foodstuffs intended for particular nutritional uses) from the scope of Proprietary Foods, File No. 15(15)2018/CLAs/RCD/FSSAI, dated 6 November 2020
10.	Direction regarding the allowances of encapsulated ferrous sulphate as one of the source nutrients for double fortified salt under the Food Safety and Standards (Food Products Standards and Food Additives) Regulations, 2011, dated 29 January 2021
11.	Clarification on the Food Safety and Standards (Fortification of Foods) First Amendment Regulations, 2020 related to the exclusion of High Fat Sugar Salt (HFSS) Foods from Fortified Processed Foods category, dated February 2021
12.	SOP for applying for +F Endorsement Certificate for Fortified food products in FoSCoS, 45/+F logo/FFRC/Fortification/FSSAI-2019, dated 12 April 2021
13.	Revised SOP for applying +F Endorsement Certificate for Fortified Food products in FoSCoS-reg., File No.- 15(31)2020/FoSCoS/RCD/FSSAI pt.8, dated 31 May 2022
14.	Direction regarding operationalisation of Draft Food Safety and Standards (Food Product Standards and Food Additives) Amendment Regulations regarding the standards of Fortified Rice Kernel, F.No. STD/FA/38/FSSAI, dated 23 June 2022
15.	Order on Referral Food Laboratories is notified by FSSAI under Section 43(2) of the FSS Act, 2006, File No. QA-12013/7/2021-QA-FSSAI, dated 1 July 2022
16.	Order on Validity of FSSAI recognised Food Testing Laboratories, File No. AQ-12012/2021-RARD-FSSAI, dated 4 July 2022
17.	Order on compliance with respect to time limit for analysis of samples by FSSAI notified laboratories, File No. QA-12015/22/2021-QA-FSSAI, dated 12 July 2022
18.	Order on compliance with manuals of the method of analysis published by FSSAI for analysing the samples of food articles by FSSAI notified laboratories-reg., F.No. QA-12015/22/2021-QA-FSSAI (E. No. 4039), dated 13 July 2022
19.	Office Memorandum on removal of Food Safety Supervisor (FSS) Certificate validity, File No. T-17014/3/2021-Training-FSSAI, dated 21 July 2022
20.	Office Order related to appointment of Designated Officer (DOs) for Central Licensing at Seaport / Airport, F.No. RCD-10002/1/2022-Regulatory-FSSAI, dated 22 July 2022
21.	Office Order related to appointment of Designated Officer (DOs) for Central Licensing, File No. RCD-05007/2/2021-Regulatory-FSSAI, dated 22 July,2022
22.	Order related to extension of recognised NRLs and ANRLs, File No. QA-12015/28/2022-QA-FSSAI, dated 28 July 2022
23.	Validity Order of FSSAI recognised Food Testing Laboratories, File No. QA-12012/1/2021-RARD-FSSAI, dated 5 August 2022
24.	Notification of important guidelines in reference to the old and new FoSTaC portal, File No. T-15012/27/2022-Training-FSSAI (E file: 6829), dated 22 August 2022
25.	Letter regarding Quarterly Training Calendar (October to December 2022) – Training of Trainers programme under FoSTaC programme, F.No. T-15012/5/2021-Training-FSSAI, dated 13 September 2022
26.	Order regarding approved test methods for detection of Iron, Folic Acid and Vitamin B12 in Fortified Rice, File No. 11014/02/2021-QA, dated 8 September 2022
27.	Order on revision of inspection checklists, File No.- 15(31)2020/FoSCoS/RCD/FSSAI pt 1-part (2), dated 2 November 2022
28.	Letter regarding Quarterly Training Calendar (January to March 2023) – Training of Trainers programme under FoSTaC programme, F. No. T-15012/5/2021-Training-FSSAI, dated 8 December 2022
29.	Notice related to Expression of Interest (EoI) for Empanelment of Training Partners under Food Safety Training & Certification (FoSTaC) Programme, T-15012/26/2022-Training-FSSAI, dated 21 December 2022
30.	Order related to Suspension of FSSAI Notified Laboratories for not uploading of test reports on INFoLNET 2.0, F. No. QA-12015/1/2021-RARD-FSSAI-Part (2), dated 22 December 2022
31.	Order related to Ease of Doing Business: Instant Modification of License - in case of addition / deletion of non-high risk standardised food products in the existing license by Manufactures, File No. – RCD-01003/2/2022-Regulatory-FSSAI, dated 29 December 2022

32.	Notice related to Approval of Rapid Analytical Food Testing (RAFT) Kit/Equipment/Method along with Application Form, File No.11014/06/2021-QA, dated 9th January 2023
33.	Order relating to Ease of Doing Business: Instant Renewal of License/Registration-reg., File No. – 15(31)2020/FoSCoS/RCD/FSSAI pt1-part (4), dated 11 January 2023
34.	Order relating to Manufacturers [including Repacker and Relabellers] to upload or link mandatory Lab Testing Report [Six-monthly] on FoSCos, File No.-15(31)2020/FoSCoS/RCD/FSSAI pt 1-Part (1), dated 13 January 2023
35.	Order relating to De-recognition and de-notification of in-house testing laboratories of Food Business Operators, File No. QA-12015/17/2021-QA-FSSAI, dated 14 February 2023
36.	Validity Order of Food Testing laboratories, File No. QA-12012/1/2021-RARD-FSSAI, dated 9 March 2023
37.	Direction regarding re-operationalisation of Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations with respect to the standards of Fortified Rice Kernel, F. No. SS-T010/1/2023-Standard-FSSAI, dated 11 April 2023
38.	Clarification on format of test reports i.e., 'Report of the Food Analyst' (for primary notified laboratory) and 'Certificate of Analysis by the Referral Food Laboratory', File No. QA-11023/31/2022-QA-FSSAI, dated 13 April 2023
39.	Protocol to all the notified laboratories to reinforce the prescribed method for fortificants testing, dated 30 May 2023
40.	Advisory on Shelf life of Fortified Rice and Fortified Rice Kernel-reg., F.No. IEC-34011/1/2021-IEC-FSSAI (E-2194), dated 2 August 2023
41.	Order relating to list of Labs capable of testing Fortified Rice (FR), Fortified Rice Kernel (FRK) and Premix for FRK, QA-11023/9/2022-RARD-FSSAI-Part (1) (E-8226), dated 13 October 2023
42.	Order relating to revised List of Labs capable of testing Fortified Rice (FR), Fortified Rice Kernel (FRK) and Premix for FRK, QA-11023/9/2022-RARD-FSSAI-Part (1) (E-8226), dated 19 October 2023
43.	Order relating to revised List of Labs capable of testing Fortified Rice (FR), Fortified Rice Kernel (FRK) and Premix for FRK, QA-11023/9/2022-RARD-FSSAI-Part (1) (E-8226), dated 26 October 2023
44.	Order relating to mandatory uploading of the test reports of the samples of Fortified Rice Kernel (FRK) and Vitamin-Mineral Premix for Fortified Rice Kernel on the Infolnet portal by FSSAI notified laboratories, QA-11023/9/2022-RARD-FSSAI-Part (1) (E-8226), dated 31 October 2023
45.	Order relating to direction regarding source of iron salts prescribed for vitamin and mineral premix and Fortified Rice Kernel (FRK), File No. STD/SP-18/MISC/2023-Part (1), dated 30 October 2023
46.	Order relating to revised list of FSSAI notified laboratories for testing of fortificants in Fortified Rice (FR), Fortified Rice Kernel (FRK) and Vitamin-Mineral Premix for Fortified Rice Kernel, QA-11023/9/2022-RARD-FSSAI-Part (1) (E-8226), dated 2 November 2023
47.	Order relating to strengthening the Quality Control Mechanism of Fortified Rice, Fortified Rice Kernels [FRK] and Premix for FRK, File No. IEC-34011/1/2021-IEC-FSSAI-Part 6, 8 November 2023
48.	Order regarding approved test methods for detection of Iron, Folic Acid & Vitamin B12 in Fortified Rice Kernel, File No. 11014/07/2021-QA, dated 8 November 2023
49.	Order regarding mandatory uploading of the test reports with source of iron in Fortified rice (FR), Fortified Rice kernel (FRK) & Vitamin Premix for FRK samples on the InFoLNet portal by FSSAI approved laboratories, File No. QA-11023/9/2022-RARD-FSSAI, dated 16 November 2023
50.	Guidelines on sampling of Fortified Rice Kernels (FRK) and Fortified Rice (FR), File No. QA-11023/9/2022-RARD-FSSAI, dated 16 November 2023
51.	Guidelines on sampling of Fortified Rice (FR), Fortified Rice Kernels (FRK) and Vitamin Mineral Premix for FRK, File No. QA-11023/9/2022-RARD-FSSAI, dated 17 November 2023
52.	Direction 2006 regarding operationalization of Draft Food Safety and Standards (Food Products Standards and Food Additives) Amendment Regulations w.r.t. the standards of Vitamin and Mineral Premix for manufacturing of FRK, File No. SS-T0SP18(SG)/1/2023-Standard-FSSAI-Part (1), dated 17 November 2023
53.	Order regarding QR code on test reports issued for Fortified rice (FR), Fortified Rice kernel (FRK) & Vitamin Premix for FRK, F. No.QA-11023/9/2022-RARD-FSSAI (E-4935), dated 13 December 2023
54.	Validity Order of FSSAI notified laboratories, QA-12012/1/2021-RARD-FSSAI, dated 24 January 2024
55.	FSSAI User Manual for Manufacturer of Premixes for FRK

Indonesia

Overview and nutritional landscape

Indonesia is the largest economy in Southeast Asia. Consisting of a diverse archipelago and ethnic groups, the country succeeded in halving the poverty rate between 1999 and 2019 (World Bank, 2024[89]). In line with Presidential Regulation 72/2021 on Strategy for Acceleration of Stunting Prevention, the Indonesian Nutrition Status Study (*Studi Status Gizi Indonesia*, SSGI) is carried out annually by the Ministry of Health to assess the nutritional status of children under five, teenage girls, women of reproductive age and pregnant women, and its determinants at the national, provincial, and regency/municipality levels. In

Indonesia, although some maternal and child malnutrition indicators demonstrate a decreasing trend, micronutrient deficiencies remain a challenge (Global Nutrition Report, 2022[90]). As per the 2023 Indonesian Health Survey, 27.7% of pregnant women and 23.8% of children aged 6-59 months suffer from anaemia (Kemenkes BKPK, 2023[91]).

In Indonesia, food fortification has been identified as one of the ways to address micronutrient deficiencies. Hence, the National Action Plan of Food and Nutrition 2021-2024 (RAN-PG 2021-2024) includes food fortification as part of the national programme to improve nutritional state of citizens. Mandatory salt fortification has been implemented since 1994 while mandatory wheat flour fortification and palm cooking oil fortification initiated in 2001 and 2019, respectively.

Legislative and institutional framework

The current development planning in Indonesia is regulated by Law 25/2004 and consists of the national long-term (20 years), mid-term (5 years) and annual development plans, and is co-ordinated by the Ministry of National Development Planning/National Development Agency (BAPPENAS). To co-ordinate food and nutrition sector plans in line with the national development plans, Law 18/2012 concerning foods has mandated the formulation of the Action Plans on Food and Nutrition at national (RAN-PG) and regional (RAD-PG) levels. The current Action Plans on Food and Nutrition at national (2021-2024) and regional (ranging from 2021-2026) levels are developed in line with the national mid-term plan and feature food fortification as a policy priority. This is expected to continue in the future as the new national long-term development plan 2025-2045 includes food fortification as a public health strategy to address micronutrient malnutrition and create a sustainable, health and resilient food system (Government of Indonesia, 2024[92]).

The strengthening of the food fortification programme in Indonesia is led by the Ministry of National Development Planning/National Development Agency (BAPPENAS) with the participation of several government institutions. The Ministry of Health's role is to advise on the foods to be fortified by providing nutritional status data as well as the micronutrients to be added. The consultation also involves food experts, who contribute to determining food vehicles and fortificants. The Indonesian Food and Drug Authority (BPOM) supervises food safety and quality including of fortified wheat flour, palm cooking oils and iodized salt. The National Food Agency (BAPANAS) is mandated to ensure the supply and distribution of rice through its Rice Food Aid program.

Regulations identifying fortification standards: Staple foods and premixes

The National Standardisation Agency (BSN) develops Indonesian National Standards (SNI) for fortified products, stipulating food vehicles, premixes, and the minimum fortification level (minimum quantity of micronutrients to be added), while the maximum fortification level is not defined. According to Law 20/2014, the implementation of SNI can be voluntary or mandatory. For fortified foods, compliance with SNI is mandatory, when specifically mandated through Ministerial regulation.

Currently, three types of foods are subject to mandatory fortification with micronutrients: wheat flour with iron, zinc, folic acid, vitamin B1 and B2 (SNI 3751:2018, MoI 1/2021); palm cooking oil with vitamin A and/or provitamin A (SNI 7709:2019, MoI 46/2019), and salt with iodine (SNI 3556:2016 SNI 3556:1994 through MoI 29/M/SK/1995).

According to the Ministry of Trade No. 7 of 2024 on the Second amendment to the regulation of the Ministry of Trade No. 36 of 2023 on Import Policies and Regulation importers of the fortificant follow general policies in this regulation. The Indonesian Food and Drug Authority (BPOM) regulates the Import Permit (Surat Keterangan Impor) for vitamin and mineral.

Ensuring industry compliance

Industry compliance is verified through self-monitoring of product quality by fortified food producers as well as inspections of the product conformity by government inspectors. Producers must obtain business licenses for producing fortified foods by the Ministry of Industry. The Online Single Submission (OSS) is used for the authorisation of business licensing, and it applies a risk-based licensing approach. The business activities are classified into three levels and different level of licenses which are given to manufacturers of (i) low risk: business identification number (NIB), (ii) medium risk: NIB and standard certificate, (iii) high risk: NIB and a permit. In addition to business licenses, the Indonesian Food and Drug Authority (BPOM) mandates that fortified food producers, even small-scale producers, must undergo marketing authorization and obtain a Market Authorisation (*Nomor Izin Edar dan Izin Penerapan Cara Produksi Pangan Olahan yang Baik*) through an online system built by the Indonesian Food and Drug Authority (BPOM) which is integrated in the OSS. Wheat flour, palm cooking oil and salt producers need to acquire a Certificate of SNI-Certified Product (SPPT-SNI) by passing product quality tests and audit process. This certificate also allows the manufacturers to distribute their product in the country.

Mandatory food fortification products such as salt, wheat flour, and palm cooking oil, have different labelling requirements than other food products. Food fortification labelling that includes the food category as mentioned in SNI, premix's name, the minimum fortification level and relevant SNI marking, whereas only relevant SNI marking is necessary for fortified wheat flour and palm cooking oil. Labelling and traceability are challenged in settings where fortified palm cooking oil is sold in bulk, i.e., where traders bring own containers and resell to consumers directly who also bring their own containers or packing in unproper packaging. However, the Indonesian government has tried to reduce cooking oil in bulk by establishing regulations on the people's cooking oil to manage the distribution.

To increase the compliance of food business operations, the Indonesian Food and Drug Authority (BPOM) also provides capacity building, such as assistance and training, to improve human resource competence and the production process. In addition, BPOM also conducts several activities to increase stakeholders' participation in the following up on the monitoring results.

Measures and tools for enforcing LSFF

The Industry Standards Inspector (*Petugas Pengawas Standar Industri*: PPSI) under the Ministry of Industry carries out the monitoring of the compliance with the regulations that enforce the Indonesian National Standards (SNI) on a mandatory basis. PPSI also inspects documents and the sampling conducted by the Sample Collector Officer (*Petugas Pengambil Contoh:* PPC). Inspections are conducted periodically and/or on special occasions at factory and market level. Factory inspection consists of document checking and sample taking. Sampling is done to inspect production process and quality control which includes inspection of the product marketed and conformity testing of the product quality according to the Indonesian National Standards (SNI). The Industry Standards Inspector (PPSI) send samples to a laboratory accredited and/or appointed by the Ministry of Industry. The Indonesian Food and Drug Authority (BPOM) holds responsibility for food safety and quality, including ensuring compliance with food fortification requirements. To execute its responsibilities, BPOM conducts both pre-market and post-market controls. Pre-market control involves the registration of food product including evaluation on requirement safety and quality standard, which results in the issuance of a Market Authorisation Number (Nomor Izin Edar). This permit authorises food producers to distribute their products in the domestic market. The pre-market control process includes inspection of facilities to confirm compliance with good manufacturing practices (GMP) by the issuance of the GMP Certificate (*Izin Penerapan Cara Produksi Pangan Olahan yang Baik*). The Indonesian Food and Drug Authority (BPOM) also conducts post-market control in order to verify compliance with fortification requirements through facilities inspection, product sampling and testing. BPOM regularly takes product samples from the market covering businesses of all sizes and across all provinces in Indonesia.

The Indonesian Food and Drug Authority (BPOM) plays a leading role in enforcing fortification requirements for wheat flour, palm cooking oil and iodized salt alongside with the Ministry of Industry, which regulates fortification of these three staple foods and enforce the implementation of SNI. Enforcement measures include issuing written notices and imposing administrative sanctions such as fines, temporary suspension of production and distribution activities, compensation, and license revocation. These sanctions range from lighter to stricter measures, depending on severity of non-compliance. Criminal liability serves as a final recourse if it is caused by criminal intention.

Way forward: Incentivising key stakeholders

Under the initiative of the Ministry of Social Affairs, social assistance programmes (*Bantuan Sosial*, Bansos) have been implemented and distribute fortified palm cooking oil and fortified wheat flour to lower income households and vulnerable household such as families with pregnant and lactating women, children till 6 years old, students in elementary, middle and high schools, as well as children 6-21 years old who have not completed formal education, and elderly (60 years old or above), and disabled people. The integration of fortified food products as an in-kind item of social assistance programmes could lead to foster public-private partnership and motivate industry to engage in fortified food production.

The recent advancement of forming a National Food Fortification Coordination Forum (*Forum Koordinasi Fortifikasi Pangan Nasional*) would facilitate co-ordination across different ministries and sectors and provide a platform to discuss all issues concerning food fortification as the programme implementation needs political, commercial, societal and scientific support.

List of regulations reviewed

	Regulation	Abbreviation
1.	Law Number 19 of 2003 on State Owned Enterprises	Law 19/2003
2.	Law Number 25 of 2004 on National Development Planning System	Law 25/2004
3.	Law Number 12 of 2011 on Legislation Making	Law 12/2011
4.	Law Number 18 of 2012 on Food	Law 18/2012
5.	Law Number 20 of 2014 on Standardisation and Conformity Assessment	Law 20/2014
6.	Law Number 7 of 2021 on Harmonisation of Tax Regulations	Law 7/2021
7.	Government Regulation Number 17 of 2015 on Food and Nutrition Security	GR 17/2015
8.	Government Regulation Number 5 of 2021 on The Organization of Risk-Based Business Licensing	GR 5/2021
9.	Government Regulation Number 28 of 2021 on Industry Organization	GR 28/2021
10.	Government Regulation Number 69 of 1999 on Food Labels and Advertisements	GR 69/1999
11.	Government Regulation Number 57 of 2015 on Quality and Safety Assurance System and Fishery Product Safety and the Increase of Added Value in Fishery Products as partially revoked by Government Regulation Number 27 of 2021 on Organisation of Marine and Fisheries Sector	GR 57/2015
12.	Presidential Regulation Number 63 of 2017 on Non-Cash Social Assistance Distribution	PR 63/2017
13.	Presidential Regulation Number 83 of 2017 on Strategic Policy on Food and Nutrition	PR 83/2017
14.	Presidential Regulation Number 68 of 2019 on Organisation of Ministry States	PR 68/2019
15.	Presidential Regulation Number 18 of 2020 on National Medium Term Development Plan 2020-2024	PR 18/2020
16.	Presidential Regulation Number 72 of 2021 on Strategy for Acceleration of Stunting Prevention	PR 72/2021
17.	Presidential Regulation Number 66 of 2021 on National Food Agency	PR 66/2021
18.	Presidential Regulation Number 126 of 2022 on Acceleration of National Salt Development	PR 126/2022
19.	Presidential Decree Number 69 of 1994 on Supply of Iodised Salt	PD 69/1994
20.	BSN Regulation Number 8 of 2022 on Guidelines of Developing Indonesian National Standard Updated version of BSN Regulation Number 3 of 2018	BSN Regulation 8/2022
21.	BSN Regulation Number 1 of 2020 on Conformity Assessment Scheme Against Indonesia National Standards in Food and Beverage Sector	BSN Regulation 1/2020
22.	BSN Regulation Number 4 of 2024 on Conformity Assessment Scheme for Indonesian National Standards in the Plant Products and Derivatives Sector	BSN Regulation 4/2024

	Regulation	Abbreviation
23.	BSN Regulation Number 5 of 2024 on Conformity Assessment Scheme for Indonesian National Standards in the Animal Products and Derivatives Sector	BSN Regulation 5/2024
24.	BSN Regulation Number 3 of 2021 on Amendment of BSN Regulation Number 1 of 2020 on Conformity Assessment Scheme Against Indonesia National Standards in Food and Beverage Sector	BSN Regulation 3/2021
25.	Minister of National Development Planning/National Development Planning Agency Regulation Number 1 of 2018 on Food and Nutrition Action Plan	BAPPENAS Regulation 1/2018
26.	National Agency of Drug and Food Control (BPOM) Regulation Number 31 of 2018 on Processed Food Label	BPOM Regulation 31/2018
27.	National Agency of Drug and Food Control (BPOM) Regulation Number 20 of 2021 on Amendment of National Agency of Drug and Food Control (BPOM) Regulation Number 31 of 2018 on Processed Food Label	BPOM Regulation 20/2021
28.	National Agency of Drug and Food Control (BPOM) Regulation Number 23 of 2023 on Processed Food Registration	BPOM Regulation 23/2023
29.	National Food Agency (BAPANAS) Regulation Number 2 of 2023	BAPANAS Regulation 2/2023
30.	Minister of National Development Planning/National Development Planning Agency Decree Number KEP 124/M.PPN/HK/10/2021 of 2021 on Establishment of National Action Plan of Food and Nutrition 2021-2024	RAN-PG 2021-2024
31.	Ministry of Agriculture Regulation Number 38 of 2020 on Implementation of Indonesian Sustainable Palm Oil Plantation Certification	MoA 38/2020
32.	Minister of Industry Regulation Number 46 of 2019 on Mandatory Implementation of Indonesian National Standards of Palm Oil as Staple Food	MoI Regulation 46/2019
33.	Minister of Industry and Trade Decree Number 153/MPP/Kep/5/2001 of 2001 on Mandatory Implementation of Indonesian National Standard for Wheat Flour as Staple Food	MoI Decree 153/2001
34.	Ministry of Industry and Trade Decree Number 323/MPP/Kep/11/2001 on Amendments on Minister of Industry and Trade Decree Number 153/MPP/Kep/5/2001 of 2001 on Mandatory Implementation of Indonesian National Standard for Wheat Flour as Staple Food	MoI Decree 323/2001
35.	Minister of Industry Regulation Number 1 of 2021 on Mandatory Implementation of Indonesian National Standards of Wheat Flour as Staple Food	MoI Regulation 1/2021
36.	Minister of Industry Regulation 42/M-IND/PER/11/2005 on Packaging, Processing, and Labelling of Iodised Salt	MoI Regulation 42/2005
37.	Minister of Industry Regulation Number 45 of 2022 on Industry Standardisation	MoI Regulation 45/2022
38.	Ministry of Trade Regulation Number 18 of 2024 on Packaged People's Palm Cooking Oil and its Governance	MoT Regulation 18/2024
39.	Minister of Marine Affairs and Fisheries Number 14 of 2021 on Standards for Non-Food Fishery Products and Development of Quality Standards for Fishery Products	MoMAF 14/2021
40.	Minister of Marine Affairs and Fisheries Regulation Number 59 of 2021 on Increasing the Added Value of Fisheries Products	MoMAF Regulation 59/2021
41.	Minister of Social Affairs Regulation Number 1 of 2018 on Programme Keluarga Harapan	MoSA Regulation 1/2018
42.	Minister of Trade Regulation Number 20 of 2021 on Policy and Arrangement of Import	MoT Regulation 20/2021
43.	Minister of Trade Regulation Number 25 of 2022 on Amendment of Minister of Trade Regulation Number 2o of 2021 on Policy and Arrangement of Import	MoT Regulation 25/2022
44.	Director General of Food Crops of the Ministry of Agriculture Number 48-HK.310-C-2-2020 on Instructions for the Implementation of Biofortified Rice Cultivation Activities for Fiscal Year of 2020	Director General of Food Crops Decree 48/2020

Nigeria

Overview and nutritional landscape

Nigeria has the largest population in Africa, with more than 210 million, and the largest economy in sub-Saharan Africa. It also has the largest number of people living in extreme poverty, almost 100 million people. Development challenges are compounded by health and nutrition challenges. Malnutrition remains a major obstacle to addressing the disease burden, more than 50% of women of reproductive age suffer from anaemia. The most recent National Food Consumption and Micronutrient Survey (Federal Ministry of Health of Nigeria et al., 2021[93]) revealed varying levels of micronutrient inadequacies amongst various

segments of the population. For example, zinc inadequacy was prevalent among almost 50% of pregnant women, more than 35% of non-pregnant women and less than 5% of children; iron deficiency was observed amongst more than 40% of women and almost 20% of children; and vitamin A inadequacy amongst more than 25% of non-pregnant women and more than 10% of children. Nigeria has committed to addressing micronutrient deficiencies through a variety of methods, including the fortification of staple food vehicles.

Legislative and institutional framework

While there is no primary legislation on fortification in Nigeria, the Federal Government recognises food fortification as a strategic nutrition intervention in its National Policy on Food and Nutrition (NPFN) (Ministry of Budget and National Planning of Nigeria, 2016[94]), which is developed by a multi-sectoral committee and is under the custodianship of the Federal Ministry of Budget and Economic Planning. It also endorses fortification of specific staples in the National Guidelines for the Prevention and Control of Micronutrient Deficiencies in Nigeria (Federal Ministry of Health of Nigeria, 2026[95]), adopted by the Federal Ministry of Health. The government declares its intention to prescribe mandatory fortification for food vehicles through these non-legislative instruments and it realises this intention through binding and non-binding subsidiary instruments such as regulations and standards. The Standards Organisation of Nigeria (SON), an agency under the Federal Ministry of Industry, Trade and Investment, sets industry standards on food fortification through a collaborative effort with relevant partners and the standards, known as Nigerian Industrial Standards (NIS) are reviewed periodically. There are fortification standards on salt, sugar, flour, margarine and edible oils. The National Agency for Food and Drug Administration and Control (NAFDAC) is an agency under the Federal Ministry of Health and Social Welfare (FMOHSW) with the power to regulate and control the food industry. NAFDAC issues regulations on food fortification, which generally endorse the prescriptions in the industry standards set by SON and are binding. In addition to the specific intervention of SON and NAFDAC, the Federal Competition and Consumer Protection Commission (FCCPC), an agency under the Federal Ministry of Industry, Trade and Investment, has also been recognised as a critical government actor in the administration of food fortification. The enabling laws of these agencies empower them to prescribe and enforce rules on fortification through standard setting, the adoption of subsidiary legislations, inspection, investigation, enforcement, prosecution and sanctions. The operations of these Ministries, Departments and Agencies (MDAs) constitute a robust multi-sectoral framework for food fortification in Nigeria.

Regulations identifying fortification standards: Staple foods and premixes

The NAFDAC Food Grade (Table or Cooking) Salt Regulations, 2021, provide the current prescriptions on salt iodisation. The NAFDAC Food Fortification Regulations 2021, adopted by the NAFDAC Governing Council, are the latest regulations on food fortification. The Regulations stipulate the food vehicles for which fortification is mandatory, such as flour, edible oils, sugar and margarine, as well as those for which it is voluntary, including milk, pasta and breakfast cereals, amongst others. For all food vehicles for which fortification is mandatory, there are specifications on the level of fortification, which are based on the relevant fortification standards. The standards for micronutrient premixes are supported by a code of practice, which provides a detailed guide on the production of micronutrient premixes for fortification. Codes of Practice for fortified rice and bouillon are currently awaiting approval by the Governing Council of SON.

Ensuring industry compliance

Producers of fortified food and premixes are required by NAFDAC to register and receive approval for each product, for which they need to submit satisfactory documentation, undergo including Good Manufacturing Practices (GMP) assessment of the production facilities and laboratory analysis of the premixes. After

issuance of a product registration certificate, producers must also apply to NAFDAC for an advertisement permit if they intend to engage in advertisement. Registration fees vary depending on the business size and whether food is imported (NAFDAC and FR&RD, 2021[96]). NAFDAC maintains a database of registered micronutrient premixes. Food producers are required to ensure that they acquire and use only premixes that have been duly registered by NAFDAC and bear the assigned NAFDAC Registration Number. SON issues a Mandatory Conformity Assessment Programme (MANCAP) certification for all locally manufactured goods, and this certification, which is renewable every three years, is required for all products that are subject to the industry standards adopted by SON. Section 5(i) of the Standards Organisation of Nigeria Act, Cap S9 Laws of the federation of Nigeria 2004, provides for the power of SON to enforce the mandatory conformity assessment programme. MANCAP certification is not granted to products that do not comply with the requisite standard specifications. SON also supports industry through the adoption of codes of practice for the production of certain food vehicles and fortificants. These serve as a guide and are not enforced by SON as mandatory stipulations. In addition to government interventions, there are public-private sector and private sector mechanisms that are used to promote industry compliance with the relevant fortification requirements. The National Fortification Alliance (NFA) is a public-private sector platform that brings together all stakeholders in the fortification space to share information and work together to ensure compliance with fortification standards and regulations. Through the NFA, research findings and new developments in fortification are shared and discussed, the government agencies share information on the result of fortification compliance monitoring exercises, and industry stakeholders discuss compliance challenges. Private sector compliance facilitation includes collaborative self-regulatory mechanisms like the Micronutrient Fortification Index (MFI) which ranks participating producers based on their compliance with the relevant fortification standards, relying on results from product testing and self-assessment.

Measures and tools for enforcing LSFF

Industry standards are enforced through the issuance of MANCAP certifications for compliant products. Thus, while non-compliance may not constitute a legal violation, it would limit market access for affected goods. In line with the arrangements of the NFA for national compliance monitoring and reporting, the SON undertakes unscheduled inspections of food production facilities to monitor compliance, while NAFDAC conducts market level assessments at retail and distribution level to assess the levels of the mandated micronutrients in the selected food vehicles. Assessments involve sampling and testing, which may be rapid or based on detailed laboratory analysis. Both SON and NAFDAC have accredited laboratory facilities to facilitate their monitoring activities. The Regulations make non-compliance with fortification specifications, labelling and logo requirements, and nutritional claims a crime, which could result in prosecution and sanctions (NAFDAC, 2021[97]).

Way forward: Incentivising key stakeholders

The legal and institutional framework and the general landscape for food fortification in Nigeria is diverse and comprehensive, including various sectors of the government and multiple stakeholders. An important platform to improve the existing framework of public, public-private, and private sector engagement is the NFA, which brings together all stakeholders and promotes collaboration and co-ordination for improved compliance and enforcement. Also, public advocacy should be advanced through the FCCPC whose role has remained minimal, largely due to gaps in that segment of the fortification implementation chain. A risk-based approach could be adopted that would target monitoring and enforcement and preserve government resources.

Finally, tax incentives and reduced duties have also been proposed for fortification-related products and imports. The Nigerian government recently, in 2023, endorsed the classification of fortificant (vitamins) as raw materials, reducing the customs tariff requirement from 20% to 5%.

List of regulations and public instruments reviewed

	Legal instruments
1.	Nigerian Industrial Standard, NIS 121:2015, Standard for Wheat Flour
2.	Nigerian Industrial Standard, NIS 389:2000, Standard for Edible Cottonseed Oil
3.	Nigerian Industrial Standard, NIS 294:2015, Standard for Composite Flour
4.	Nigerian Industrial Standard, NIS 289:2000, Standard for Edible Palm Kernel Oil
5.	Nigerian Industrial Standard, NIS 393:2000, Standard for Sesame Seed Oil
6.	Nigerian Industrial Standard, NIS 390:2000, Standard for Edible Sunflower Oil
7.	Nigerian Industrial Standard, NIS 383:2000, Standard for Plantation White Sugar
8.	Nigerian Industrial Standard, NIS ARS 58:2019, White Sugar - Specification
9.	Nigerian Industrial Standard, NIS ARS 876:2019, Brown Sugars - Specification
10.	Nigerian Industrial Standard, NIS 396: 2015, Standard for Wheat Semolina
11.	Nigerian Industrial Standard, NIS 475: 2019, Standard for Fortificants Premix
12.	Nigerian Code of Practice, NCP 15: 2015, Code of Practice for Fortificants Premix
13.	Nigerian Industrial Standards, NIS 168:2004, Standard for Food Grade Salt
14.	Nigerian Industrial Standard, NIS 723:2014, Standard for Maize Flour
15.	Federal Ministry of Health, National Guidelines on Micronutrients Deficiencies Control in Nigeria, 2021
16.	The Food and Drug Act Cap F32 Laws of the Federal Republic of Nigeria, 2004
17.	The National Agency for Food and Drug Administration and Control Act CAP N1 Laws of the Federation of Nigeria, 2004
18.	The Food, Drugs & Related Products (Registration etc.) Act Cap F33 Laws of the Federation of Nigeria 2004
19.	The Counterfeit & Fake Drugs and Unwholesome Processed Foods (Miscellaneous Provisions) Act Cap C34 LFN 2004
20.	The National Agency for Food and Drug Administration and Control, the Food Fortification Regulations 2021
21.	The National Agency for Food and Drug Administration and Control, the Food Grade Table Cooking Salt Regulations 2021
22.	The National Agency for Food and Drug Administration and Control, the Food Products Advertisement Regulation 2019
23.	Standards Organisation of Nigeria Act, Cap S9 Laws of the Federation of Nigeria 2004
24.	The Federal Competition and Consumer Protection Act 2018
25.	The Animal Disease Control Act 2022
26.	The National Food Consumption and Micronutrient Survey 2021
27.	National Policy on Food and Nutrition 2016
28.	National Guidelines for the Prevention and Control of Micronutrient Deficiencies in Nigeria
29.	National Agency of Food and Drug Administration and Control, Food Registration and Regulatory Affairs Directorate 3 (2021), Guidelines for Registration of Food Products & Packaged Water Manufactured in Nigeria.
30.	Standards Organisation of Nigeria, Checklist for Monitoring of vegetable oil at factory level. 2020

Viet Nam

Overview and nutritional landscape

The Socialist Republic of Viet Nam is a home to a population of 98.2 million people, with the majority, 61%, residing in rural areas (World Bank, 2024[79]). Viet Nam's governance extends to 63 provinces, 705 districts and 10,598 communes. According to the latest National Nutrition Survey (2020), 16.2% of women of reproductive age, 19.6% of children under the age of 5, and 25.6% of pregnant women suffer from anaemia. Vitamin A deficiency remains a significant issue, affecting 18.3% of breastfeeding women, 9.5% of children under the age of 5, and 9% of children aged 6-9 years. Zinc deficiency affects 58% of children under the age of 5 and 63.6% of pregnant women, to be compared with the global average of 17% (Black et al., 2013[98]). The urban population generally exhibits better nutritional outcomes compared to rural areas, while populations in remote mountainous regions lag significantly behind in nutrient intake when compared to both urban and rural populations (National Institute of Nutrition of Viet Nam, 2020[99]). Viet Nam ranks among 34 countries globally facing the highest burden of nutritional deficiencies. Stunting, or chronic malnutrition, is a particularly pressing concern, with 1.8 million children under the age of 5 at risk of permanent physical and cognitive damage (UNICEF, 2024[100]).

Legislative and institutional framework

In 2010, the National Assembly of Viet Nam promulgated the *Food Safety Law* in response to the country's concerns regarding food safety risks and issues that have implications for trade and human health. The Law stipulates that fortification activities must adhere to fundamental safety requirements established by the Law, and specific permissible micronutrients may be added to food for fortification purposes (National Assembly of Viet Nam, 2010[101]). It also introduces the terms: "food fortified with micronutrients", for mandatory fortification initiatives, and "supplemented food", for voluntary fortification initiatives. Furthermore, the Law on Food Safety assigns food safety responsibilities to three ministries: Ministry of Health (MoH), Ministry of Agriculture and Rural Development (MARD) and Ministry of Industry and Trade (MoIT), each being responsible for overseeing specific food product chains. The MoH, through the Viet Nam Food Administration (VFA), holds the overarching responsibility for food safety and food fortification, and establishes the permissible list of micronutrients. MoH, MARD and MoIT oversee food safety control at the national level. At the provincial level, the Law provides that the People's Committees, which are local government authorities, take charge at the provincial level, with one committee assigned to each province.

The Decree 09 on Fortification of Food with Micronutrients (Decree 09/2016), adopted by the executive government of Viet Nam in 2016, is a key legal document, regulating mandatory food fortification in the country. The Decree 09, 2016 specifies the staple foods to be fortified and their respective fortificants: iodine for salt, intended for direct consumption and food processing, iron and zinc for wheat flour, used in food processing, and vitamin A for vegetable edible oils (such as soybean, palm, rapeseed, and peanut) (Government of Viet Nam, 2016[102]). This Decree also assigns responsibilities in food fortification as follows: MoH is responsible for developing National Technical Regulations on fortified foods and fortificants, MARD is assigned to salt iodisation, while MoIT is responsible for fortification of wheat flour and vegetable oil.

Regulations identifying fortification standards: Staple foods and premixes

Viet Nam follows two types of national standards: national technical regulations, which are mandatory and national standards which are of voluntary application (National Assembly of Viet Nam, 2006[103]). Under the provisions of the Food Safety law and Decree 09/2016 on mandatory food fortification, the MoH developed a series of national technical regulations. These technical regulations cover the fortification of wheat flour with zinc and iron (2010), of food grade salt with iodine (2011), fortificants for salt iodisation (2011), the specification of micronutrients for fortification (2011), and the fortification of edible vegetable oils with vitamin A (2019).

Ensuring industry compliance

Food business operators (FBOs) begin operations by notifying authorities though self-declaration using mass and social media, and submit required documentation to the relevant local office, designated by the People's Committee, which is usually a VFA subdivision. They should obtain a certificate of food safety satisfaction, except for small businesses and those adhering to globally recognised food safety standards (GMP, HACCP, ISO 22000, FSSC 22000 etc.). The ministries control specific products throughout the entire food chain. While MoH manages micronutrients, MARD supervises iodised salt and the MoIT monitors fortified wheat flour and vegetable oil. People' Committees along with the MoH (VFA), MARD, MoIT regional/provincial departments exercise control over local food businesses.

The ministries annually issue sector-specific inspection plans aimed at co-ordinating and verifying activities related to food processing and trading. Since mandatory fortification was introduced, the scope of inspections has not been updated to include food fortification aspects. The primary focus remains on food

safety management in accordance with the general Food Safety Law. Fortified foods should also meet common labelling requirements applied to all food products.

Measures and tools for enforcing LSFF

The oversight of fortification measures is integrated into the existing food safety control system. The official control over food products, that are subject to mandatory fortification, are delineated among public agencies: MoH, MARD and MoIT at the central level, with the MoH leading overall co-ordination, and People' Committees at the local level. National legal framework grants these authorities the power to oversee the compliance with food fortification requirements including the authority to inspect and enforce in case of a non-compliance. Enforcement measures include imposing sanctions for failing to fortify.

Since the introduction of Decree 09/2016 mandating fortification for three staple foods, which came into a full force in 2018 after two-year transition period, foods fortified with micronutrients have been regulated within the existing control framework, similarly to conventional food, without specific approaches to control this food group. The implementation of the Decree has encountered challenges stemming from both the regulatory framework and practical experiences within the food industry in Viet Nam. Consequently, in 2019, implementation of the Decree was suspended and currently pending government review and potential revision to address these challenges. The latest development involves conducting impact assessment and producing a comprehensive report on the implementation challenges of the Decree 09/2016. This assessment will play a crucial role in determining further advancements in food fortification.

Way forward: Incentivising key stakeholders

Since 2003, Viet Nam has implemented food fortification initiatives on a voluntary basis, including the Programme on Prevention and Control of Iodine Deficiency Disorders, which was subsidised by the government to support salt iodisation programmes. Similarly, the fortification of oil with vitamin A received substantial government and international partners' support. With the introduction of mandatory fortification, these initiatives were phased out and the responsibility for expenses shifted to the food industry.

The effective implementation would benefit greatly from strong education and communication initiatives emphasizing the advantages of fortified foods, while also highlighting the risks associated with micronutrient deficiencies. It requires measures such as securing adequate budget allocations, fostering greater stakeholder engagement and developing effective communication strategies.

List of regulations reviewed

	Legal act	Abbreviation
1.	Law on Standards and Technical Regulations	68.2006 QH11
2.	Law on Food Safety	55/2010/QH12
3.	Law on Inspections	56/2010/QH12
4.	Decree on regulations on administrative sanctions in the domain of standards, metrology and quality of products and goods	80/2013/ND-CP
5.	Decree on penalties for administrative violations pertaining to culture, sports, tourism, and advertising	158/2013/ND-CP
6.	Decree on provisions of administrative sanctions in trade, production, trade in counterfeit goods, products prohibited and protect consumers benefit	185/2013/ND-CP
7.	Decree on regulations on organisation and activities, the group working relationship and order inspection procedures conducted inspection	05/2014/TT-TTCP
8.	Decree on fortification of food with micronutrients	09/2016/ND-CP
9.	Decree amending certain regulations on investment and trading conditions in international trade of foods under the state MOIT	77/2016/ND-CP
10.	Decree on management of salt production and trading	40/2017/ND-CP

	Legal act	Abbreviation
11.	Decree related to business conditions under management of the MOIT	08/2018/ND-CP
12.	Decree elaborating on some articles of the law on food safety	15/2018/ND-CP
13.	Decree on product labelling	43/2017/ND-CP
14.	Decree on penalties for violations against regulation on food safety	115/2018/ND-CP
15.	Decree amendments to some articles of decree related to necessary business conditions in fields under the management of the MOIT	17/2020/ND-CP
16.	Decree amendments to some articles of government's decree 43/2017/NƏCP dated April 14, 2017, on goods labels	111/2021/ND-CP
17.	National technical regulation on substances may be added for zinc fortification in food	QCVN-3-1:2010/BYT
18.	National technical regulation on Folic acid for food fortification	QCVN-3-2:2010/BYT
19.	National technical regulation on substances added for iron fortification in food	QCVN-3-3:2010/BYT
20.	National technical regulation on micronutrient fortified food	QCVN-9-2:2010/BYT
21.	National technical regulation on substances may be added for iodine fortification in food	QCVN-3-6:2011
22.	National technical regulation on the limits of heavy metals contamination in food	QCVN-8-2:2011/BYT
23.	National technical regulation on the limits of mycotoxins contamination in food	QCVN 8-1:2011/BYT
24.	National technical regulation Food grade iodised salt	QCVN-9-1:2011/BYT
25.	National Technical Regulation on vitamin A fortified in oil	QCVN 3-7:2019/BYT
26.	National Technical Regulation on food-grade salt	QCVN 01-193: 2021/BNNPTNT
27.	Circular on promulgating the regulation on addition of micronutrients to food	6289/2003/QƏBYT
28.	Circular Additional product and goods likely unsafe under the management of the ministry of agriculture and rural development	44/2011/TT-BNN
29.	Circular Issuing list of goods exported and imported Viet Nam	156/2011/TT-BTC
30.	Circular on regulating the management of functional foods	43/2014/TT-BYT
31.	Circular providing for the inspection of agricultural production/trading establishments and certification of safety conditions for agro-forestry-fishery products	45/2014/TT-BNNPTNN
32.	Circular on the list of micronutrients added in foods	44/2015/TT-BYT
33.	Circular on food safety supervision of Agro-aqua-forestry products	08/2016/TT-BNNPTNT
34.	Circular safety regulations of Agro-Forestry-fishery food manufacturing and trading business under the management of Ministry of Agriculture and Rural Development	38/2018/TT-BNNPTNT
35.	Circular stipulating food safety management by the Ministry of Industry and Trade	43/2018/TT-BCT
36.	Circular providing guidance on inspection of food safety and quality of imported salt under authority of the MARD	39/2018/TT-BNNPTNT

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