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Regulatory governance of large-scale food fortification: Literature review

Theoretical and empirical foundations for developing a measurement framework

30th meeting of the Regulatory Policy Committee (RPC)
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This literature review synthesizes research findings relevant to the design and implementation of sustainable food fortification programmes to inform the development of a measurement framework for the regulatory governance of large-scale food fortification [GOV/RPC(2024)4]. It includes a discussion on the main sources, databases and the findings and an annotated outline of the reviewed materials. Delegates to the Regulatory Policy Committee are invited to provide comments by 12 April 2024.

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Introduction

1. Large-scale food fortification is the practice of adding vitamins or minerals to commonly consumed foods during processing to increase their nutritional value and provide a public health benefit with minimal risk to health. It has long been recognised as an efficient and cost-effective measure in reducing the burden of preventable diseases associated with micronutrient deficiencies.

2. This literature review focuses on trends, issues, and challenges in LSFF programmes implementation worldwide, and in particular where micronutrient deficiencies are most prevalent. It identifies the most frequently raised points and common themes throughout the literature on food fortification with the aim of informing the development of a measurement framework for LSFF regulation.

3. The literature review on large-scale food fortification is divided into two parts. Part I provides a summary of the literature, highlighting research findings relevant to the design and implementation of sustainable food fortification programmes, and laying the empirical and theoretical foundation for the measurement framework. It also provides relevant findings from our research in five countries: Burkina Faso, India, Indonesia, Nigeria and Vietnam. Part II contains an annotated outline of reviewed materials, which includes the most important sources and their contribution. This part was prepared with the contribution of Harvard Law School Food Law and Policy Clinic.

4. Part I is divided in three sections:

    1. *Section 1* provides context, concepts and main sources of food fortification, its role in the battle against malnutrition; international agreements and fora that have enabled the development of food fortification policies and programmes; international standards and guidelines that serve as a basis for launching of national LSFF programmes.
    2. S*ection 2* attempts to consolidate the main points spread across the literature on the key regulatory and institutional factors required for LSFF. It takes into account relevant academic literature, country reviews, programme reports and policy guides. The academic literature included largely comprises of case studies carried out on LSFF programmes in developing and emerging countries. This literature reveals the regulatory and institutional backgrounds which proved either detrimental or essential to the success of the programmes. Similarly, country reports and policy guides are also included which provide best practices and practices to be avoided. Where possible, real-world examples of regulatory and institutional frameworks and LSFF practices in various countries have also been included in the review.
    3. *Section 3* describes databases that provide essential records on food fortification including details of food fortification legislation and standards, fortification data on main staple foods; health and nutrition statistics, best practices for monitoring and implementation; comparative studies of fortification practices etc. Emphasis is placed on databases that include information on regulatory and institutional elements and could therefore be used as a source for regulatory indicators.

5. Part II is divided in five sections, which provide a high-level summary of (i) international and regional agreements, declarations, and action plans on LSFF, (ii) guidelines and reports by

international organizations, and (iii) databases on food fortification standards, policies, and regulation, (iv) assessment of food fortification programmes and (v) regulatory control and monitoring.

6. This literature review finds that food fortification is an effective, cost-efficient tool for combating malnutrition, micronutrient deficiencies, and associated health problems. However, launching food fortification programmes is challenging as there is need to select an optimal food to fortify, determine how to distribute that food efficiently, and organize the logistics for food distribution. Furthermore, the literature finds that the creation of comprehensive legal frameworks, adequate enforcement by regulatory bodies, and cooperation with private industry constitute critical factors for successful food fortification programmes. These challenges are compounded for low- and middle-income countries, which must address these challenges with constrained budgets.

7. The international agreements, guidelines, reports, and databases offer valuable insights to evaluate food fortification programmes and develop recommendations for improving future programmes. Regional and supranational support is also a key enabler of fortification policies. The databases covered in this literature review can help identify existing legislation and indicators to monitor the implementation of fortification programmes. Case studies and assessments of food fortification policies in a number of low- and middle-income countries highlight best practices and common pitfalls of these programmes in Africa, the Middle East, and Asia. While many reports are country-specific, these assessments offer lessons learned relevant to other countries implementing or considering the implementation of fortification programs. These insights cover the development of appropriate legal and regulatory environments to ensure adequate coverage of fortification programs, and compliance with fortification requirements. Overall, this literature review can serve as a reference to inform and support the ongoing development of a measurement framework for LSFF regulatory indicators.

Part I : Literature review and theoretical foundations

1 Context, concepts, and main sources

The global prevalence of malnutrition

8. Malnutrition refers to an imbalance of energy and nutrient intake. Malnutrition encompasses the maladies that result from poor nutrition, including not just undernourishment, but also overweight (World Health Organization (WHO), n.d.[1]). While it is estimated that 1.9 billion adults worldwide are overweight, at least another 462 million adults are underweight (World Health Organization, n.d.[2]). Overweight and micronutrient-related malnutrition can however often accompany one another (Oddo et al., 2012[3]). Micronutrient-related malnutrition (or micronutrient deficiency) typically refers to a lack of one or more vitamins or minerals which are essential to normal human development and function (Food and Agriculture Organization (FAO), 1997[4]). The burden of micronutrient deficiencies has long been a worldwide concern. Previously, the oft-cited estimate of the number of people living with micronutrient deficiencies worldwide was 2 billion (World Health Organization (WHO), 1992[5]). However, this figure only considered the prevalence of anaemia. Recent data suggests that 372 million preschool-age children and 1.2 billion non-pregnant women of reproductive age worldwide have one or more micronutrient deficiencies, suggesting that the previous global estimate of 2 billion worldwide may have been too low (Stevens et al., 2022[6]).

9. Micronutrient deficiencies are surprisingly common in OECD countries. Despite rising obesity rates, it is estimated that nearly half of women in high-income countries have one or more micronutrient deficiencies. The United States, for example, is "overfed but undernourished" (Astrup and Bügel, 2018[7]). At least 41.9% of adult Americans are obese (CDC, n.d.[8]), while at the same time, 31% of Americans are at risk of at least one micronutrient deficiency (Bird et al., 2017[9]). Micronutrient deficiencies are however most prevalent in the Global South, with 90% of all stunted and wasted children living in Africa and Asia (FAO et al., 2023[10]). UNICEF estimates that at least half of all children worldwide suffer from micronutrient deficiency. It is estimated that 22% of children worldwide under five years old are stunted, while 6.7% of children under five are wasted (UNICEF, WHO and World Bank Group, 2021[11]). Micronutrient deficiencies during pregnancy and early childhood can cause severe developmental problems, and are linked to poor growth, intellectual impairments, perinatal complications, and increased risk of morbidity and mortality (Bailey, West Jr. and Black, 2015[12]). Micronutrient deficiencies are a significant burden to the overall socioeconomic state of a generation in terms of lost wages, productivity, and increased healthcare costs (Nugent et al., 2020[13]). Therefore, early intervention in micronutrient deficiency is crucial to ensuring optimum development and preventing compounding effects in later life. Worldwide, the five most widespread micronutrient deficiencies are in iron, folate, vitamin A, zinc, and iodine (Bailey, West Jr. and Black, 2015[12]).

1. **Iron deficiency:** Inadequate iron intake during pregnancy can result in low birth weight and impaired development, yet it is estimated that at least 29.9% of women of reproductive age (15-49 years) worldwide are anaemic (FAO et al., 2023[10]). 38.9% of women in this

age group in Africa are anaemic, compared to 14.6% of women in Northern America and Europe. The prevalence is higher in Western Africa, where 51.8% of women aged 15-49 are anaemic. In India, 64.2% of children in urban areas and 68.3% of children in rural areas under five years old are anaemic. Similarly, 53.8% of women aged 15-49 years in urban areas are anaemic, and 58.5% of women aged 15-49 in rural areas are anaemic (Ministry of Health and Family Welfare of India, 2021[14]).

2. **Folate deficiency:** Inadequate intake of folic acid (the synthetic and more bioavailable form of folate) during pregnancy increases the risk of preventable neural tube defects such as anencephaly and spina bifida. While worldwide deficiency rates are difficult to obtain, the rate of folic acid deficiency in women of reproductive age has been estimated to be 5% for high income countries, but 20% for low income countries (Rogers et al., 2018[15]). In India, 37% of the overall population are deficient in folic acid (CSIR Summer Research training team, 2021[16]).
3. **Zinc deficiency:** Zinc plays a versatile role in metabolic processes. Low zinc intake in children is associated with impaired childhood growth and increased child morbidity. Similar to folic acid, national-level data on zinc deficiency is scarce (Gupta, Brazier and Lowe, 2020[17]). However, the prevalence of zinc deficiency in low- and middle-income countries (LMIC) is estimated to be high, ranging from 23% in Afghanistan to as high as 82% in Cameroon. Zinc deficiency also continues to exist in upper middle income to high income countries. In Europe, the rate of zinc deficiency has previously been estimated to be 7.5%, with higher rates estimated for countries such as Turkey (21.7%), Slovakia (13.6%), and Czech Republic (11.0%) (Wessells and Brown, 2012[18]).
4. **Iodine deficiency:** Iodine deficiencies can cause stunted growth, as well as infertility and lethargy (Simpong, 2017[19]). Worldwide, nearly 2 billion people are at risk of iodine deficiency, with 241 million children not consuming enough iodine in their diet. In India, 17% of the population are deficient in iodine (CSIR Summer Research training team, 2021[16]). In Europe, the WHO has noted that iodine deficiency remains a continuing public health problem (WHO and UNICEF, 2007[20]). A 2020 study showed that mild to moderate iodine deficiency is still common in vast swathes of the European population, particularly amongst pregnant women and other adults (Ittermann et al., 2020[21]).
5. **Vitamin A:** Vitamin A deficiency is one of the leading causes of childhood blindness. Vitamin A deficiency is an issue in more than half of all countries (World Health Organization (WHO), n.d.[22]), with 19% of Indian population being deficient in vitamin A (CSIR Summer Research training team, 2021[16]). In 2011, it was estimated that at least 34% of the population in the United States consume inadequate amounts of vitamin A (Fulgoni et al., 2011[23]).

The role of food fortification in the battle against malnutrition

10. Food fortification has long been recognised as an efficient and cost-effective measure in reducing the burden of preventable diseases associated with micronutrient deficiencies (Bishai and Nalubola, 2002[24]). Food fortification is the practice of deliberately increasing the vitamin or mineral content of a food to improve its nutritional quality and to provide a public health benefit with minimal risk to health (WHO and FAO-UN, 2006[25]). Some of the most common fortifications include the addition of folic acid and iron to wheat flour, vitamin A to vegetable oil, and iodine to salt (WHO and FAO-UN, 2006, pp. 93-122[25]) (WHO, 2016[26]) (see Table 1.1).

Table 1.1. Common food vehicles and fortificants

Food	Commonly used fortificants
Salt	Iodine, iron
Flours (wheat/maize)	Iron, folic acid, vitamin A, vitamin B12, thiamine, riboflavin and niacin, calcium
Vegetable oils	Vitamin A, vitamin D
Milk	Iron, vitamin A, vitamin D, iodine
Rice	Iron, folic acid, vitamin A, vitamin B12, thiamine, riboflavin, niacin, zinc

Source: (WHO and FAO-UN, 2006, pp. 93-122[25]) (WHO, 2016[26])

11. The typical process of food fortification occurs where micronutrients are added to the food during the industrial process. The biofortification of crops via genetic modification is a new and emerging research area which requires further research. Although less common, home or community-led fortification is also possible. This can take varying forms, for example micronutrient powder being sprinkled into food, or crushable micronutrient tablets added to food.

12. Food fortification programs can be designed in three ways: mass or large-scale (or "mandatory") fortification, targeted fortification and market-driven (or "voluntary") fortification. Mass fortification is the addition of one or more micronutrients to foods commonly consumed by the general public, such as cereals, condiments and milk, and is typically mandated by governments. Targeted fortification focuses on specific subgroups of the population; for example, a targeted program for children might focus on fortification of school meals. Market-driven fortification involves food manufacturers voluntarily adding micronutrients to food, usually within government-set standards. This approach is commonly seen in the United States (Backstrand, 2002[27]). Mandatory, large-scale fortification is more suitable in instances where there are serious and urgent public health concerns, where consumer demand for the product or education on nutrition is low, or where the food processing industry is quite centralised (WHO and FAO-UN, 2006, p. 36[25]). Voluntary fortification on the other hand does not need to account for industry structure and can be more effective where high consumer demand already exists for the food in question. Voluntary fortification can sometimes be introduced as a precursor to mandatory fortification. This allows time to develop the appropriate regulatory mechanisms and tools. In Viet Nam, the voluntary food fortification program first started with iron-fortified fish sauce in 2003 (Thuy et al., 2003[28]). After that, the voluntary program expanded to other food vehicles including condiments to be fortified with zinc and iron, fish sauce and soya sauce to be fortified with iron, vegetable oil to be fortified with vitamin A (Van Thuy et al., 2005[29]). The second phase of the voluntary program was from 2010-2015 which provided the basic foundation and scientific and evidence for the government of Viet Nam to develop and ratify the mandatory decree of food fortification in 2016 (Government of Viet Nam, 2016[30]). Since 2016, food fortification has been regulated by both a mandatory and a voluntary legal framework.

13. Based on initially available information from the Global Fortification Data Exchange, which may not be complete as there is no data available for all countries, currently, 123 countries mandate the fortification of salt, 85 countries mandate fortification of wheat flour, 32 countries mandate oil fortification, 18 mandate the fortification of maize flour, and just 8 countries mandate fortification of rice (GFDx, n.d.[31]). Table 1.2 denotes the number of countries which have either mandatory or voluntary fortification standards in place for each micronutrient. The GFDx database does not cover all countries worldwide, so there may be more countries with fortification standards.

Table 1.2. Number of countries with micronutrient fortification standards

Micronutrient	No. of countries worldwide with mandatory fortification standards	No. of OECD countries with mandatory fortification standards	No. of countries worldwide with voluntary fortification standards	No. of OECD countries with voluntary fortification standards
Iodine	123	16	17	10
Iron	85	7	18	1
Folate	69	8	15	1
Thiamin	60	8	17	1
Niacin	58	7	17	1
Riboflavin	57	7	15	0
Vitamin A	38	0	13	1
Zinc	34	2	7	0
Vitamin B12	25	1	5	0
Calcium	18	3	8	0
Vitamin D	16	3	9	1
Fluoride	14	4	7	6
Vitamin E	1	1	2	1
Selenium	1	1	1	0

Source: Global Fortification Data Exchange https://fortificationdata.org/map-number-of-nutrients/ (accessed on 20.3.2024). GFDx covers a total of 196 countries which include all 38 OECD member countries. However, information on regulation is not available in the database for all micronutrients for all countries covered, so the number of countries mandating food fortification or with voluntary fortification standards is likely to be underestimated in the table.

International efforts in establishing food fortification practices

14. The role of intergovernmental associations and organizations has been a crucial factor in the development of large-scale food fortification ("LSFF") policies worldwide. Frequently, international efforts have been the driving force behind the creation of food fortification policies in many developing countries (Tarini et al., 2021[32]). Since the first salt iodization program in the United States in 1920, the practice of large-scale food fortification has gained international recognition (Bishai and Nalubola, 2002[24]). Governments worldwide have recognized the importance of large-scale food fortification in combatting micronutrient malnutrition. International and regional agreements, resolutions, and conferences have played an important role in developing globally recognized standards for large-scale food fortification policy.

International standards and international agreements

15. The discussion on the development of food fortification policies and programs warrants consideration of the impact of international food standards and international trade agreements. International food standards promote consumer protection, facilitate fair trade, and contribute to global harmonization and cooperation in food safety and quality and help mitigate relevant risks.

16. The Codex Alimentarius Commission is a body established by FAO and WHO in 1963 to develop international food standards under the Joint FAO/WHO Food Standards Program. Membership is open to all FAO Member Nations and Associate Members, and the Commission has over 180 members. The standards developed by the Commission are recognized internationally (Codex Alimentarius Commission, 2012[33]). In 1987, the Commission developed the General Principles for the Addition of Essential Nutrients to Food (Codex Alimentarius Commission, 1987[34]), a key step in the development of food fortification standards and policy. The General Principles outline universal guidelines for national and regional governments to follow when adding nutrients to foods

and establish basic principles and key considerations for food fortification policy. The General Principles include, among others, the conditions under which micronutrients should be added to food, guidance on selecting foods to be fortified, guidance on setting standards that should specify minimum and maximum levels of the micronutrient to be added, and on the monitoring of the micronutrient intakes of populations by authorities. The General Principles of the Codex Alimentarius serve as a global benchmark upon which many countries have developed their policies on LSFF.

17. In a similar way as international food standards, international trade agreements aim to reduce barriers to trade, promote international trade and stimulate economic growth. When developing regulation on fortified foods, national lawmakers of WTO members must take into account the relevant international agreements on trade.

18. The WTO Technical Barriers to Trade agreement (TBT Agreement) 1995 is a multilateral trade agreement which seeks to ensure "*that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade*". The TBT Agreement limits regulations that unnecessarily restrict trade but permits countries to adopt policies that restrict trade when the policy is intended to improve human health. As a result, LSFF programs to combat micronutrient deficiencies would generally be permissible. In addition, the TBT Agreement encourages member countries to adopt international standards to reduce barriers to trade. Even though the TBT agreement does not explicitly cite any international standard, the key point is that as long as a regulation is based on an international standard the regulation is presumed to be in line with WTO obligations. Therefore, national regulations that are based and comply with the Codex Alimentarius General Principles for the Addition of Essential Nutrients to Food would not violate WTO obligations (World Trade Organization, 1995[35]).

19. The WTO Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) 1994 is also relevant, but it is more applicable to food safety overall rather than fortified food specifically. The SPS Agreement consists of the harmonization of sanitary and phytosanitary measures between WTO member states (i.e., measures on the protection of human, animal and plant health from disease-causing organisms, additives or toxins in foods, beverages, or feedstuffs). The SPS Agreement encourages harmonized sanitary and phytosanitary measures between members on the basis of international standards, guidelines and recommendations developed by the relevant international organizations. The SPS Agreement explicitly cites the Codex Alimentarius Commission (World Trade Organization, 1994[36]) as reference, therefore, members are encouraged to comply with the General Principles for the Addition of Essential Nutrients to Food.

20. The culminated effect of these agreements on the trade of fortified food is significant. The adoption of international standards such as the international food standards developed by the Codex Alimentarius Commission, helps to reduce barriers to trade for fortified food. While member states may adopt trade-restricting measures to promote health under the TBT Agreement, the harmonization of standards serves to remove the trade barrier created by diverging national regulations on food fortification. When analysing a country's food fortification policy, a first consideration should therefore be whether the General Principles of the Codex Alimentarius have been taken into account for its development.

WHO and FAO Guidelines and Guidance Documents

21. Despite being a key reference for food fortification, the document of the General Principles itself is quite short. In 2006, the WHO and the FAO developed the Guidelines on Food Fortification with Micronutrients (WHO and FAO-UN, 2006[25]), a more elaborate, detailed guide which complements the Codex Alimentarius General Principles. The Guidelines are structured in four sections:

- Part I outlines the role of food fortification in the control of micronutrient malnutrition and introduces the basic forms of LSFF (i.e., mandatory vs. voluntary fortification, mass fortification vs. targeted fortification etc.).
- Part II discusses the prevalence of various vitamin and mineral deficiencies, along with their risk factors and health consequences.
- Part III of the Guidelines concerns scientific considerations for fortificants, such as physical characteristics, selection, use with specific food vehicles, safety, and sensory issues along with specific examples from existing programs.
- Finally, Part IV discusses the steps for implementing effective and sustainable food fortification programmes.

22. The Guidelines are a key document for food fortification especially because for a time they have been one of the few comprehensive sources of guidance on the design and implementation of LSFF programs. It has however been some time since the Guidelines were published in 2006. In addition, while comprising largely of technical information on fortification, the scope of information provided on the design and implementation of the regulatory framework for LSFF as well as on how to embed LSFF regulation in the overall regulatory system is limited. In Part IV the Guidelines include a few important considerations on the regulatory framework needed for LSFF. For instance, the Guidelines recommend evidence-based interventions, and provide information on factors to be taken into account to inform food fortification decisions. The Guidelines recommend the establishment of monitoring systems for quality assurance, along with consumer marketing and public education campaigns and provide recommendations on how to develop national fortification laws. Given the long time that has elapsed since their initial publication, the Guidelines are now being updated. The update of the Guidelines is foreseen to include a more elaborate chapter on the regulatory framework for large-scale food fortification.

23. To provide guidance on technical considerations and taking into account the most commonly consumed foods globally, the WHO has furthermore developed a set of more specific guidelines on food fortification for each of the following food vehicles:

- **Wheat flour:** Monitoring Flour Fortification to Maximize Health Benefits: A Manual for Millers, Regulators, and Program Managers (2021); Guideline: fortification of wheat flour with vitamins and minerals as a public health strategy (2022)
- **Maize flour:** Guideline: fortification of maize flour and corn meal with vitamins and minerals (2016)
- **Salt:** Guideline: fortification of food-grade salt with iodine for the prevention and control of iodine deficiency disorders (2014)
- **Rice:** Guideline: fortification of rice with vitamins and minerals as a public health policy (2018)

24. The guidelines provide important recommendations and valuable technical advice on the upper and lower levels of micronutrients to be added in foods, the process of fortification as well as advice on the monitoring and evaluation of fortification implementation.

International summits

25. International efforts, venues and conferences have raised the much-needed awareness and calls to actions for food fortification. At the international level, most conferences discuss micronutrient deficiencies within the larger context of hunger prevention and food security initiatives. Food fortification tends to be cited as one of several strategies to address malnutrition rather than being the primary focus.

26. However, there have been conferences that focused specifically on food fortification. One of the first international venues highlighting and raising attention to the practice of food fortification to

combat malnutrition has been the Global Summit on Food Fortification in 2015 (Sight and LIfe and Global Alliance for Improving Nutrition (GAIN), 2015[37]). The summit was co-convened by the Government of Tanzania and sponsored by a number of organizations, including the Bill & Melinda Gates Foundation (BMGF), the United States Agency for International Development (USAID), Global Alliance for Improved Nutrition (GAIN), FHI 360, Institute for Global Nutrition (IGN), Centers for Disease Control and Prevention IMPACT (CDC Impact), Helen Keller International (HKI), the Micronutrient Initiative (MI), PATH, Project Healthy Children (PHC), Sight and Life/DSM, and the United Nations World Food Programme (WFP). The summit brought together many stakeholders involved in LSFF, with a view to reviewing past achievements and challenges, and plotting the path forward for LSFF policy. The summit produced the Arusha Statement on Food Fortification Recommendations. The statement highlights five critical action areas including:

1. generating new investment in the sector,
2. improving oversight and enforcement of fortification,
3. generating more evidence to guide fortification policy and program design,
4. increasing accountability and global reporting, and
5. continuing to advocate at the global and country level (Sight and LIfe and Global Alliance for Improving Nutrition (GAIN), 2015[21], Annex 1).

27. This summit served an important role in bringing attention to food fortification as a tool in the struggle against malnutrition. The critical action areas of the Arusha Statement further highlight the ongoing need to review and improve existing LSFF regulation and policy.

28. More recently, the UN Food Systems Summit 2021 was organized as an opportunity to support the recovery of food systems in the wake of the ongoing COVID-19 pandemic and to refocus global attention on achieving Sustainable Development Goals (SDGs) by 2030. One particular Action Track (Action Track 1: Ensure Access to Safe and Nutritious Food for All) references food fortification numerous times as a tool which can help to achieve the goals under the track (UN Food Systems Summit, 2021[38]).

29. These summits reflect the increased attention given to food fortification worldwide in recent years. Moreover, these events play an important role in defining the trajectory and norms of LSFF policy.

Regional forums

30. In certain parts of the world where malnutrition is more pronounced, regional forums exist to promote and scale up food fortification. Often, the focus of these regional efforts is food security more generally, while food fortification also plays an important role. Regional forums can therefore play a role in shaping LSFF standards. For instance, in Africa a number of regional bodies and forums exist for national governments to coalesce. The Economic Community of West African States (ECOWAS) is a political and economic bloc of West African countries, which has significant political influence on its member states. ECOWAS works towards regional economic integration, which entails the harmonization of national policies and standards. The West African Health Organization (WAHO) is the health body of ECOWAS and has been instrumental in advancing food fortification in the region (Frederick Grant, Becky L. Tsang and Greg S. Garrett, 2018[39]). Covering the sub-regional West African franc zone of eight ECOWAS countries, the West African Economic and Monetary Union (WAEMU) has also contributed to support of food fortification by working closely with regional industry associations and providing financial support. Regional coordination, financial support, development of regional fortification standards, regional quality assurance and quality control guidelines have significantly helped supporting food fortification implementation in West Africa.

31. ECOWAS has been active in advancing mandatory LSFF as a tool to counter micronutrient malnutrition and has been developing regional standards. In 1994, the ministers of Health of all its member states voted for the adoption of a resolution in favour of universal salt iodization. In 2006, ECOWAS passed a resolution at the Assembly of Ministers on Mandatory Fortification, to make fortification of flour and oil mandatory in member countries. ECOWAS has a significant influence on the national regimes of its member states, and the resolution was later adopted by the vast majority of its members. Table 1.3 identifies the national level regulations on mandatory food fortification in ECOWAS countries.

Table 1.3. National-level regulatory status on food fortification in ECOWAS member states

ECOWAS countries	Status of fortification regulation (year mandated)			
(UEMOA italicized)	Vegetable oil	Wheat flour	Sugar	Maize flour
Benin	Mandatory (2012)	Mandatory (2012)		
Burkina Faso	Mandatory (2012)	Mandatory (2012)		
Côte d'Ivoire	Mandatory (2007)	Mandatory (2007)		
Cape Verde	Voluntary	Mandatory (2014)		
The Gambia	Voluntary	Voluntary		
Ghana	Mandatory (2006)	Mandatory (2006)		
Guinea-Bissau	Mandatory (2014)	Mandatory (2014)		
Guinea	Mandatory (2012)	Mandatory (2005)		
Liberia	Mandatory (2014)	Mandatory (2014)	Mandatory (2014)	
Mali	Mandatory (2017)	Mandatory (2011)		
Niger	Mandatory (2012)	Mandatory (2012)		
Nigeria	Mandatory (2002)	Mandatory (2002)	Mandatory (2002)	Mandatory (2002)
Senegal	Mandatory (2009)	Mandatory (2009)		
Sierra Leone	Mandatory (2011)	Mandatory (2011)		
Togo	Mandatory (2012)	Mandatory (2012)		

Source: Grant et al (2018) 'Food Fortification in West Africa: Progress and Lessons Learned' Sight and Life, WFP https://sightandlife.org/wp-content/uploads/2018/12/09_RFSuppl18_en_art05.pdf.

32. Diverging national standards in the area can limit the trade of fortified food in the region. Regional standards pursued by ECOWAS thus help to facilitate the trade of fortified food. In 2014, standards for fortified oil, flour and iodized salt were integrated into ECOSHAM (ECOWAS Standards Harmonization Model). As a result of this process and after two years of deliberation, every country in the region was required to modify their legal frameworks to integrate these norms. This harmonization of standards has the effect of allowing fortified products to move freely within the region without violating national standards. Other contributions of ECOWAS and its affiliated organizations include the development of a regional infrastructure network of accredited and equipped laboratories to support implementation of food fortification as well as the creation of a logo to be placed on fortified food products (ECOWAS, 2007[40]).

33. Similarly, the East, Central and Southern African Region (ECSA) Health Community created the Regional Fortification Initiative, with the aim of fast-tracking the implementation of food fortification in the region, focusing on capacity building to produce and monitor fortified and nutritious foods. A report produced by ECSA-HC, GAIN and USAID provides a helpful overview of the successes and failures of this regional initiative thus far, and provides the following recommendations for increasing micronutrient coverage across ECSA countries:

- Development partners should support and advocate for legislative frameworks and policies on fortification across ECSA countries.
- An enabling environment for enhanced public-private sector participation in fortification projects needs to be in place, not relying solely on development partners.
- Increase the capacity of sector players involved in consumption monitoring, surveillance, and impact evaluation, and increase their budget allocation.
- Intensify social marketing countrywide to increase demand and consumption of fortified foods and use the existing ECSA Portal to create an information exchange and dissemination platform on fortification (GAIN, 2017, pp. 93-94[41]).

34. Other regional organizations in Africa include the Southern African Development Community (SADC) which is planning to generate unified standards for food fortification in the region under its Food and Nutrition Security Strategy (2015-2025). Regional organizations and forums in other parts of the world that have supported food fortification include the Commonwealth of Independent States (CIS) in central Asia and the Association of Southeast Asian Nations (ASEAN).

Other important resources and guidance documents

35. The documents and guidelines produced as a result of regional forums and summits can be a useful resource in understanding the needs of the region, current challenges and ways forward. Furthermore, international organizations such as the FAO, WHO, GAIN, UNICEF, which are often involved in supporting the implementation of LSFF policy in developing countries have produced important documents shedding light on the challenges of implementing LSFF and on potential good practices. When studied collectively, these resources enable a better understanding of the existing bottlenecks to a sustainable and effective implementation of LSFF, the challenges that need to be addressed across jurisdictions and the important issues for the implementation of LSFF.

36. As part of its strategic investment in development cooperation, the European Commission has produced a guidance note on the importance of food fortification (European Commission, 2020[42]). The guidance note emphasizes food fortification as an effective solution to address food insecurity while stressing that specific fortification measures should be tailored to local contexts after conducting situational analysis. The note discusses engaging the private sector to encourage private funding in fortification efforts and recommends supporting food control and regulatory enforcement and monitoring. It also notes the importance of promoting information campaigns to generate demand for fortified food.

37. UNICEF's publication on Advancing Large-Scale Food Fortification (UNICEF, 2021[43]) addresses necessary conditions of successful LSFF programs, common weaknesses of existing LSFF programs, and UNICEF's approach regarding LSFF. UNICEF offers a number of insights into the legal and policy conditions for the successful fortification of staple foods. UNICEF advocates mandatory fortification for staple foods where there is an identified public health problem, as mandatory fortification can ensure more equitable access to the food than voluntary fortification. The food should already be readily available in the country (i.e., widely produced or imported), widely consumed and remain affordable after fortification.

38. For the legal aspects of mandatory fortification programs, UNICEF recommends legislating food fortification under existing food control legislation rather than a new law for easier implementation. Integrating food fortification into existing systems for food safety is preferred, such using the same principles for regulatory monitoring, the same coordination and oversight structure, and the same systems for data collection and impact evaluation. It is also important for governments to create an economically safe and supportive environment for industry so that fortification is sustainable. In this regard, according to UNICEF, governments should adopt fortification requirements

that can be reasonably implemented by industry, reduce financial and regulatory barriers to fortification such as excessive registration and taxes, and create reliable, efficient, and low-cost external and import regulatory monitoring and enforcement practices within the existing food control system. This is to create a level playing field amongst businesses and encourage compliance.

39. Among the challenges currently identified in existing LSFF programmes, UNICEF highlights the following five common weaknesses:

Table 1.4. Common weaknesses of existing food fortification programmes

Poor choice of food vehicle for fortification	In several countries, staple foods and condiments are mandated to be fortified because they are widely consumed but the feasibility of the selected food vehicle to be fortified (fortifiability) remains low and Governments cannot effectively enforce compliance. This is particularly challenging where the food vehicle is not produced by large formal industries or is not sufficiently aggregated to create opportunities for fortification.
Fortification requirements are inadequate to have an impact	Many countries do not appear to have evidence-based fortification requirements (frequently referred to as standards); i.e., global guidance and/or evidence has not been taken into consideration such as sufficient levels of nutrients or efficacy of nutrient compounds to fulfil the desired nutrient gaps within the population.
Inadequate or ineffective external and import regulatory monitoring and enforcement	Although multiple countries have mandatory requirements for food fortification, far fewer enforce such requirements through effective external and import regulatory monitoring by authorized government agencies. Lack of enforcement of fortification requirements disadvantages compliant food producers who must compete with noncompliant producers who do not have the added costs associated with fortification.
Lack of, and poor use of, data for program design, oversight, and evaluation	Many countries lack critical data and information, or insufficiently use available data on industry structure, food supply chains, compliance, coverage, food intake and nutrition status. Such data issues impede program design, oversight, and evaluation. Data quality, frequency, utility, and analysis needs to be prioritized in several countries to create efficient large-scale fortification programs
Low sustainability and integration into routine systems	There are a number of examples of successful fortification programs that have not sustained achievements. Most frequently low sustainability is attributable to the ending of external donor funding and/or insufficient integration of food fortification activities into routine systems and budgets."

Source: (UNICEF, 2021[43])

40. Another important guidance document, developed by the Global Alliance for Improved Nutrition (GAIN), focuses in particular on the Regulatory Monitoring of National Food Fortification Programs (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]). The overall objective of the guidance document is to strengthen regulatory monitoring and compliance by proposing a feasible approach to determine compliance and offering country specific examples and good practices in addressing common challenges in monitoring, faced by the public and the private sector. The document emphasizes the importance of adding fortification activities into existing methodologies for monitoring food safety and discusses the relevance of developing an IT system for record keeping. It also stresses the importance of implementing realistic compliance measures and incentives to induce industry compliance. It is considered an important resource, especially with regards to implementation and enforcement of food fortification.

2 Regulatory and institutional lessons in LSFF literature

41. There is a wealth of literature available on the regulatory and institutional factors which are conducive to the successful design and implementation of LSFF programs. This section attempts to consolidate the main points spread across the literature on the key regulatory and institutional factors for LSFF. The following paragraphs take into account relevant academic literature, country reviews, program reports and policy guides.

42. The academic literature included largely comprises of case studies carried out on LSFF programs in developing countries. This literature reveals the regulatory and institutional backgrounds which proved either detrimental or essential to the success of the programs. Common trends are thus identified throughout this literature. A number of studies highlights the relevance of political will to support LSFF, along with food fortification being integrated into national public health policy (Dijkhuizen et al., 2013[45]) (Frederick Grant, Becky L. Tsang and Greg S. Garrett, 2018[39]). Others note the importance of having a trained inspectorate along with effective sanctions and enforcement processes in place to be able to address noncompliance (Ebata et al., 2021[46]) (Luthringer et al., 2015[47]). Similarly, country reports and policy guides that were taken into account, provide best practices and practices to be avoided in the regulatory and institutional framework for LSFF. Where possible, real-world examples of regulatory and institutional frameworks and LSFF practices in various countries have also been included in the review.

43. Overall, this section discusses the most frequently raised bottlenecks and challenges and commonly identified good practices throughout the literature. The commonalities identified in the literature concerning regulatory and institutional factors for LSFF have been categorized under six headings:

- Choosing the right food vehicles and fortificants for the population;
- Establishing the right laws and requirements;
- Creating efficient and transparent authorization processes;
- Ensuring sufficient enforcement;
- Communicating effectively to consumers and businesses; and
- Incentivizing businesses and consumers.

Right vehicles, right fortificants

1. Micronutrients to be added address deficiencies of the population that are verified based on scientific evidence

44. When creating a food fortification program, an important first step is gathering scientific evidence. The WHO notes that at the outset, data must be sourced on the scale and severity of specific nutrient deficiencies in different population groups, dietary patterns, and usual sources for

nutrient intake (WHO and FAO-UN, 2006[25]). Using data to inform program design is important for a number of reasons. It allows specific micronutrient deficiencies in populations to be targeted, and it identifies which micronutrients to add to which foods. It also identifies and helps to understand any potential constraints which may affect the addition of micronutrients to foods (such as safety, technological or cost constraints).

45. It is important to add micronutrients to food based on the deficiencies identified in the population (Osendarp et al., 2018[48]). Where possible, it is good practice to use evidence obtained from national health surveys. For instance, one study notes that at the outset of LSFF programs in the Rajasthan and Madhya Pradesh provinces of India, the National Family Health Survey was used to identify that the population had low levels of iron, and low vitamin A and vitamin D intake (Bhagwat et al., 2014[49]). In Viet Nam, National Nutrition Surveys provide regular nutrition data playing a key role in defining priorities of the national policy to improve the nutritional status of the population. The latest National Nutrition Survey of 2020 for instance, shows a significant micronutrient deficiency particularly in iron, vitamin A and zinc especially among women of reproductive age and children under five. The survey also finds that population in urban areas fares better than population in rural areas, while population in remote mountainous areas significantly lags behind in nutrients' intake (Vietnam National Institute of Nutrition, 2023[50]). The National Nutrition Survey findings have been used to set the objectives of Viet Nam's National Strategy on Nutrition for 2021-2030.

46. To define the appropriate levels of essential nutrients that should be added to foods, it is important to determine the Dietary Reference Intake (DRI) values, which specify the average daily nutrient intake levels that are needed to meet the nutritional requirements of the population. The use of DRIs as a reference helps to determine the appropriate amounts of nutrients that should be added to the food product and to ensure that fortification levels are safe and effective in meeting the nutritional needs of the population. Based on DRI reports, public health officials establish an upper intake level (the highest amount of a micronutrient which a person can tolerate) for each micronutrient being added to foods to avoid overconsumption by the population, especially for micronutrients that may be dangerous when consumed in high amounts, like Vitamin A. In the U.S. and in Canada, where food fortification is voluntary, DRI reports are used to set fortification policy and to avoid the over or under-consumption of micronutrients (Institute of Medicine (US) Committee on Use of Dietary Reference Intakes in Nutrition Labeling, 2003[51]).

47. The prevalence of micronutrient deficiencies is one of the important factors in determining which type of fortification is effective for any given country. Public health officials should therefore create a set of metrics to use in determining (i) whether there is a micronutrient deficiency in the population that requires attention and (ii) whether the need is widespread enough for fortification to be the proper solution. Other factors, which are discussed below, include dietary composition of that population, available infrastructure, food processing and production system capacities, and national regulation and governmental leadership (Olson et al., 2021[52]).

2. Food vehicles include most commonly consumed foods of the population

48. Selecting the right food vehicle is key to implementing a successful LSFF program (Osendarp et al., 2018[48]). Failure to select an adequate food vehicle is a common pitfall of LSFF programs. In one study of eight countries, poor choice of food vehicle and a failure to fortify a fortifiable food vehicle were two of the main problems that hindered the success of programs (Aaron et al., 2017[53]). The food products selected to be fortified should be frequently consumed by the population (including the target groups at risk of micronutrient deficiency), be affordable and centrally processed (Chadare et al., 2019[54]). In one study conducted in India, the food vehicles selected to be fortified were wheat flour, soybean oil, and milk. This selection was based on data identifying the consumption patterns of staple foods which could be fortified (Bhagwat et al., 2014[49]). The decision also took into

account the incremental cost of fortification of these foods, along with the ease with which they could be fortified and the willingness of industry to fortify.

49. Consumer preferences also play an important role. Sensory problems such as odour, colour, texture, and appearance will affect consumers' preferences, along with the cost of the fortified food (WHO and FAO-UN, 2006[25]). For instance, in a fortification scheme in Uttar Pradesh in India, the presence of black specs in double-fortified salt had the effect of decreased use of the salt over time (Cyriac et al., 2020[55]). Other studies noted that significant changes in colour, smell, and taste caused by the micronutrients added to rice, potentially lead to reduced acceptability of fortified rice by consumers (Alavi et al., 2008[56]). The sensory properties of fortified rice and its acceptability among consumers was also studied in Southeast Asia and more specifically in Viet Nam and Cambodia, where yearly rice consumption is more than 150 kg per capita. Even though the study identified that the organoleptic (sensory) qualities of fortified rice differed significantly from these of conventional rice, fortified rice is found to be acceptable in both countries (Khanh Van et al., 2014[57]). Other, more technical considerations to take into account when selecting the appropriate foods and micronutrients to be fortified are the chemical form of the micronutrient to be added, the bioavailability of the micronutrient in a food, the stability and chemical forms of different compounds, interactions of the fortificant with other foods in the diet, the amount/proportion of the fortificant to be added, the water/fat solubility of the fortificant, and acceptable upper/lower limits of the micronutrient in the food (WHO and FAO-UN, 2006[25]) (WHO, 2022[58]).

50. A tool that has been used to collect and analyse data needed to determine fortification vehicles, particularly in African countries, is the Fortification Rapid Assessment Tool (FRAT) (Aaron et al., 2017[53]). The FRAT combines simple 24-hour recall and food frequency questionnaires to provide minimum information about consumption patterns (including consumption of fortifiable vehicles). The FRAT is carried out at the household level amongst a population group that is representative of the target group for fortification (i.e., usually mothers and children) and not the national level (Micronutrient Initiative, 2003[59]). Furthermore, the FRAT concerns consumption patterns and does not specifically identify micronutrient intakes. Given its limitations, the FRAT survey can be carried out alone or in combination with other surveys.

51. Food Balance Sheets (FBS), carried out by the FAO, can be used to estimate food supply and per capita consumption at the national level, in combination with data from industry (Dary and Imhoff-Kunsch, 2012[60]). Household Consumption and Expenditure Surveys (HCES) can also be used to estimate consumption. HCES can be defined as a group of complex surveys which aim to ascertain household socio-economic conditions (including dietary trends), such as Household Income Expenditure Surveys (HIES), Living Standards Measurement Studies (LSMS), and National Household Budget Surveys (NHBS). An advantage of HCES over traditional dietary surveys is that they allow analysis of data from different population strata, such as from different geographical and socioeconomic backgrounds. HCES as a standalone measure to ascertain fortification vehicle selection also has its limitations. HCES may not also include food consumed away from home. Furthermore, HCES reflect a representative sample and not the full national picture. Given that most countries do not have national-level surveys on consumption patterns, a combination of individual- and household-level surveys such as FRAT and HCES may be most appropriate to fill in data gaps on fortification vehicle selection.

52. Food vehicle selection is therefore a choice which must take into account a multitude of factors, at the scientific, industrial and economic level, including but not limited to the bioavailability of the micronutrient in the food, chemical interactions, the incremental cost of fortification, the consumption of and access to the vehicle, industry attitudes and ability, and consumer taste preferences.

3. Engaging stakeholders in the beginning of the program

53. The implementation of LSFF programs involves a variety of stakeholders across the value chain and their feedback is critical. Consultations with stakeholders about implementing a LSFF program should take place early in the program. In one example in Australia, consultation with stakeholders had no impact on the ultimate outcome of LSFF efforts because conversations with stakeholders took place too late in the process (Ashton et al., 2021[61]). Stakeholder involvement at the outset can include scientific councils to provide specific advice on fortification. A system should be in place during the lifespan of the LSFF program to consult and gather feedback from stakeholders. At the local level, stakeholders include regional health bodies, which may be involved in distribution of fortified foods and awareness programs. Their capacity and needs should therefore be assessed (Diasso, Halidou Doudou and Savadogo, 2020[62]). NGOs also often play a role on the ground in implementation. Industry is a key collaborator and stakeholder as the actual fortifier of the foods. Industry feedback is crucial to identify potential bottlenecks in the production of fortified foods and collect information.

Right regulations – right levels and requirements

1. Food fortification integrated in a public policy defining the base level of the problem and objectives

54. Experience shows that the absence of national objectives related to the prevention of micronutrient deficiency are a barrier to food fortification programs (Tarini et al., 2021[63]). Hence, developing relevant public policy and strategic plans is important. Usually this will be a policy on public health, as for instance is the case in Nigeria (see Box 2.1), food and nutrition security, and/or agricultural policy. Given the problems that micronutrient malnutrition may cause on the overall socioeconomic state of a generation in terms of lost wages, productivity, and increased healthcare costs (Darnton-Hill et al., 2005[64]), food fortification may be included or even mentioned in economic policy documents (or economic resilience and recovery policy documents). The insertion of a provision on food fortification in economic policy documents can make easier and more evident the need to allocate a budget for food fortification. Failure to allocate sufficient budget is another common pitfall of LSFF programs (see below section 5).

Box 2.1. An example of integrating food fortification in public health policy

The case of Nigeria

Nigeria has been integrating and promoting food fortification in public health policy. LSFF was included as an intervention in Nigeria's National Policy on Food and Nutrition (NPFN) (Ministry of Budget and National Planning of Nigeria, 2016[65]), the main goal of which is to improve the nutrition of all Nigerians providing that food fortification is an avenue to address micronutrient deficiencies, especially among children and pregnant women. Food fortification continues to be an intervention in NPFN's subsequent iterations, the most recent being the National Multisectoral Strategic Plan of Action for Food and Nutrition (NMPFAN 2021-2025) (Ministry of Finance, 2020[66])

55. Governments should set clear public health objectives to optimize food fortification strategies (Dijkhuizen et al., 2013[45]). The absence of national objectives related to the prevention of micronutrient deficiencies are a barrier to some food fortification programs (Tarini et al., 2021[63]). At the same time, LSFF should be one part of a comprehensive strategy to combat micronutrient

deficiencies in the population (Osendarp et al., 2018[48]). The policy, based entirely on scientific evidence and information, should define the base level of the problem (i.e., micronutrient malnutrition). It should define objectives which are specific, measurable, attainable, relevant, and timely. The policy should state the means of achieving these objectives. This requires mention of which public institutions shall be involved in the implementation of the policy and their role, and similarly include the role of the private sector. The strategy should be solidified by identifying what policy instruments will be used to attain it, such as regulations, standards, and guides to be introduced, and advocacy campaigns to be conducted.

56. It is also important for fortification programs to set clear and achievable goals to assess programs over time and ensure complementarity with other strategies to control micronutrient deficiencies (Neufeld et al., 2017[67]). Researchers assert that on average, it takes a government about 3-5 years to get a fortification program up and running, including the time it takes to prepare industry to meet the standards. The policy should define medium term and longer-term goals to allow an interim milestone or checkpoint, such as reducing micronutrient malnutrition of a specific micronutrient by x% by 2030. In India, fortification is largely covered by the National Nutrition Mission, popularly named as the Prime Minister's Overarching Scheme for Holistic Nutrition (POSHAN). The next phase of the program (POSHAN 2.0) seeks to address the challenges of malnutrition in children, adolescent girls, pregnant women, and lactating mothers and has identified a road map for the short (6 to 12 months), medium (1 to 3 years) and long term (3 to 5 years) (Ministry of Women and Child Development of India, 2022[68]). POSHAN 2.0 also identifies the roles and responsibilities of the key ministries and departments involved in implementation. The POSHAN 2.0 includes the 'POSHAN Tracker', an application for real-time monitoring that should provide feedback to program managers on the impact of the scheme. It is important for policies to have the tools in place to measure the success of the policy, and it is advisable that there is a mention of the ways to evaluate the policy results.

2. Data collection to periodically assess performance and impact of LSFF

57. Periodic review of LSFF programs is important to ensure that a program is achieving its goals. Governments must periodically reevaluate the assumptions about micronutrient deficiencies in target populations to ensure that the program remains effective and is tailored to evolving needs. LSFF programs should evolve and require frequent review and revision in order to be successful (Frederick Grant, Becky L. Tsang and Greg S. Garrett, 2018[39]). Central to this is the continual collection and aggregation of data. A critical weakness in many lower-income countries, despite the widespread practice of LSFF, is the failure to generate, access or apply data during program design and implementation (Aaron et al., 2017[53]). The WHO points to the need to have established and standardized procedures, methodologies and reporting requirements in place to allow for continuous assessment of a program (WHO and FAO-UN, 2006[25]). One such tool for gauging program performance is the Fortification Assessment Coverage Toolkit (FACT), developed by GAIN in 2013. The FACT was designed to assess program coverage and utilization, and to create a feedback loop by identifying bottlenecks and barriers to coverage that can be addressed during implementation (Aaron et al., 2017[53]). The FACT is comprised of a manual and 10 tools and templates to help design surveys and interviews of households. These tools and templates provide standardised methods for the collection, analysis, and synthesis of data on quality, coverage, and consumption of fortified foods (Friesen et al., 2019[69]). Surveys such as FACT can provide useful feedback on whether a fortification program is achieving its goals.

3. Right level of regulation mandating fortification integrated in existing regulatory framework

58. The choice of the right level of regulation mandating fortification depends on legal and administrative considerations, including the hierarchy of laws, separation of powers, and the practicality of implementation. It is important to ensure that the chosen level of regulation aligns with the existing legal framework, respects potentially relevant constitutional provisions, and provides clear guidance for both regulators and food manufacturers.

59. A number of considerations should therefore be taken into account when deciding to create laws and regulations on food fortification. Whether it is preferable to create mandatory or voluntary fortification laws (or both) is dependent on the country-specific context (as discussed earlier in this document). Some degree of mandatory fortification legislation is often desirable if there is a pressing public health need to tackle a deficiency widespread in the population (Codling et al., 2015[70]).

60. To introduce food fortification, primary legislation mandating food fortification should be established, setting out its purpose and boundaries (Nathan, 1999[71]). The law should include a framework for addressing future needs. This means that the primary legislation should provide the relevant public authority with discretion for establishing new fortification requirements via implementing regulations. The advantage of regulation is that it can be amended more quickly than legislation. This allows space to adapt fortification requirements to new technologies and/or nutritional needs. In the case where it is not appropriate for legal, political, or cultural reasons to vest discretion in the public authority, it may be more advisable for the originating legislation to specify all requirements, albeit this reduces flexibility.

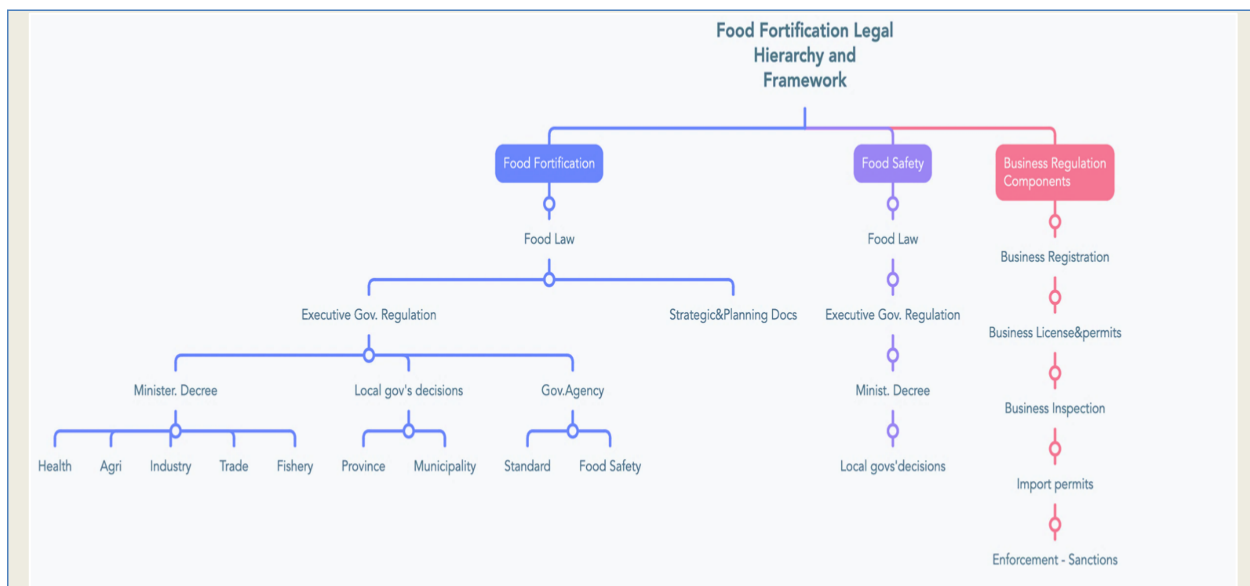
61. Legal frameworks for food fortification should be integrated into existing food law frameworks where possible (Dijkhuizen et al., 2013[45]). A comprehensive legal framework that encompasses the various levels of regulation to ensure effective and coordinated implementation of fortification is essential. Box 2.2 includes an illustration of how food fortification interacts and may be integrated in existing legal hierarchy and legal framework.

Box 2.2. Food fortification legal hierarchy and framework

Figure 2.1 illustrates the complexity of the food fortification regulatory framework which commonly consists of:

1. specific food fortification regulation;
2. which is (or should be!) integrated into the food safety regulation; and,
3. which is linked with regulatory components that shape a country's overall business environment.

Figure 2.1. Food fortification legal hierarchy



The **first pillar** of the food fortification legal framework, on the left side of the chart, involves specific legal framework on food fortification, which may for instance include adoption of standards, institutional responsibilities for food fortification etc.

Food law and related regulations, together with the broader food control system are included in the **second pillar**.

The **third pillar** involves complementary business environment regulations that stipulate requirements for a range of business activities, which are closely linked to food fortification.

62. In addition, lawmakers should also be cognizant of international agreements which affect the trade of fortified foods, namely the Agreements of the WTO as previously mentioned (WHO and FAO-UN, 2006[25]). It is essential that the law also includes provisions on quality assurance, licensure/registration of food producers/importers, wholesalers (and possibly retailers), labelling, claims and advertising, penalties and incentives, inspections, and legal proceedings (Nathan, 1999[71]).

4. Clear description of fortification requirements and standards

63. The law should state unambiguously the fortification requirements so that all involved parties are unequivocally clear on their role (Nathan, 1999[71]). This means that all relevant bodies in the chain – including producers, importers, exporters, enforcers – are aware of their responsibilities and any subsequent penalties for deviance from their responsibilities.

64. LSFF frameworks should specify the fortificants, fortification levels, food vehicles, fortification procedures and accommodate aspects of costing, include product labelling, integrate social marketing, and provide monitoring and enforcement provisions (Dijkhuizen et al., 2013[45]). Regulations should also include clear sampling and testing procedures (Makhumula et al., 2014[72]).

65. It is furthermore advised that governments provide clear regulatory guidance, accredit premix suppliers, and engage in public dialogue to help the regulated industry and other stakeholders understand the regulatory requirements (Flour Fortification Initiative, 2004[73]). Mandatory regional standards are likely to improve food fortification programs (Tarini et al., 2021[63]). The technical fortification standards provided by the government should leave no room for ambiguity and should be carefully worded so as to avoid confusion for producers. Both mandatory and

voluntary fortification standards should contain specific information on the following (WHO and FAO-UN, 2006[25]):

- Clear identification of the range of foods or food categories to be fortified
- Minimum/maximum levels and concentrations of micronutrients in food
- Composition of the fortified food(s)
- Name of micronutrient(s)
- Names and purity levels of permitted micronutrient compounds/interactions
- Labelling and advertising requirements
- Standardized provision on how the producer should convey that the product is fortified
- Provisions on nutrition or health-related claims made by the product.

5. Budget allocations for food fortification

66. In order to remain successful, food fortification requires continuous commitment and investment by governments (Osendarp et al., 2018[48]). Under-resourced and underfunded programs are subject to limited success. It is therefore important at the outset of program design that sufficient resources are allocated for implementation, monitoring and enforcement (Dijkhuizen et al., 2013[45]). While for many countries some external funding is necessary, an over-reliance on external donors will result in low sustainability of the program, particularly when the external donors exit the program (UNICEF, 2021[43]).

67. The cost of food fortification may also be significant for businesses especially when the market environment does not enable them to recover the incurred costs if there is lack of consumer demand for fortified products, or, due to cash flow pressure because of the time lag from the purchase of premix to receipt of customer payment etc (Flour Fortification Initiative, 2004[73]). This may be the case especially during the initiation and early phases of food fortification programs. In such situations governments may assist during the initial phase by providing financial assistance including subsidization, or tax exemptions. Financial provisions in the form of tax reductions, subsidies and credit could be made to incentivize businesses. Governments may also need to assist with the upfront costs of a fortification program but should not fund the cost of premixes as this will likely not be sustainable in the long run (Mkambula et al., 2020[74]).

68. Sustainable funding is important, and industry should not be entirely reliant on governments to pay for the costs of fortification after its initial phase. Cost-sharing with industry can reduce the cost of fortification for governments. It is therefore advised that a sharing scheme for food fortification costs that is affordable and sustainable for all parties is developed in a multisectoral consultation process with different stakeholders (Dijkhuizen et al., 2013[45]). Review of funding models is recommended to improve financing of the overall food control system including control of food fortification. There are countries where all monitoring costs are financed through national budget allocation, while other countries adopt mixed models with a combination of public budget allocations and supplementary revenues potentially including fees for licensing, product registration, inspection, laboratory testing charges, direct government levies to finance food control and donor funds (Mkambula et al., 2020[74]).

6. Regulation clearly delineates institutional responsibilities for food fortification and ensures no duplications

69. Legislation should clearly define responsibilities between the various institutions that may be involved in food fortification. Clear delineation of responsibilities will help avoid ambiguity, prevent overlaps or gaps, and enable institutions effectively enforce the regulations within their purview.

70. For supervisory bodies, the clear delineation of roles is particularly important to prevent the duplication of work, and to ensure efficiency and transparency in enforcement. A lack of consideration in the legislative process for enforcement can be a critical weakness of an LSFF programme (Dijkhuizen et al., 2013[45]). The legislation should identify the Ministry/ Authority responsible for supervision and clearly delineate its mission and role, along with the roles of every other institution involved in food fortification supervision (OECD, 2018[75]).

71. The roles of various institutions should be established in the early stages of program planning also to ensure that adequate resources can be allocated to them (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]). In the United States, the Food and Drug Administration (FDA) and the United States Department of Agriculture (USDA) are both responsible for food control. The distinction between their roles is clearly demarcated. It is dependent on the category of foodstuffs controlled, irrespective of whether the food is fortified. Often, multiple institutions are involved in the supervision of food fortification at different stages of the supply chain, such as imports, export, production, and trade. In some countries such as India and Nigeria, responsibility for supervision may be largely concentrated in the central food regulator (the Food Safety and Standards Authority of India (FSSAI) and the National Agency for Food and Drug Administration and Control (NAFDAC) respectively). In other countries the supervision chain is more complex. In Indonesia, the Ministry of Industry is largely responsible for food control, but supervision is also divided amongst a multitude of other agencies, such as the National Agency for Drug and Food Control (BPOM) and the National Standardization Agency (BSN) (Dijkhuizen et al., 2013[45]). It is thus important to clearly define the roles of the institutions involved. The clear delineation of responsibilities and an efficient feedback mechanism are essential so that corrective measures can be established and implemented when operational problems arise (Dijkhuizen et al., 2013, p. 182[45]).

72. Depending on how public administration is organized in each country, supervising implementation of LSFF may fall under the responsibility of multiple authorities such as various ministries, food authorities, central, regional, and local authorities, in-land and border inspection agencies, market surveillance agencies, testing laboratories etc. It is therefore important that the work of the institutions involved is coordinated in such a way as to leverage resources effectively, as a lack of coordination and collaboration can be a barrier to the program's implementation and success. Including a provision on the coordination of the workstreams of the institutions involved is a valid way to enable coordination, avoid duplication of efforts and ensure that resources are allocated appropriately. Another approach is to establish administrative arrangements to improve coordination and ensure information is shared, for instance by the signature of a multi-agency memorandum of understanding (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]) or by assigning the responsibility of coordination to a lead agency as demonstrated in Box 2.3.

Box 2.3. Assignment of co-ordination responsibilities to a lead agency

The example of India's Food Safety and Standard's Authority

In India the FSSAI is the apex body and a single reference point for all matters related to food safety and standards in the country.[1] The FSSAI is the standards-setter for foods and bears the overall responsibility for enforcement. The FSSAI delegates responsibility to officers at the State/Union Territories, and the FSSAI Central Advisory Committee acts as an interface between the FSSAI and the State authorities. The FSSAI comprises of 22 members representing various Ministries and Departments such as Agriculture, Commerce, Consumer Affairs, Food Processing, Health, Legislative Affairs, and other stakeholders representing farmers, scientists and technologists, small scale industries and retail organisations.

1. Food Safety and Standards Act 2006, Chapter 2.

73. UNICEF notes that effective collaboration and coordination is frequently hampered by the lack of an appropriate and effective oversight structure which convenes and coordinates all parties and ensures the execution of necessary responsibilities. Collaboration between and within Government institutions, and with the business/civil sector is crucial to the success of LSFF. In Viet Nam, a lack of clearly assigned responsibilities and a coordinating mechanism in the public sector is a critical barrier to food fortification implementation among other shortcomings (WHO and UNICEF, 2018[76]).

Authorization and labelling requirements to produce and trade

1. Transparent, publicly available, and predictable authorization requirements and processes

74. The requirements and procedures to produce, trade, import and export fortified foods should be clear, as well as freely and publicly available. Transparent requirements provide clarity and predictability to businesses, allowing them to prepare adequately, invest resources and plan their activities accordingly. Transparency and clarity also reduce the risk of arbitrary decision-making by licensing authorities. Transparency and accessibility can be increased for authorization processes by the use of online systems providing easy access to guidelines and requirements. In Viet Nam, the requirements for business registration (including fortified food-producing businesses) (Government of Viet Nam, n.d.[77]) are available online. Similarly, the guidelines for inspection and requirements for producers and packers of packaged (fortified) food in Nigeria are available online (NAFDAC, 2018[78]). The Food Fortification Regulations 2021 are publicly available online through the NAFDAC website and published in the Official Gazette of Nigeria (NAFDAC, 2021[79]).

75. Besides transparent requirements, it is important for industry that the authorization process is also transparent, efficient, and predictable. Authorization process and requirements should not be so stringent so as to have a discouraging effect on industry participation. Existing licensing systems should be expanded to include fortified food production to reduce the need for multiple concurrent systems (Nathan, 1999[71]). Online permit systems can help streamline the authorization process. In Indonesia, online portals exist where businesses can submit applications for the granting and renewal of business licenses (OSS, n.d.[80]), food business certificates (OSS, n.d.[81]), and food product registration. In India, the FSSAI has launched the Food Safety Compliance System (FoSCoS). FoSCoS is an integrated, multi-purpose online system that is used by both businesses and government agents (FSSAI, n.d.[82]). One use of FoSCoS is that food business operators (FBOs) may apply for licences/registration certificates and track the progress of their application through the system. FoSCos also contains a list of the mandatory requirements needed to apply for a licence/registration certificate per type of business. A list of conditions for the FBOs that are to be complied with at all times during the course of their food business is also available (FSSAI, n.d.[83]).

2. Label clearly displays ingredients including added micronutrients

76. Fortified food law should include provisions on labelling and advertising. It is important that the label of the fortified food indicates that the food product is fortified and provides essential information regarding the name and micronutrient content added. It is also imperative that labels are accurate and do not contain misleading health claims. Labelling is especially important for

enforcement bodies as it increases traceability (Nathan, 1999[71]). Basic guidance on the contents of food labelling is provided by the Codex General Standard for the Labelling of Pre-packaged Foods (Codex Alimentarius Commission, 2018[84]). With respect to fortified foods, labels should also include at a minimum the name of the fortifying agent added, and the weight content of the micronutrient (Nathan, 1999[71]).

77. While labelling is important for both voluntary and mandatory fortification systems, the need for labelling is even more pronounced for voluntary systems. In voluntary systems, labelling is crucial for promoting the consumption of fortified goods and providing information to consumers. In the United States, for instance, where a large number of voluntarily fortified goods are available on the market (Backstrand, 2002[27]), a significant part of the Food and Drug Administration's (FDA) enforcement work in relation to fortified foods is controlling for false or misleading health claims on food packaging (US Food and Drug Administration, 2015[85]).

78. In Nigeria, a declaration is required on the label of the fortified food to which micronutrients (vitamin or mineral) have been added (NAFDAC, 2021[79]). The vitamin or mineral can only be declared on the label when it meets the required level per the schedule of fortificant levels; if the micronutrient is present in an amount less than 5% of the Nutrient Reference Value (NRV), the micronutrient cannot be declared on the label. If the amount of the mineral is not less than the scheduled requisite amount, the label must state the related health benefit. Any food fortified with Vitamin A must declare as much on the label. Fortified foods must also comply with the National Agency for Food and Drug Administration Control Pre-packaged Food, Water, and Ice Labelling Regulations (NAFDAC, 2019[86]), which apply to all pre-packaged foods manufactured, imported, exported, sold, distributed, or used in Nigeria. Manufacturers are required to ensure the brand, name, expiration date and ingredient list on the package are accurate, as well as disclose any allergens and additives. Labels of fortified foods must include the amount of vitamins or minerals added to the food, as well as the percentage daily value.

79. In Viet Nam on the contrary, no specific labelling requirements for fortified food products are applicable. Fortified food products follow common labelling regulations applied for all foods, according to which labelling content includes manufacture and expiry date, ingredient and ingredient quantity, information and warnings, instructions for use and maintenance (Government of Viet Nam, 2017[87]).

3. Label includes fortification logo

80. The use of a readily identifiable logo indicating that a food has been fortified can increase consumer awareness on fortification and make it easier for consumers to make informed choices about their food intake. It also serves as a way to easily differentiate fortified products from non-fortified products. The logo promotes public trust and confidence in the safety and efficacy of fortified foods, by providing a recognizable symbol that assures consumers that the product meets certain quality and safety standards (Turk and Spohrer, 2016[88]). The fortification logo can also be used as an effective communication tool by public health authorities to conduct targeted education and communication campaigns to raise awareness about the benefits of fortified food.

81. In India, all fortified foods must be labelled with the +F logo (Figure 2.2) (FSSAI, 2021[89]). In Nigeria, foods that are fortified with Vitamin A must include on their label a picture of an "eye with A at the centre of the eye" to indicate Vitamin A fortification.

Figure 2.2. '+F' logo

Source: F*ood Safety and Standards Authority of India* *https://fssai.gov.in/cms/fortified-food.php*.

82. The West African Monetary and Economic Union (WAEMU) developed the 'Enrichi' logo to raise awareness and facilitate identification of fortified foods (see Figure 2.3). Wheat millers and oil producers in the WAEMU countries use the logo, and it has also been adopted by three non-WAEMU countries (Cape Verde, Guinea, Liberia) (Frederick Grant, Becky L. Tsang and Greg S. Garrett, 2018[39]).

Figure 2.3. 'Enrichi' logo

Source: (Frederick Grant, Becky L. Tsang and Greg S. Garrett, 2018[39])

Proper enforcement

1. Enforcement agencies have clear mission and performance indicators

83. Having a clear mission and performance criteria is important for enforcement agencies of any policy and food fortification is no exception. A clear and well-defined mission provides enforcement agencies with a sense of purpose and direction and a well-defined mission helps guide

the allocation of resources, prioritization of activities and decision-making processes ensuring that enforcement efforts are aligned with the agency's overarching goals. The mandate of supervising food fortification implementation should therefore be clearly defined in the respective institution's mission, including in relation to the outcomes which it shall contribute to, and in relation to its risk-management approach (OECD, 2018[75]).

84. A feedback mechanism, whereby the performance of the enforcement agency can be assessed with regards to food fortification implementation and enforcement, should also be in place to provide a transparent way to evaluate the agency's effectiveness and efficiency. Clear performance indicators shall enable stakeholders such as the public, government officials or oversight bodies to monitor the agency's performance and hold it accountable for delivering on its mission. Key indicators of performance can be tracked by a number of ways, including for example: consideration of satisfaction and trust among regulated subjects, efficiency (costs to the budget, burden to regulated subjects) and effectiveness (e.g., rates of compliance for fortified foods) (OECD, 2018[75]).

85. Collecting and analysing data on enforcement activities can provide useful indicators and assist in identifying any potential bottlenecks in the performance (Wirth et al., 2013[90]). An example is the practice followed by government inspectors in Jordan, whereby inspectors not only inspect facilities but also collect data that is used to create an "external monitoring system" that allows regulators to make data-driven decisions about the effectiveness of the fortification program overall and to adjust the levels of micronutrients required to be added.

2. Inclusion of food fortification supervision in existing food safety programs

86. The high quality of the final fortified product is essential in ensuring that the micronutrients reach the consumer. It is important to ensure that FBOs perceive food fortification as part of their routine food safety management so that fortification requirements are integrated into their existing quality assurance and controls. For policymakers, this means that the requirements to produce fortified food should be integrated into existing legal frameworks on food safety management as part of the overall integration of food fortification safety into existing food safety practices. The co-existence of cheaper, non-fortified products on the market can be a significant disincentive to fortify, particularly for smaller producers (Ebata et al., 2021[46]). A unified approach is therefore desirable.

87. Similarly, the controls and monitoring protocols for fortified food should be integrated into existing food safety controls (Neufeld et al., 2017[67]). It is important to ensure that food fortification supervision is not secondary to existing food safety programs, and that sufficient resources are allocated for fortification supervision within the existing food safety system (Luthringer et al., 2015[47]). UNICEF and GAIN recommend integrating food fortification supervision into existing routine food safety systems and using the same principles for regulatory monitoring (UNICEF, 2021[43]). Where separate systems are in place, this can divert attention away from food fortification. In low-resources settings in particular, staff may prioritise other food safety issues over food fortification as food safety issues generally present a higher and more immediate risk (e.g. e-coli) than an issue of sub-standard quality of fortified foods (Luthringer et al., 2015[47]).

88. An integrated systems approach can assist in the control of fortified foods. An integrated system of control involves preventative measures along the food chain whereby under fortified foods can be identified and remedied earlier. This approach requires industry to keep good records and to take ownership of safety and quality. It envisions that industry synthesizes existing food safety procedures with fortified food controls. An integrated systems approach is caveated by the need to have a cooperative working relationship between the regulator and regulated entity, trained industry staff, and an adequate system of record-keeping. If successful however, then the burden and frequency of fortified food control can be lessened for the resource-strapped regulator (Luthringer et al., 2015[47]).

3. Risk-based approach to supervision and enforcement

89. Regulatory bodies need to have in place a risk-based approach to supervision and enforcement. The legislation underlying the LSFF program should therefore allow for risk-focus and risk-proportionality, and enforcement authorities must make risk-focus and risk-proportionality the underlying foundation of all inspection and enforcement activities (OECD, 2018[75]). A risk-based approach to supervision entails establishing a methodology to prioritize inspections and assign inspection frequency based on the risk rating of the business. This will allow making the best use of limited resources such as time, budget, manpower and professional experience, by making it possible to direct resources to high-risk activities and operators and invest in addressing key problems. The approach ensures that resources are directed towards addressing significant risks rather than being spread thinly across all supervised objects and has therefore been found to lead to more effective enforcement outcomes as is corroborated by existing empirical evidence (da Cunha et al., 2016[91]) (Unnevehr, 2015[92]) (Blanc, 2018[93]).

90. 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. 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 thus ensuring a deterrence effect for hazardous violations but also reducing burden to businesses for minor infractions. A proportionate response to violations also promotes a sense of fairness and encourages a proactive attitude towards meeting regulatory requirements (*ibid.*).

91. Having a risk-based system requires having in place a standardized system of assessing and reporting risk and adequately trained inspectors in assessing and reporting risk. Further, the risk management system should be communicated to all stakeholders to improve awareness of potential risks and raise levels of compliance. When supervision and enforcement are guided by an evidence-based assessment of risk, this demonstrates a rational and objective approach which creates trust and fosters a culture of compliance (*ibid.*).

3. Availability of business register including fortified food and premixes producers, traders, importers, exporters

92. It is useful to have in place an online database containing information on all fortified food producers, importers, exporters, wholesalers, and retailers (Nathan, 1999[71]). Having a business registry in place helps regulatory bodies to keep track of businesses operating within their jurisdiction, making it easier to conduct inspections and enforce regulations. A registry provides a centralized database of information, including the location, ownership, and nature of the business, which can help regulators identify potential risks and target inspections and enforcement efforts more effectively. The business registry will enable inspectorates to compile a database of the objects under their supervision. The registry need not be sophisticated but should be reasonably comprehensive and sufficiently updated. This is the first step for a risk-based approach in supervision and enforcement of food fortification (OECD, 2018[75]).

93. In Indonesia, for instance, the Online Single Submission (OSS) for risk-based business licensing allows food producing-businesses to be categorized by risk and the licences granted accordingly. Food producers with a higher level of risk must go through a more stringent application process before being granted a business license (OSS, n.d.[80]). The OSS allows government bodies to build a risk profile of the company in question. A supervision subsystem is also contained within the OSS, and so the portal also serves as a database of businesses for monitoring by the Ministry of Industry. In India, inspections must be carried out through the FoSCoS system with inspection reports

uploaded to the system. The authorities also have access to databases of expired licenses and registrations to initiate enforcement activities. In the future, the aim is to build a national database of inspections conducted and lay the foundation for risk-based inspection scheduling (FSSAI, 2020[94]).

4. Information integration and sharing

94. Results of inspections and enforcement activities should be stored in a digital database and shared with other agencies where relevant. The digital storage of results allows for rapid data collection and analysis (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]). In particular, information management systems can allow for the storage of results from food production facilities, import sites, and laboratories, and the quick generation of reports and graphs to identify trends.

95. The rapid dissemination of inspection results with food business operators is important for quick rectification of issues and to foster a cooperative environment. Furthermore, the sharing of information and inspection results between the relevant government bodies is also important for coordinating work and avoiding the duplication of supervisory activities. Data management systems can also alert the relevant bodies to any potential regulatory monitoring issue to allow for faster remediation. At a broader level, the digital collection of inspection activities results provides invaluable information on LSFF program performance. The aggregation of such data allows trends and problems to be tracked, which can inform program performance and evaluation and inform any changes to LSFF policy (Hwalla et al., 2017[95]).

5. Proportionate enforcement actions and compliance promotion

96. Enforcement should be based on the principles of responsive regulation. This means that the response of the enforcer should accord with the profile of the business, their previous behaviour, their attitudes towards compliance and the risk posed by the infraction (OECD, 2018[75]). Enforcers should have a toolbox of differentiated and targeted approaches to enforcement as blanket 'one-size-fits-all' approaches will not be appropriate for every situation (Baldwin, 1990[96]).

97. In the first place, the legislation underlying the enforcement framework for food fortification needs to support responsive regulation by allowing for differentiated and progressive enforcement approaches. Legislation should vest enforcement bodies with an appropriate framework of discretion (within limits) to vary their enforcement actions, depending on the context and the risk level posed (OECD, 2018[75]). 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. At the same time, it is crucial that enforcement against non-compliance is carried out consistently so that non-compliant fortified food producers do not gain a significant competitive advantage. The enforcement system should also require a degree of flexibility, so that enforcement can respond appropriately depending on the risk.

98. Challenges to enabling fortification compliance include lack of prioritization and capacity, and perceptions of political risk around enforcement at the government level (Luthringer et al., 2015[47]). Two country case studies found that insufficient enforcement can reduce the potential for impact of existing LSFF regulations (Dijkhuizen et al., 2013[45]). Despite the existence of adequate legal provisions for enforcement and penalties, limited use of these provisions may lead businesses to reduce their compliance efforts. The situation is further complicated by the predominance of small-scale and very local food production, which are more easily incentivized to comply when enforcement is entrusted to a local government structure, yet capacity and commitment for inspection and enforcement may be lacking at the local government level.

99. In the practice of enforcement, understanding the drivers of compliance and attitudes of businesses towards compliance can help to determine the appropriate course of action. Some

businesses may be willing compliers but might struggle to some extent with technical capacity. Others might only be incentivized to comply when there is an economic benefit to it but may struggle with competition from non-fortifying competitors. Other businesses may be completely lacking in knowledge of requirements or capacity to fortify and may be consistent non-compliers (Luthringer et al., 2015[47]). Therefore, a differentiated enforcement response can be required where there are different attitudes and behaviours towards compliance. It is important to not overly-penalize infrequent, minor infractions, for instance where a smaller food business operator is willing to comply but has encountered some technical barriers to compliance. It is important to avoid dissuading food business operator from fortifying in the first place. On the other hand, a heavier-handed response may be warranted where a larger food business operator with the capacity to comply frequently ignores the rules and does not fortify.

100. A progressive application of sanctions is important. For first-time offenders, the issuance of a warning letter along with the guidance of the inspector on how to remedy the shortcoming may be warranted, with a short follow-up for a specified remedy period (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]). For concurrent offences, more heavy sanctions may be warranted, such as larger fines, temporary closures, or revocation of licenses. The severity of the fine should be based on the risk posed and the attitude of the business towards compliance. The gradation of sanctions should allow for the necessary escalation of sanctions by the enforcer if needed to create a credible threat and deterrence (OECD, 2018[75]). The sanctions should be sufficiently dissuasive in order to be effective, but at the same time there should not be too low – the fine imposed should cost more to the producer than the cost of not fortifying (Ebata et al., 2021[46]). It is also important to not penalize the business too harshly, as this may have a disincentivizing effect and damage the relationship between the business and the regulatory body. For instance, the revocation of a license to produce in response to a minor breach by a typically compliant producer may be too much of a heavy-handed response. Indonesia for instance has a variety of differentiated tools available to deal with instances of non-compliance. Fortified wheat flour producers or packaging businesses can be subject to a variety of sanctions, depending on the severity. If it is found following inspection that that the business does not comply with the requirements set out in the fortified wheat flour standard (Standards Authority of Indonesia, 2018[97]), the Directorate General of Industrial Development will issue a written notice to the business. The written notice will ask the producers to improve their product quality and ask the business players to withdraw any products not in accordance the standard (Ministry of Industry of Indonesia, 2021[98]). Where the business does not follow through with the request, the Directorate General will publicize the violation. Criminal or administrative sanctions may also be imposed.

101. It is further important that the results of inspections and laboratory analyses are clearly communicated to food business operators in a timely manner to allow for rapid correction. In addition, recommendations for improvement, any necessary corrective actions, and a timeframe for a follow-up visit should also be shared with the food business operator as soon as possible (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]). The FoSCoS application in India allows for instant availability of inspection reports to food business operators as soon as the report is generated by the food safety officer (FSSAI, 2020[94]).

6. Laboratories to verify the fortification status

102. Testing the fortified food is an important part of assuring the presence of micronutrients. To this end, independent, accredited laboratories are needed to carry out control measures (Bhagwat et al., 2014[49]). These laboratories need to be adequately resourced in terms of using the internationally recommended methods, having adequate supplies and equipment and appropriately trained staff so that businesses and inspectors receive correct information about the levels of fortificants and act upon results quickly (Luthringer et al., 2015[47]). Laboratories should have sufficient capacity, regardless of whether the laboratory is government- or privately-owned. Accredited

laboratories which provide services for official control should be periodically audited by an independent third-party body and should undergo periodical proficiency testing to obtain and keep the desired level of competency.

103. In the Rajasthan and Mutta Pradesh provinces of India, previous studies have identified external laboratories which carry out quantitative evaluation of fortified food samples from producers (Bhagwat et al., 2014[49]). The Food Safety and Standards Authority of India (FSSAI) has also introduced the 'Food Safety on Wheels' project. These mobile units serve as a conduit for samples to be transported to laboratories and have on-the-spot testing functionality. The presence of these units also serves to increase food safety awareness amongst the population (FSSAI, n.d.[99]).

104. Testing of samples can be carried out in a qualitative or quantitative manner. Rapid, qualitative tests such as the iron rapid-spot test are low-cost and user-friendly and can be carried out on site (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]). They provide immediate results and are used for process control. Confirmation tests should be carried in external accredited laboratories, using standardized methods for quantitative measurements. In India, qualitative methods (e.g. iron spot test) are used by government inspectors for rapid screening of whether the level of fortificants conforms to the rules. If the result of the rapid test shows that a product is in the acceptable range, further confirmation is to be achieved by quantitative testing. In cases when the rapid test shows that the levels of fortificants are out of the prescribed range, there is no need for further confirmative testing.

105. Rapid tests are useful for food industry since they can be used for process control of every production batch and can immediately inform the producer whether the expected level of fortification has been achieved. In case of deviation, the producer can react immediately and apply corrective measures. This entails significant cost savings, since a non-conformant lot is immediately recognized and can be reprocessed. Producers who do not perform process control and rely only on control of final products can risk having to withdraw or recall huge quantities of final products due to non-conformities. This is especially significant for producers that work in continuous regime of production and where lots are massive (for example: all flour produced from one silo of raw wheat). Fortified foods and premixes that are imported should be tested at the import stage. At the production level, the typical process of monitoring the fortified foods at the production side should be complemented by the testing and sampling fortified foods at production and/or trade sites (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]).

106. Accreditation of laboratories is used internationally to evaluate the quality management system in a testing laboratory. In food laboratories, accreditation is carried out according to the ISO 17025 series of standards which define the use of ISO standardized methods, equipment to be used, the need for appropriately trained staff and periodical checks on how laboratories follow the ISO 17025 requirements. The management system can be certified (it is not required) by accredited bodies. This includes the initial certification and periodical re-certification audits (Global Alliance for Improved Nutrition (GAIN) et al., 2018[44]). In India for instance, accreditation of laboratories is done by the National Accreditation Board for Testing and Calibration Laboratories (NABL), an autonomous body under the aegis of Department of Science & Technology. NABL is a full member of International Laboratory Accreditation Co-operation (ILAC) and Asia Pacific Laboratory Accreditation Co-operation (APLAC) which ensures that it performs accreditation of laboratories according to internationally recognized standards. NABL provides third-party services to government and industry as a voluntary accreditation body with no regulatory powers. Therefore, NABL may certify laboratories, while the responsibility of checking compliance with the regulatory requirements falls under the respective regulator.

107. Proficiency testing is required as per standard ISO 17025 (Nucleus India, n.d.[100]). It is an external control of accuracy for accredited laboratories. Laboratories participating in such testing are

supposed to test the unknown sample prepared by a laboratory in charge of conducting the round of proficiency testing. Usually, these are high level international laboratories which organize proficiency testing, prepare and dispatch samples which accredited laboratories (participating in that round) should test using the standard methods and equipment (accredited laboratories use ISO methods- standardized methods where both the type of chemical analysis and the equipment is prescribed and each standardized method is specific for one type of testing: for example, the standard method for testing of iron in cereals or the standard method for testing of iodine in salt). The level of accuracy of testing is estimated for each laboratory participating in one testing round.

108. While it is beyond the scope of this review to provide specific technical advice on testing, there are a number of guidelines available on these issues some of which have already been mentioned above:

- GAIN Verifying Laboratory Performance and Quality Control in the Context Of Micronutrient Testing of Fortified Foods
- GAIN Regulatory monitoring of National Food Fortification Programs: A Policy Guidance Document
- WHO, FAO Guidelines on food fortification with micronutrients.

7. Resources and training for inspectors and food business operators

109. Having appropriately trained and resourced inspectors is an imperative part of monitoring and enforcement (Luthringer et al., 2015[47]). Lack of adequately trained staff is a key obstacle to regulatory monitoring of fortified foods (Sight and LIfe and Global Alliance for Improving Nutrition (GAIN), 2015[37]). In a survey of regulatory agencies in low and medium income countries, a lack of adequately trained inspectors and analysts was cited as a key challenge to creating a legal and regulatory environment conducive to compliance (Luthringer et al., 2015[101]).

110. Inspectors should be equipped with adequate tools such as checklists and guidelines on food fortification requirements. A checklist is a tool that can be used by inspection authorities while inspecting businesses to examine the businesses' compliance with legally set standards. The checklist contains the minimum requirements with which businesses must conform. Inspectors use them to elicit detailed information about the inspected business. Checklists also serve as a basis for the decision of the enforcement action that the inspector will make after the inspection has been concluded and the measure she will impose on the activity. Checklists simplify and improve the inspection procedure by consolidating all major requirements in a single document, thus facilitating, and making inspections quicker while at the same time enhancing uniformity and consistency given that inspectors focus on the requirements included in the checklist. Checklists can also significantly promote compliance if made available to businesses in advance, so that they can understand the legal requirements and be aware of the crucial points of the inspection.

111. To make inspections of food businesses more transparent, consistent, and fair, it is advisable to develop official guidelines that include the latest food fortification regulatory requirements and instructions on how to verify they are complied with. Such guidelines may also include detailed explanation on the use of checklists, instructions on the appropriate use of enforcement powers, e.g., what type of compliance measure should be imposed depending on the type of violation etc., and clearly articulate the rights and obligations of inspectors. These guidelines will help educate inspectors, including less experienced or trainee inspectors and align inspection practices hence making the process clearer and fairer.

112. Similar guidance documents should also be developed to assist businesses comply with regulatory requirements. Regulated businesses also need to be guided, advised, and informed. Addressing effectively potential questions from businesses is essential to increase compliance. The

guidance and information documents should be accessible to businesses and explain the regulatory requirements for food fortification and how to comply in a way that is understandable by businesses.

113. The FSSAI in India have released a guidebook entitled 'Guidebook for Food Fortification for Food Safety Officers' which contains details such as levels of fortificants in various products, checklist for inspections, and specifications of fortification logo. A user manual for authorities to use the FoSCoRIS (now integrated with the FoSCoS) is also available. For the process of fortification, there are number of guides available from international organizations to assist food business operators. For example, the WHO's manual for "millers, regulators, and program managers" in flour fortification includes information on the following: quality management systems, quality assurance procedures for fortified flour, quality control measures for fortified flour, quality control and quality assurance by millers, external, import, and commercial monitoring, and consumption monitoring (WHO, 2021[102]).

Communication to consumers and businesses – building awareness and the right mindset

1. Advocacy: campaigns to explain food fortification advantages to businesses and consumers

114. Consumer education is an important part of any food fortification program (Chadare et al., 2019[54]). It is important to generate consumer demand for fortified products, and education can help achieve this. One study in Central Java, Indonesia has identified the importance of parents' education on nutrition, finding a link between the nutritional status of their child and the parents' level of nutritional education (Lowe et al., 2021[103]).

115. In another report focusing on two Indian states, social marketing and communication were critical tools in informing the public about LSFF (Bhagwat et al., 2014[49]). The Voluntary Organization in Interest of Consumer Education (VOICE) in India works to increase consumer awareness of scientific evidence and strengthen consumer rights. VOICE has resources available on increasing consumer nutritional education, providing positive information on food fortification (VOICE, n.d.[104]). In the United States, mass media advertisements and promotional campaigns have played a critical role in increasing consumer awareness and demand for fortified food (Bishai and Nalubola, 2002[24]). Consumer awareness of fortified products is particularly vital in voluntary fortification systems which are entirely dependent on consumer demand for the product.

116. Advocating the benefits of food fortification to industry is another part of the equation. Industry education is important for increasing compliance. Previous research in Bangladesh has found that (i) education of industry, (iii) more in-person interactions with industry groups, and (iii) explaining to industry why it is important to comply (reinforcing incentives and penalties at stake) are important for increasing compliance (Saha et al., 2021[105]).

2. Encourage industry-wide compliance by publishing inspection results

117. The publication of inspection results can motivate compliance amongst industry members. However, positive reinforcement is also possible by 'naming and praising' the most compliant businesses. Traditionally, Nigeria has suffered from poor compliance in the food fortification sector. In recent times, the government and industry have worked to enhance their cooperation with a view to improving compliance. Recently established, the Micronutrient Fortification Index (MFI, n.d.[106]) is an industry-led online portal which features a simple list of the names of the participating food processors who are most compliant with mandatory food fortification regulations in Nigeria. MFI is part of a broader strategy in Nigeria to enhance public-private cooperation, to digitalise quality

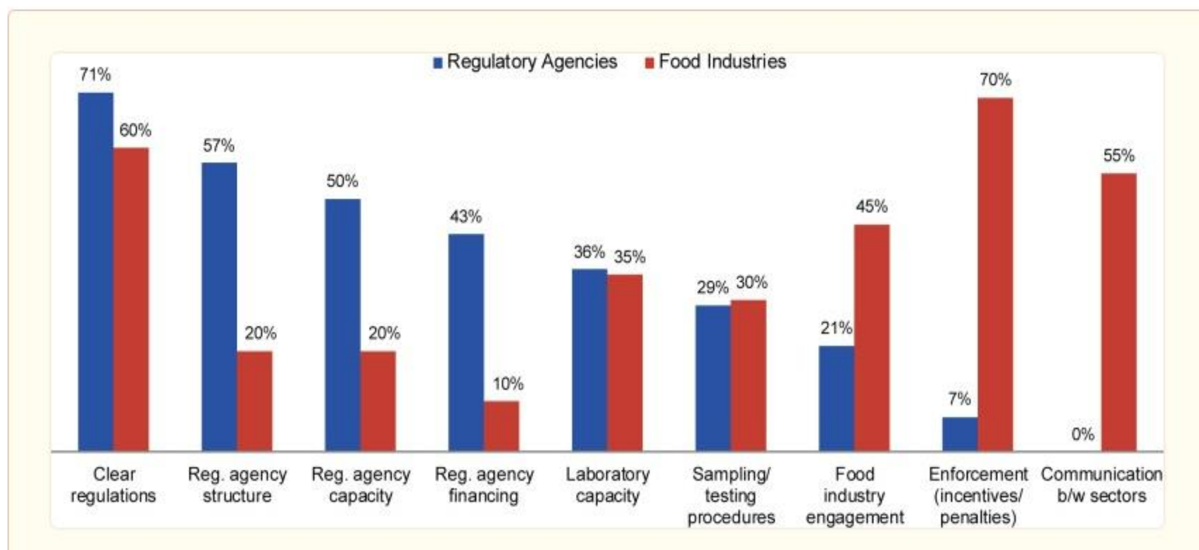
assurance, and increase transparency for consumers, policymakers, and stakeholders. The compliance score is determined in the following manner: 60% self-assessment, 20% product quality testing, and the final 20% is determined by an industry expert group. Companies can register themselves on the website to complete the self-assessment section. MFI allows consumers to make a more informed choice when purchasing fortified products. It also has the positive effect of encouraging a culture of industry compliance by recognizing the efforts of compliant companies.

3. Conduct satisfaction survey/polls for government initiatives

118. Fostering a positive working relationship between industry and government can lead to improved compliance. One way to achieve this is by conducting satisfaction surveys of industry members with regard to their opinion on government initiatives which can also provide a useful feedback mechanism on the strengths and weaknesses of government initiatives.

119. It is important to align the interests of regulatory agencies and industry on the value of compliance. Figure 2.4 demonstrates different priorities in challenges to monitoring between regulators and industry in a survey conducted in low- and middle-income countries. Regulatory agencies should improve their ability to communicate with industry in order to understand what barriers to compliance persist, and help them to achieve compliance targets (Luthringer et al., 2015[101]).

Figure 2.4. Top Regulatory Monitoring Priorities Requiring Improvements at the Regulatory Agency Level to Ensure Industry Compliance with Fortification, According to Rankings by Questionnaire Respondents from Regulatory Agencies (n=14) and Food Industries (n=20)



Source: (Luthringer et al., 2015[101])

120. In Nigeria, there is continued cross-sectoral research and conferences to strengthen food fortification initiatives (Friesen, Ojo and Mbuya, 2021[107]). For instance, the National Fortification Alliance (NFA) forum exists for government and private sectors to meet to address issues relating to fortification (Osakwe, 2020[108]). At the 4th Annual Nigerian Food Processors and Nutrition Leadership Forum - organized under the Strengthening African Processors of Fortified Foods (SAPFF) program, industry and government officials came together to discuss compliance with fortification requirements, COVID-19, and public-private partnership (News Agency of Nigeria,

2022[109]). Reports have also indicated industry and government collaboration on research regarding ongoing market and industry assessments to revise and review standards (Friesen, Ojo and Mbuya, 2021[107]).

4. Political commitment

121. Ongoing government commitment and investment in food fortification is critical to its long-term success (Osendarp et al., 2018[48]). Lack of political support and or political buy-in is often a constraining factor for LSFF program initiation and strengthening (Mkambula et al., 2020[74]). What is also important is that there is political understanding of the benefits of the program and its costs. At the same time, high political commitment cannot be a panacea in case of problematic program design (Codling et al., 2015[70]). A study finds that despite increased political support, the salt iodization program as designed and implemented between 1994 and 2005 in Vietnam was not sustainable due to issues in programme design.

122. To support implementation food fortification, including through increased political support, any perceived or actual political risk in enforcing compliance should be addressed. In one survey of regulatory agencies in low- and medium-income countries, over 60% of respondents cited potential pushback from interest groups as a barrier to enacting enforcement. The legal and political background needs to sufficiently insulate regulatory agencies from unjust threats of retaliation for carrying out enforcement (Osendarp et al., 2018[48]). Political influence from industry and corruption can disrupt the work of enforcement agencies (Ebata et al., 2021[46]). The lack of willingness to take on the political risk of enforcement may be a major barrier and regulatory agencies have frequently claimed that imposing sanctions is politically risky due to perceived or real resistance from interest groups (Luthringer et al., 2015[47]).

Other incentives

1. Tax reductions, subsidies, provision of in-kind equipment and credit

123. The extra cost of fortification can be a barrier to producers, particularly smaller ones. The additional costs to fortifying may lead to deliberate under-fortification (Osendarp et al., 2018[48]). Particularly in emerging markets, targeted financial incentives can encourage participation in fortification. Tax reductions, subsidies and credit may encourage industry participation, investment, and compliance with fortification requirements.

124. Tax reductions or exemptions to food manufacturers who engage in fortification will reduce the financial burden on the industry and create a favourable economic environment for fortification. Tax incentives can take various forms; reduced rates of value added tax (VAT) on fortified food products, elimination of import duties and VAT on fortification equipment and premixes can help meet the needs of industry in emerging markets (WFP and GAIN, 2022[110]). In Rwanda for instance, the Rwanda National Fortification Alliance identified VAT as a significant barrier for stakeholders, and discussions were held with the Ministry of Finance to reduce or waive VAT on fortified flour (Olson et al., 2021[52]).

125. Governments can also provide subsidies and in-kind equipment at the outset of an LSFF program, as this can be a significant boost for industry. Direct subsidies can be provided to food manufacturers to offset the costs associated with fortification. These subsidies can help cover expenses related to the purchase of fortification equipment, the procurement of premixes or the cost of testing and monitoring compliance. Provision of in-kind equipment may also make fortification more accessible and cost-effective and improve compliance with fortification standards. This can include micronutrient premix blending facilities, dosing equipment, or testing laboratories.

126. Premix is typically one of the largest costs in fortification, and so the large-scale tendering or procurement of premix can assist with these costs (Jarvis, 2007[111]). It is important at the same time for industry not to be wholly reliant on government, rather that the government assists with the upfront costs of fortification. In a case study of salt iodization in Viet Nam, consumption of fortified salt dropped off because it was a government-funded activity, not an industry norm (Codling et al., 2015[70]). Managers of LSFF programs should work to strengthen industry capacity/resources in order to ensure adequate capacity and quality control. (Osendarp et al., 2018[48]).

127. It is also important to ensure that smaller producers and fortifiers have sufficient access to credit facilities. Government-backed loans, low-interest loans or grants can provide significant support and reduce financial barriers and risks associated with fortification implementation. In Viet Nam, many small, private rice farmers and millers often have difficulty in gaining access to traditional lines of credit, which limits their ability to obtain equipment and paddy. The repayment system for credit also does not account for the seasonal nature of their income (Purcell, 2012[112]). This lack of credit support makes it less attractive to engage in fortification efforts.

2. Public distribution schemes / school meals

128. Public distribution schemes (PDS) involve the distribution of food to vulnerable populations such as low-income households. By including fortified food items in PDS programs, a stable market demand is generated for the specific items which can incentivize food industries to produce fortified food to meet the requirements of the program. Especially because PDS programs typically involve the distribution of very large quantities of food, which creates economies of scale for food manufacturers involved in the production of these foods, making it more economically viable for food industries to produce them.

129. An additional incentive inherent in PDS is that these are implemented with government support and collaboration, which implies potential support from government to encourage the production of the fortified food to be distributed. This support can further reduce production costs and facilitate compliance with fortification regulations hence creating a positive environment for food industries to engage in fortification. In India, the targeted public distribution scheme (TPDS) is the country’s largest social safety net. Over 800 million people are targeted, with the government providing subsidized grains through fair price shops (Bhattacharya, Falcao and Puri, 2017[113]). It was agreed that a pilot will take place in the context of the TPDS whereby 15 states will provide fortified rice via the TPDS, with the government supporting the cost of fortification (Ministry of Consumer Affairs, Food & Public Distribution of India, 2021[114]).

130. Distribution of fortified foods via non-commercial means may also be necessary to target micronutrient deficiencies in certain parts of the population. For interventions targeting school-age children, young children are not direct purchasers of food, and interventions may need to take place through prepared school-meals or through public distribution schemes. The choice of food vehicle is also a crucial factor as children’s tastes and preferences differ from adults. Some of the most commonly fortified foods in schools include milk, biscuits, grains/cereals and oil (GCNF, 2022[115]). Again, programs like school meals ensure stable consumer demand and therefore create a similar incentive structure for food industries to engage in food fortification.

3. International aid by public and private donors

131. Public and private donors play a crucial role in supporting food fortification efforts and their involvement has proved to enable more successful food fortification programs (Tarini et al., 2021[32]). International development partners often kickstart fortification efforts in low- and middle-income countries. They provide support in the design and planning of fortification programs which may

involve recommendations on the identification of suitable foods to fortify, fortification equipment, packaging, labelling and distribution systems. Development partners may also provide technical support, including guidance on best practices and training to help stakeholders acquire the necessary skills and knowledge to effectively implement and sustain fortification efforts. Guidelines published by international partners (such as the WHO-FAO, GAIN etc.) are often very influential in shaping LSFF knowledge and policy. Development partners also often provide financial support in the form of funding for equipment, and covering other costs associated with fortification activities. They also fund or help conduct start-up activities such as surveys, capacity assessments, capacity building, and standards development therefore laying the ground for food fortification programs to be designed and implemented.

132. Numerous projects around the world have been completed with the support of public and private donors. Indicatively, in India, different rounds of the National Family Health Survey (Ministry of Health and Family Welfare of India, 2021[14]), which is important for ascertaining the level of micronutrient deficiency in the population, have been conducted with funding support by the United States Agency for International Development (USAID), the Bill and Melinda Gates Foundation, UNICEF, the United Nations Population Fund (UNFPA) and the United Kingdom’s Department for International Development (DFID). In another example from Burkina Faso, the World Food Programme (WFP) and GAIN commenced the ALTAAQ (Achats Locaux, Transformation Alimentaire et Amélioration de la Qualité) program to work with local farmers to produce fortified foods, primarily for women of reproductive age and children (Condes and Dahdah, 2018[116]).

3 Databases and resources pertaining to fortification

The existence of sufficient data and evidence is instrumental for the correct design and implementation of food fortification programs as explained in the previous section. As food fortification programs need to be based on evidence, knowledge of the existing available information is important.

Data on food fortification is spread across various resources. The most important are listed below. Emphasis is placed on databases that include information on regulatory and institutional elements and could therefore be used as a source for regulatory indicators.

For each database/ source of information a short summary is provided, describing the contents of each database, the timespan of the information it contains and any other important details. A separate paragraph explains what the potential added value and contribution of each source is in the context of developing a measurement framework for large-scale food fortification regulation. The section concludes with key takeaways from the reviewed databases/ sources.

Global fortification data exchange (GFDx, n.d.[31])

Developed by the Food Fortification Initiative (FFI), Global Alliance for Improved Nutrition (GAIN), Iodine Global Network (IGN), and Micronutrient Forum, this database on FF also includes *regulatory indicators*. The GFDx is based on a survey and provides maize flour, oil, rice, salt, and wheat flour fortification data for 196 countries from 1940 to present. GFDx includes the details of food fortification legislation, fortification standards, health status before/after mandatory fortification, percent of fortified products, legislation scopes, proportions of industrially processed food, availability of regulatory monitoring protocols for imports and exports, and a limited amount of data on fortification compliance. These parameters are applied to each country, and profiles are created for each country. The country profiles also include the name of the relevant legislation or standards for fortification. In some cases, unpublished information is included, having been verified with a country official by a member of the GFDx team. The website has the feature to generate charts and maps, whereby countries may be compared along the above-mentioned parameters. GFDx also includes nutrient intake for different minerals (like Folate, Iodine, Iron, Niacin, Riboflavin, Thiamine, Vitamin A, Vitamin B12, Vitamin B6, and Zinc).

Contribution: This database is a helpful resource for analysing legislative materials and food fortification data on maize flour, oil, rice, salt, and wheat flour. The site can be used for comparative studies on countries' normative frameworks, and in identifying gaps in fortification regulatory frameworks. However, the website has a number of limitations. For example, GFDx only considers fortification standards which are in place for five staple food fortification vehicles: wheat flour, maize flour, oil, salt, and rice. Furthermore, for a number of countries, data may be incomplete, or the source may be out of date.

Maternal, newborn, child and adolescent health and Ageing Data Portal (WHO, n.d.[117])

A WHO data portal of global health data, including regional and country data. The portal contains a repository of indicators on maternal, newborn, child, and adolescent health. While the indicators concern a broad range of factors relating to healthcare, two indicators on malnutrition are included. The data contained therein is displayed in charts and maps and can be downloaded in files. The portal also contains a function to search the relevant national health policies of individual countries.

A separate article (Katwan et al., 2021[118]) was issued detailing the methodology behind the creation of the portal. From 2018-2019 a survey was carried out on Ministry of Health respondents from 155 countries with the help and facilitation of WHO regional offices. The survey was scheduled to be updated in 2022.

The methodology followed is of interest:

1. Establishment of a policy reference group to obtain external expert advice on the contents of the survey – the members
2. identified priority areas to include in the survey and suggested topics that could be excluded.
3. WHO researched existing global policy and legislative databases and found thirty data sources identifying key topics that could thus be eliminated from survey.
4. Review of questionnaire.
5. Development of glossary to ensure common understanding of technical terms (including difference between laws, policies, guidelines, strategies).
6. Survey administration
7. Validation of country responses by 2 institutions.

Contribution: The database contains a repository of national laws that may be useful for identifying the health policies of a country (including nutrition). The portal does not contain every single policy relating to food fortification or nutrition, but it does however give a useful overview of a country's health policies.

eCatalogue of indicators for micronutrient programs (WHO and CDC, 2015[119])

eCatalogue has been developed by the World Health Organization (WHO) and Centers for Disease Control and Prevention (CDC). The eCatalogue of indicators is a repository of program indicators for micronutrient programs which include food fortification program indicators. The catalogue includes a logic model, which gives a systematic overview of how micronutrient programs should be monitored and evaluated effectively at different stages of program implementation (inputs, activities, outputs, and outcomes). Therefore, these indicators are linked to program implementation stage. The catalogue describes strengths, limitations, and examples on how to use for each indicator. The target audience for the catalogue is advisors or program managers who monitor the impact of micronutrient programs. The purpose of the catalogue is to help program managers track the implementation performance of micronutrient programs, and to see whether the programs are achieving their objectives. The data used to create the indicators comes largely from practice-based evidence (i.e., from program manuals, literature, country reports and expert opinions).

Contribution: The indicators are largely related to best practices for monitoring and implementation, however there are specific and technical indicators included on how to best measure the level of micronutrients. The logic model is also a good overview of how to carry out effective monitoring of

fortification programs. However, the website may not be so user-friendly, and the catalogue was last updated in 2015.

Global database on the implementation of Nutrition Action (WHO, n.d.[120])

GINA is a repository for sharing nutrition policies, guidelines, and actions. It contains the legislation, nutrition policies and action plans for each country, including an interactive world map. The WHO claims that GINA can be used to link policies and actions to nutrition status indicators, to monitor implementation, and to identify overlaps and gaps in nutrition policy. Users can also submit and share experience on implementation. The database appears to be regularly updated also. 3,401 policies in 203 countries are included, while it has also incorporated information from GDFX, Global Iodine Network etc. The specific nutrition themes covered by GINA are: "complementary feeding, acute malnutrition, stunting, low birth weight, vitamin A, iron and/or folic acid, other micronutrients, overweight and diet-related NCDs, nutrition and HIV, breastfeeding, code of marketing of breast-milk substitutes".

The website includes interactive map presenting policies, programs/actions, mechanisms, and commitments by country.

1. Policies include legislations, and specific policies (nutritional, health sector, healthy diet), strategies, plans, guidance.
2. Programs/actions include governmental and NGOs programs on several topics including specifically on fortification (of salt, rice, flour, oil, condiment, and seasoning), school feeding programs etc.
3. Mechanisms include mechanisms on coordination and monitoring
4. Commitments: only for Brazil, Italy, Ecuador.

Contribution: The database can be used to identify the legislation, policies, and action plans regarding fortification in any given country. However, it is unclear how often the database is updated, and not all food fortification regulation is likely presented.

Food and Agriculture Organization of the United Nations legislation database (FAO, n.d.[121])

FAOLEX is a database that includes national legislation, policies, and bilateral agreements in relation to food, agriculture, and natural resource management for over 200 countries, territories, and regional economic integration organizations. It is regularly updated, with the website indicating that 8,000 new entries are added every year. For each document uploaded, its key elements are summarized in English, French and Spanish.

Contribution: This database is a helpful resource for finding national regulations and legislative materials and is constantly updated. It could therefore be used for comparative studies on normative frameworks. However, the search function is sightly limited , thus food fortification regulations and food and nutrition policies appears in the same search result page.

Food and Agriculture Organization of the United Nations - FAOSTAT (FAO, n.d.[122])

Following the recommendation of experts gathered in the Committee on World Food Security (CFS) Round Table on hunger measurement, hosted at FAO headquarters in September 2011, the database includes a

core set of food security indicators. It also includes a range of indicators on nutrition levels, such as the number of children under 5 affected by stunting. The website has the function to search and compare data either by country, year, indicator, and by value or confidence interval. The data can be exported or visualized in a graph.

Contribution: The website is a useful tool for obtaining data on rates of mal/under-nourishment, and on food availability, access, utilization, and stability and not on regulatory indicators. It is useful for also comparing data across different variables, such as country and year.

Apart from the above important databases, a number of other resources exist providing information on specific topics e.g. Food Fortification Initiative (FFI) annual reports, Global Alliance for Improved Nutrition (GAIN) country reports and datasets, Push! Global report card focusing on folic acid fortification (Push!, 2018[123]), etc.

Food Fortification Initiative (FFI, n.d.[124])

FFI is a public, private, and civic partnership based at Emory University's Rollins School of Public Health. This database provides wheat flour, maize flour, and rice fortification data. The database also includes various annual reports, and has profiles for Zimbabwe, Uganda, South Africa, Namibia, Mauritius, Mozambique, Morocco, Ethiopia, Egypt, Angola, Tajikistan, Mongolia, Bangladesh, Sri Lanka, Malaysia, Indonesia, Viet Nam, Solomon Islands, Papua New Guinea, and India. Each country profile includes information on grain practices, legislation status, grain available for human consumption, milling industry information, and nutrient deficiency indicators.

Contribution: This database is a helpful resource for food fortification data as well as voluntary and mandatory legislative materials on wheat flour, maize flour, and rice.

Global Alliance for Improved Nutrition (GAIN, n.d.[125])

GAIN is a Swiss-based foundation launched at the United Nations in 2002. GAIN provides reports, publications, and data sets on large-scale food fortification. It includes different country reports. These reports cover topics like Vitamin A fortification for oil and wheat flour in Senegal, (Centre de Recherche pour le Développement Humain, GAIN and Westat, 2013[126]) and Vitamin A fortification for oil in Pakistan (Institution of Home and Food Science and GAIN, 2016[127]).

Contribution: GAIN is a significant resource for country reports and important guidance documents including on regulatory monitoring and enforcement. It can be used for comparative studies of fortification practices and lend insight on food fortification developments in specific countries as well as challenges, experiences, and good practices in food fortification.

Push! (Push!, n.d.[128])

PUSH! is a combined effort between Hydrocephalus Association, Child Help International, Cure, Food Fortification Initiative, Sunnybrook Health Science Centre, Spina Bifida Association, March of Dimes, Boston Children's Hospital, and International Federation for Spin Bifida and Hydrocephalus. This database provides folic acid fortification data and folic acid fortification legislation. The database uses a scorecard system to evaluate the effectiveness of folic acid fortification (Push!, 2018[123]).

Contribution: While PUSH! is aimed at preventative care for Spina Bifida and Hydrocephalus, this resource provides helpful information on folic acid fortification. The country reports can be used to evaluate folic acid

fortification strategies, compare approaches by different countries, and analyse best practices for folic acid fortification based on demonstrated success in other countries.

Key takeaways from the reviewed databases

The above databases comprise a crucial resource in the research and investigation of food fortification regulation. On some databases, data on maize flour, oil, rice, salt, and wheat flour fortification and legislation status in specific countries are available. Ample data is available on malnutrition rates globally. However, for many of the databases the frequency of updates is unclear, along with any potential gaps in the datasets. Secondly, country reports are available for tracking specific food fortification policies and implementation strategies. However, the information is spread across various resources. Third, to date, no one database comprehensively collects data on compliance rates and enforcement actions in relation to food fortification. Furthermore, while databases containing troves of legislation on food fortification exist, there is no database which tracks regulatory performance.

Part II : Annotated outline of the literature

4 Methodology

The review of existing literature and subsequent annotated outline seek to answer the following questions:

1. What international and regional agreements and guidelines related to large-scale food fortification (LSFF) currently exist?
2. What databases that aggregate LSFF information and/or data exist?
3. What academic literature provides an assessment of LSFF programs, with an emphasis on analysing regulatory requirements and monitoring practices?

The key search terms that have been used include food fortification, large-scale food fortification, fortificant, food vehicle, premix, vitamin, mineral, micronutrient deficiency, voluntary fortification, mandatory fortification, international agreement, regional agreement, guidelines, database, compliance, monitoring, evaluation, and enforcement.

Prior to beginning the search process, researchers—including law students, clinical staff, and clinical faculty—at Harvard Law School, completed a training with an international law reference librarian. The training included instruction on effective research strategies for using publicly available search engines, like Google, as well as internal resources, including HOLLIS, a unified search tool that searches the broadest collection of databases, catalogues, and articles available through the Harvard Library system.

Searches for Research Questions one and two were not time-bound. The search for Research Question three was limited to the previous 20 years. Researchers review search results for overall relevance to LSFF and then, more specifically, whether the search result responds to a specific Research Question. Relevant search results were then aggregated in a shared document and categorized based on which Research Question they respond to.

Researchers reviewed each source and provided a description that summarizes the source as well as the contribution it makes towards answering the relevant Research Question. After analysing each source and drafting an appropriate description, researchers worked collaboratively to synthesize the research to identify and document the degree to which the existing literature answers the relevant Research Question. Last, researchers synthesized information from all sources to identify existing gaps in the literature and areas for potential additional research.

International agreements, declarations, and action plans on LSFF

Codex Alimentarius (FAO, 2024[129])

- Description: Codex Alimentarius means "food code" and refers to a collection of "international food standards, guidelines and codes of practice" which "contribute to the safety, quality and fairness of [the] international food trade." Standards are developed by the Codex Alimentarius Commission (CAC) to which FAO member states send delegations. Although the standards are internationally recognized and developed, they are voluntary and are not binding on member countries.
- Contribution: These standards are a well-respected source of food and nutrition policy and reflect a wealth of knowledge OECD could pull from as this project continues. Some Codex standards

and guidelines are relevant for food fortification programs (see below) and are identified as best practice by several multilateral WTO agreements.

Codex General Principles for the Addition of Essential Nutrients to Foods (GL 9-1987) (Codex Alimentarius Commission, 1987[34])

- Description: The General Principles outline general guidelines for national and/or regional governments to follow when adding nutrients to foods. It outlines the reasons why nutrients may be added to foods and provides guidance on how to decide which nutrients to add and in what amounts. It also provides guidance on selecting foods to be fortified.
- Contribution: The General Principles outline a helpful overview of high-level considerations for governments interested in implementing a fortification program. It identifies the purposes for which Codex thinks the addition of nutrients in the food supply is appropriate, which could be relevant when developing indicators of a successful fortification program.

Agreement on Technical Barriers to Trade (the "TBT Agreement") (World Trade Organization, 1995[35])

- Description: The TBT agreement is a multilateral trade agreement which seeks to ensure "that technical regulations, standards, and conformity assessment procedures are non-discriminatory and do not create unnecessary obstacles to trade."
- Contribution: Although the TBT Agreement limits regulations that unnecessarily restrict trade, the agreement permits countries to adopt policies that restrict trade where the policy is intended to improve human health. As a result, LSFF programs to combat micronutrient deficiencies would generally be permissible. Furthermore, it is important to note that the TBT Agreement encourages signatories to adopt international standards such as those developed by Codex.

Agreement on the Application of Sanitary and Phytosanitary Measures (the "SPS Agreement") (World Trade Organization, 1994[36])

- Description: The SPS Agreement sets out standards for food safety and animal and plant health among WTO member states.
- Contribution: When evaluating food fortification programs, it may be relevant to be aware that the SPS Agreement recommends the harmonization of standards among the signatories and calls out the Codex Alimentarius as a source of such harmonized standards.

UN Milestones with respect to Food and Nutrition (UN Library, n.d.[130])

- Description: This is a consolidated list of international conferences and agreements on food and nutrition plans. It collects UN milestones on food and nutrition from 1943 through 2016.
- Contribution: This list may be helpful when searching for international food and nutrition plans and commitments. It includes several international agreements which reference food fortification as a method of reducing micronutrient deficiencies. See below for more details about individual agreements.

World Declaration and Plan of Action for Nutrition (International Conference on Nutrition, 1992[131])

- Description: This document was developed at the International Conference on Nutrition held in Rome in 1992. It sets forth a plan of action to eradicate hunger and malnutrition and was designed as a guidance document for governments and NGOs. Specifically, the plan recommended steps to eliminate iodine, vitamin A and iron deficiencies. LSFF is one of the action items included in the plan which also suggests other strategies to combat malnutrition such as dietary diversification.
- Contribution: This document is somewhat outdated, but it is one of the earliest examples of international commitments to end malnutrition. It is also used as a starting point for later international agreements to eradicate malnutrition.

World Food Summit Plan of Action (World Food Summit, 1996[132])

Description: In 1996, the FAO convened a summit at which world leaders came together to renew their commitment to combat global hunger. The conference discussed world hunger and food security at a high level. The conference attendees produced a number of reports including the **World Food Summit Plan of Action**. It also generated several background technical documents, one of which discussed policies on nutrition and micronutrient deficiencies (World Food Summit, 1996, sections 4.30 and 4.31[8]).

- Contribution: The plan of action is somewhat outdated. However, it reflects the continued focus on eradicating micronutrient deficiencies. It also highlighted the lack of action-oriented guidance from previous international agreements related to nutrition and aimed to do better. A technical background document on food security and nutrition discussed the eradication of vitamin A, iron, iodine, and zinc deficiencies and presented a number of suggestions to maximize the effectiveness of fortification programs to increase demand and to incentivize the private sector to comply with the programs. Furthermore, the technical document specifies that fortification is a short-term solution and emphasizes the importance of dietary improvement over the long run.

World Food Summit +5 (2002) (FAO et al., 2002[133])

- Description: The FAO called this conference as a follow-up to the 1996 World Food Summit. The 2002 conference sought to assess whether the international community was on track to meet goals set in 1996. Unfortunately, the conference found that the world had not met 1996 goals and lagged behind the targets set. Attendees resolved to get back on track.
- Contribution: This is an important follow-up to the 1996 World Food Summit. It also represents the challenges the international community can face in meeting various goals and targets.

Zero Hunger Challenge (UN Secretary-General, 2012[134])

- Description: This challenge was launched by the United Nations Secretary-General in 2012. As of 2015, 133 countries have committed to the Zero Hunger Challenge and 45 countries are in the process of implementing food security plans in connection with the challenge. The goal of the challenge is to eliminate hunger and malnutrition. Unfortunately, according to the FAO's "The State of Food Security and Nutrition in the World 2021," the world is not on track to meet the goal of ending world hunger by 2030.
- Contribution: The Zero Hunger Challenge has produced guidance reports discussing food fortification. For example, the "**Advisory Notes by the HLTF Working Groups to Respond to the 5 "Zero Hunger Challenge" Elements**" (United Nations Secretary-General's High-Level Task Force on Global Food and Nutrition Security, 2015[135]) released in 2015, discusses a number of issues including the goal of reducing the prevalence of "stunted" children which is closely associated with micronutrient deficiencies. The report lists food fortification as a suggested policy to improve micronutrient intake.

Second International Conference on Nutrition (Second International Conference on Nutrition, 2014[136])

- Description: The conference produced two documents:
  - ***Rome Declaration on Nutrition:*** The declaration reaffirms commitments made at previous international conferences and summits (see e.g. First International Conference on Nutrition in 1992, the World Food Summits in 1996 and 2002, the World Summit on Food Security in 2009, the WHO 2025 Global Nutrition Targets and the WHO Global Action Plan for the Prevention and Control of Noncommunicable Diseases 2013-2020). It also reaffirms the universal right to access nutritious food and commits to eradicating hunger and malnutrition worldwide.
  - ***Framework for Action***: The framework includes a number of action items but only mentions food fortification as a strategy in connection with the reduction of anaemia in reproductive age

women. Supplementation appears to be a slightly more common recommendation throughout the action plan.

- Contribution: This is one of the most recent international conventions on nutrition. However, food fortification does not feature prominently and as mentioned above, is only referenced as a method to reduce anaemia in reproductive aged women.

United Nations Decade of Action on Nutrition (2016-2025) (UN General Assembly, 2016[137])

- Description: Member of the UN General Assembly claim to be "conscious of the need to eradicate hunger and prevent all forms of malnutrition worldwide, particularly undernourishment, stunting, wasting, underweight and overweight in children under 5 years of age and anaemia in women and children, among other micronutrient deficiencies, as well as reverse the rising trends in overweight and obesity and reduce the burden of diet-related non-communicable diseases in all age groups."
- Contribution: This document shows that malnutrition continues to be a problem recognized by the international community. However, like many international agreements and declarations, it is vague in terms of action-items and merely acknowledges the problems.

Global Summit on Food Fortification: #FutureFortified/Arusha Statement on Food Fortification (Sight and LIfe and Global Alliance for Improving Nutrition (GAIN), 2015[37])

- Description: This conference was held in Arusha, Tanzania in 2015 and brought together many stakeholders to generate policies related to large-scale food fortification.
- Contribution: The conference produced the **Arusha Statement on Food Fortification** Recommendations (Rhoda Peace, 2016[138]). The statement highlights five critical action areas including: (i) generating new investment in the sector, (ii) improving oversight and enforcement of fortification, (iii) generating more evidence to guide fortification policy and program design, iv) increasing accountability and global reporting, and v) continuing to advocate at the global and country level.

Food Systems Summit 2021 (United Nations, 2021[139])

- Description: The Food Systems Summit was organized as an opportunity to support the recovery of food systems in the wake of the ongoing COVID-19 pandemic and to refocus global attention on achieving Sustainable Development Goals (SDGs) by 2030.
- Contribution: The summit had several action tracks, including Action Track 1: Ensure Access to Safe and Nutritious Food for All. One of the goals under this track is to "modernize the micronutrient value chain by improving data access and use to accelerate effective coverage of large-scale staple food fortification programs." (United Nations, 2021[140]) This document goes into detail about the problem of micronutrient deficiencies, how LSFF is a key strategy to combat them and provides an overview of its proposed solution which focuses on "modernizing data generation and use for the development of evidence-based fortification standards, building the capacity of government and the private sector to monitor and enforce these standards, developing new tools and approaches to accelerate progress, empowering global advocacy, and equipping civil society to hold government and industry accountable."

Zero Hunger Private Sector Pledge (World Business Council for Sustainable Development, 2021[141])

- Description: This pledge was developed at the UN Food Systems Summit in 2021 as part of *Action Track 1: Ensure Access to Safe and Nutritious Food for All*. It is a "multi stakeholder platform of cooperation and action with a single objective of ending hunger for good" involving "businesses supported by civil society, member state governments, and international organizations." Currently, companies have contributed roughly USD 391 million to the pledge. Annual progress of the initiative will be assessed by the World Benchmarking Alliance; However, the benchmark does not yet reflect pledging company data.

- Contribution: This pledge is a relatively new initiative to mobilize the private sector in the fight against hunger. Although it is not specific to food fortification, each of the companies who sign the pledge commit to investing in world hunger in one of 10 high-impact areas as identified by a Ceres report which was funded in part by the Bill and Melinda Gates Foundation. The report briefly touches on micronutrient deficiencies but does not discuss fortification. It may be helpful to understand why the report did not address food fortification as a strategy to reduce world hunger.

Regional agreements

East, Central, and Southern Africa Region (ECSA)*: Eswatini, Kenya, Lesotho, Malawi, Mauritius, Tanzania, Uganda, Zambia, and Zimbabwe.*

ECSA Regional Fortification Initiative (ECSA-Health Community, n.d.[142])

- Description: In 2002, ECSA Health Ministers passed a resolution which "directed the Secretariat to 'work with the countries to promote food fortification Initiatives.'" In response, the ECSA-HC generated regional fortification guidelines among other things. In 2015, "the second phase of the initiative focusing on capacity building to monitor fortified and nutritious foods'' began. To ensure that industry in the region had the capacity to fortify food, the initiative set-up four technical working groups to support implementation of the program. Under the initiative, sugar and oil were fortified with Vitamin A and wheat flour and maize flour were fortified with Vitamin A, iron, zinc, and folic acid.
- Contribution: The ECSA fortification initiative is a good source of information about the food fortification goals and needs in the ECSA region. A document produced by GAIN, provides a helpful overview of the successes and failures of this regional initiative thus far (GAIN, 2017[41]).

Southern African Development Community (SADC): *Angola, Botswana, Comoros, Democratic Republic of the Congo, Eswatini, Lesotho, Madagascar, Malawi, Mauritius, Mozambique, Namibia, Seychelles, South Africa, United Republic of Tanzania, Zambia, and Zimbabwe.*

SADC Minimum Standards for Food Fortification (2020) (SADC, 2020[143])

- Description: The plan to develop fortification standards arose from the SADC Food and Nutrition Security Strategy (2015-2025). Our research has not yet located a final version of these standards, though they appear to be in process.
- Contribution: It is helpful to be aware that this intergovernmental organization is generating a unified standard for food fortification in the region.

Commonwealth of Independent States (CIS): *Azerbaijan, Armenia, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Russia, Tajikistan, Turkmenistan, Uzbekistan, and Ukraine.*

Prevention of Iodine Deficiency in the Population of the Commonwealth of Independent States (CIS) member states, Minsk 2001 (GAIN, 2021[144])

- Description: An agreement among CIS countries to decrease iodine deficiency among the population which had increased in the region since the fall of the Soviet Union. The agreement established a uniform salt iodization fortification program in CIS member states.
- Contribution: This agreement marked the first time the CIS countries sought to remedy iodine deficiencies on a regional basis through fortification.

USAID Micronutrient Fortification Project in Central Asia, Afghanistan, and Pakistan (Tazhibayev, 2016[145])

- Description: This initiative aimed to develop a harmonized standard of food fortification for CIS countries, Afghanistan, and Pakistan.

- Contribution: The initiative identified the “need to ensure, at a minimum, adequate and comparable amounts of bioavailable micronutrients in all countries of the region as specified in the WHO recommendations” and identified specific foods and nutrients the region would prioritize in food fortification programs.

Economic Community of West African States (ECOWAS) **countries in bold are also part of the West African Economic and Monetary Union (UEMOA), a sub-regional group:* ***Benin****,* ***Burkina Faso****, Cabo Verde,* ***Côte d'Ivoire****, Gambia, Ghana, Guinea,* ***Guinea Bissau****, Liberia,* ***Mali****,* ***Niger****, Nigeria,* ***Senegal****, Sierra Leone, and* ***Togo****.*

ECOWAS Resolution of Assembly of Health Ministers on Mandatory Fortification (flour and oil) - 2006 (Frederick Grant, Becky L. Tsang and Greg S. Garrett, 2018[39])

- Description: This was a resolution to make fortification of flour and oil mandatory in ECOWAS countries.
- Contribution: Regional cooperation may be a relevant aspect to consider when creating the LSFF regulatory index. By cooperating regionally, the relevant countries can share best practices and support one another. Furthermore, such cooperation may facilitate regional trade of fortified products. Whereas national fortification standards may differ and can impede trade, regional standards ensure that fortified products can move freely within the region without violating national standards. This resolution is one example of regional cooperation.

QA/QC guidelines for LSFF compliance in ECOWAS (ECOWAS, 2007[40])

- Description: ECOWAS and UNIDO worked to generate a regional quality policy which developed a regional infrastructure system and fortification standards. In the process of effectuating these guidelines, several labs were certified, and testing specialists were trained.
- Contribution: These standards will help industry in the region comply with fortification standards and may serve as a model for other regions to follow when implementing LSFF programs. The existence of QA/QC guidelines may be relevant when evaluating the success of LSFF programs.

Enrichi Logo (Frederick Grant, Becky L. Tsang and Greg S. Garrett, 2018[39])

- Description: The goal of this logo was to facilitate the identification of fortified products. UEMOA has a list of standards for which fortified products may bear the logo. ECOWAS has considered regional adoption. Currently being used across the region with the exception of Ghana and Nigeria.
- Contribution: According the USAID, the logo is “a successful example of a harmonized regionally approved brand” (USAID, 2016[146]) and will help consumers identify fortified products. The existence of such a logo could be interesting to consider as a sign of a successful LSFF program when developing the regulatory index.

USAID Fortify West Africa Initiative (USAID, 2016[146])

- Description: The initiative focused on fortifying wheat flour across all 8 UEMOA countries. From there, the goal is to expand to all 15 ECOWAS countries.
- Contribution: This is another good example of regional harmonization of fortification standards.

Association of Southeast Asian Nations (ASEAN)*: Brunei Darussalam, Cambodia, Indonesia, Lao PDR, Malaysia, Myanmar, Philippines, Singapore, Thailand, and Viet Nam*

ASEAN Leaders’ Declaration on Ending All Forms of Malnutrition (ASEAN, 2017[147])

- Description: This document is a regional declaration recognizing malnutrition as a problem and resolving to fix it.
- Contribution: This declaration commits to creating “a multi-sectoral regional framework and strategic plan aimed at ending all forms of malnutrition to guide country policies.” The declaration

led to the development of the ASEAN Strategic Framework on Nutrition, the Action Plan on Nutrition, and the ASEAN Nutrition Surveillance Plan.

Summary of findings

This portion of the literature review looked at international and regional agreements, resolutions, and conferences relevant to food fortification. It provides a high-level summary of some of the main documents in the area and their contributions to this project. There are two key takeaways from this review. First, at the international level, micronutrient deficiencies tend to be discussed within the larger context of hunger prevention and food security initiatives. While there have been conferences that focused more specifically on food fortification, it tends to be cited as one of several strategies to address malnutrition rather than being the primary focus of most international agreements/conferences. Second, there are a number of regional agreements on food fortification. Overall, ECOWAS seems to have the most robust cooperation, but regional cooperation also exists in ECSA, SADC, CIS, and ASEAN. Finally, we were unable to locate regional agreements in South America, Central America, and the Caribbean, but several countries in the region have developed a guidance document for national fortification programs.

The most significant gap in this portion of the literature review is the lack of documentation reflecting the successes or failures of the agreements, resolutions, and initiatives. While the international community has come together several times to address food security and related issues, it is difficult to locate concrete action plans designed to ensure achievement of conference goals or to find data regarding whether conference goals were achieved.

Guidelines and guidance notes by international organizations on LSFF

Food Control System Assessment Framework: Introductory Framework (FAO and WHO, 2019[148])

- Description: This tool can be used to assess a national food control system. This tool is primarily based on the Codex Principles and Guidelines for National Food Control Systems (CXG 82-2013). Its use is aimed at governments to help them to assess the adequacy of their resources and the efficacy of their controls and surveillance systems, within the scope of their legal and regulatory framework. Assessment criteria are used to gauge food control systems, receiving one of three scores: the criterion is either not achieved (0 points), partially achieved (1 point), or achieved (4 points). The assessment criteria are based on four different dimensions, refined into several sub-dimensions:
    1. **Inputs and resources:** Are system resources and inputs adequate?
    2. **Control functions:** How do the controls function?
    3. **Interactions with stakeholders:** How does the system interact with stakeholders?
    4. **Science/knowledge base and continuous improvement:** Does the system facilitate continuous improvement?

  Within the four dimensions, factors such as policy and legal frameworks, the access to infrastructure and finance, the effectiveness of monitoring and controls, interaction with stakeholders, and whether evidenced-based continuous improvements take place are also considered. Potential indicators are included for all assessment criteria. For example, an indicator for the criteria of “Clear policy guidance is available for food safety and quality” might be a clear national policy document. See the below picture as an example:

Figure 4.1. Assessment Criteria of Food-borne Disease Surveillance

DIMENSION A
DIMENSION B
DIMENSION C
DIMENSION D

DIMENSION B
CONTROL FUNCTIONS

SUB-DIMENSION B.1
SUB-DIMENSION B.2

SUB-DIMENSION B.2
MONITORING, SURVEILLANCE AND RESPONSE FUNCTIONS

<< BACK TO THE STRUCTURE OF THE TOOL
< ONE STEP BACK

B.2.2 FOOD-BORNE DISEASE SURVEILLANCE

OVERALL OUTCOME: The national surveillance system ensures an effective detection of foodborne disease and contributes to the management of food safety events, including outbreaks and emergencies.

AC CODE	ASSESSMENT CRITERIA (AC)	POSSIBLE INDICATORS	RELATED CRITERIA (CLICK SELECTED CRITERIA)	SOURCES OF EVIDENCE
B.2.2.1	A fully functional Indicator-Based Surveillance (IBS) system in place that can monitor trends and detect foodborne disease outbreaks	* case definitions for each of the notifiable foodborne deseases and surveillance system database is effective * labs and health workers are aware of obligations to report positive test results to surveillance system and clear mechanism for reporting	A.1.3.12	• FOODBORNE DISEASE SURVEILLANCE PLANS • LABORATORY REPORTS • AD HOC FOODBORNE DISEASE REPORTS
B.2.2.2	A fully functional Event-Based Surveillance (EBS) system in place that can detect food-borne events	* an EBS surveillance system that receives reports from local level and are collated within 24 hours at national level for rapid risk assessment * health care workers and sanitary/food inspectors who have been trained on reporting food-borne events to EBS (focal points/units)		
B.2.2.3	An IBS system that includes lab analysis to assign aetiology for suspected foodborne deseases, investigate hazards in foods linked to cases and outbreaks, understand trends in foodborne disease and increase sensitivity and specificity of detection	* evidence that priority foodborne disease cases captured within the surveillance system are lab-confirmed and further characterized * protocols for collecting/testing clinical specimens and data reporting for all priority foodborne disease (including case definition, action requirement) * antimicrobial susceptibility testing for relevant foodborne disease * data analyses in a regular bulletin is available to all stakeholders * surveillance system includes appropriate analysis plans for monitoring trends, with thresholds for cluster detection		
B.2.2.4	Capacity to undertake rapid risk assessments of acute public health events at the national and subnational levels	* a team (trained staff) at the national level who can rapidly assess suspected foodborne disease events within 24 hours of the initial report * training for staff at the subnational level has taken place including examples of past events and technical support from national level	B.2.3.7 D.1.2.6	
B.2.2.5	Capacity for multidisciplinary and inter-sectoral subnational outbreak response and applying analytical epidemiology during outbreak investigations	* appropriate staff have been nominated to take part in outbreak response teams (ORTs) and trained to undertake outbreak investigations * a response protocol for investigating a suspected foodborne disease outbreak * ORTs have the capacity to collect and transport appropriate specimens (including clinical) to a lab to identify aetiological agents * a response capacity capable of carrying out analytic epidemiology during outbreak investigations exists at the national and subnational levels	B.2.3	
B.2.2.6	Multi-sectoral collaboration facilitates rapid information exchange and support with laboratory testing during foodborne disease outbreak investigation	* surveillance and response staff know where the focal points are for food safety, animal health and the key labs for testing samples * an effective mechanism for rapid information exchange during suspected foodborne disease outbreak investigations among all stakeholders/relevant sectors	B.2.3.3	

FOOD CONTROL SYSTEM ASSESSMENT TOOL INTRODUCTORY BOOKLET 32

Source: (FAO and WHO, 2019[148])

The tool is interactive, but a separate table (i.e., a Word table) must be used to keep track of the score. Further instructions on its use are given in its accompanying technical instructions.

- Contribution: This is a useful framework for assessing a country's food control system. While the tool is quite extensive (nearly 30 pages long), it is comprehensive and could potentially be a useful framework the OECD can use in assessing a country's food control system. Many of the assessment criteria require intimate knowledge of a country's food control systems. Therefore, it may be potentially used for interviewing public officials, or used by consultants themselves in country assessments, or both.

Regulation of Fortified Foods to Address Micronutrient Malnutrition: Legislation, Regulations and Enforcement (Nathan, 1999[71])

- Description: This manual presents a systematic design for food fortification legislation. It is designed to help lawmakers understand the key components of food fortification legislation, particularly when they may not be familiar with regulating in this area. It is also designed to help program managers understand the purpose and critical elements of food fortification legislation. The manual presupposes that most countries already have in place some level of food control law and regulations. It also assumes that lawmakers have enacted laws for salt iodization (as this is very common), but not for fortification with vitamin A, iron, or other nutrients. It designs principles and rules which are of a general applicability to most legal systems, as it draws on evidence from the composite food control laws and regulations of many developing countries.
- The manual highlights the most important principles underlying effective legislation and regulations. For instance – the law designed should provide an enforcement mechanism and should provide for quality assurance. The manual also denotes policy considerations for the introduction of new legislation. For example, such a consideration could be whether to enact new legislation or amend existing fortification legislation, or whether the legislation should make

fortification mandatory or voluntary. The manual also provides lessons from previous fortification programs and model legislative provisions for fortification. It also discusses the design of implementing regulation and enforcement procedures. Finally, it provides sample technical specifications for fortification in the annex.

- Contribution: This manual provides essential information on the design and implementation of food fortification laws, and also considers the broader policy/political background. For lawmakers and any professionals involved in the design or application of food fortification legislation, regulation, and enforcement, this manual is essential reading. Thus, for the purposes of this OECD project, it serves as a framework from which to analyse the fortification legislation of the pilot countries. The principles of this manual inform the best practices/principles for fortification being developed by the OECD.

Regional Report on Nutrition Security in ASEAN (ASEAN and UNICEF, 2016[149])

- Description: The report compiles the Food and Nutrition Security profiles of ASEAN nations. These profiles summarize policy documents addressing nutritional issues within those ten nations, including any existing policies that pertain to food fortification. Further, the document explicitly includes food fortification as a recommendation to improve child and maternal nutrition.
- Contribution: The document will serve as an advocacy tool on nutrition, with a particular emphasis on child nutrition. The document will serve as an informational tool in providing a general overview of existing fortification policies in ASEAN nations.

Regional Harmonization for Sustainable Food Fortification Program (ECOWAS Regional Feasibility Study) (WAHO, 2008[150])

- Description: The document describes a feasibility study aimed at identifying areas of both regional- and national-level intervention with respect to regional harmonization of food fortification programs. The study offers a number of recommendations, including recommendations pertaining to setting standards for vehicles of food fortification, funding a common ECOWAS regional logo to serve as a seal for quality to brand fortified foods, and supporting the private sector in funding the initial acquisition of fortificants.
- Contribution: The document will serve as an advocacy tool, as it expressly states the need for regional food fortification programs to address significant micronutrient deficiencies in West African States. The document's recommendations will serve to provide guidance as to which policies may be most effective with respect to food fortification programs.

Advancing Large-Scale Food Fortification (UNICEF's Vision and Approach) (UNICEF, 2021[43])

- Description: The document provides a general overview of food fortification. It addresses necessary conditions of successful LSFF programs, common weaknesses of existing LSFF programs, and UNICEF's approach regarding LSFF.
- Contribution: The document will be particularly helpful in providing lessons learned from UNICEF's involvement in LSFF programs. For example, UNICEF emphasizes that mandatory fortification generates more substantial public health benefits than voluntary programs, that mandatory food fortification should be regulated under only one regulation, and that the food vehicle must be made by a large industry that has adequate resources to scale and implement quality fortification.

Fortified Porridge in Mozambique: Application of the Supply Chain Analysis for Nutrition (Scan) Tool (GAIN, 2021[151])

- Description: The briefing paper "presents a supply chain analysis of fortified porridge in Mozambique, with a focus on the possible mechanisms for scaling." The paper identifies four challenges pertaining to local fortified porridge: "1) sourcing of inputs, 2) producers/millers, 3) distribution, and 4) communication and demand creation." The paper advocates for an import-

based solution, or, in the alternative, a locally based solution so long as significant investments are made with long-term perspective.

- Contribution: The paper will serve as helpful insight into challenges pertaining specifically to the supply chain of fortified foods.

Staple Food Fortification – A Commitment Guide for the UN Food Systems Summit and Tokyo Nutrition for Growth Summit (GAIN, 2021[152])

- Description: The paper describes the malnutrition crisis and the way in which food fortification can serve as a highly effective tool to combat malnutrition. The document describes “SMART" commitments that can be used to expand access to fortified foods in countries experiencing significant micronutrient malnutrition. These recommended pledges include (1) encouraging NGOs and Multilateral agencies to commit to strengthening government capacities to design LSFF programs and (2) encouraging national governments to require the distribution of fortified foods in social safety net programs.
- Contribution: The paper serves as an advocacy tool, as the authors explicitly state that staple food fortification is “widely recognized as a development and public health “best buy.”” The paper can provide guidance in terms of commitments that should be made by NGOs, Multilateral Agencies, National Governments, and the Private Sector.

Verifying Laboratory Performance and Quality Control in the Context of Micronutrient Testing of Fortified Foods - A Guidance Document (GAIN, 2021[153])

- Description: The document describes and provides guidance pertaining to quality management and quality control in laboratory settings. The document further provides recommendations based upon laboratory assessments as conducted by experts in Asian and African countries.
- Contribution: The document serves as effective guidance pertaining to (a) selecting laboratories based on testing of micronutrients in fortified foods and (b) “verification of laboratory results for reliability.”

COVID-19 is Making it Harder for Vulnerable People to Access Healthy Foods (GAIN, 2020[154])

- Description: The document emphasizes that LSFF is a significant tool in fighting micronutrient malnutrition and that COVID-19 is adversely affecting LSFF programs in low- and middle-income countries. It further provides recommendations to governments and partners to improve fortification initiatives. These recommendations include implementing mandatory staple fortification programs, increasing funding to guarantee that the private sector can ensure production of fortified foods, and eliminating taxes on micronutrient premix.
- Contribution: The document provides insight into the way in which micronutrient deficiencies were exacerbated by the pandemic and can provide recommendations specific to strengthening food fortification initiatives in a world coping with COVID-19. The document will serve as an advocacy tool in demonstrating that food fortification would be a highly effective solution in addressing micronutrient deficiencies.

Food Fortification - The Devil in the Detail (Friesen, Ojo and Mbuya, 2021[107])

- Description: GAIN reviews a recent study capturing data from women in Nigeria, South Africa, Tanzania, and Uganda, and finds that fortified foods significantly contributed to vitamin A and iodine intake, but not to iron intake. GAIN addresses concerns pertaining to fortification standards resulting in over-consumption of certain micronutrients.
- Contribution: This article provides insight into the risks pertaining to over-consumption of micronutrients due to fortification standards. This article also reviews a study that examines how food fortification initiatives can be evaluated to determine whether they are working.

Doubling Down on Food Fortification to Fortify the Future (Garrett et al., 2019[155])

- Description: GAIN discusses the way in which food fortification can address diseases that are preventable through a sufficiently nutritious diet. GAIN further provides specific data pertaining to how food fortifications in low- and middle-income countries have already led to "dramatic reductions" in serious diseases. GAIN concludes that food fortification is still not sufficiently available and should be increased to save lives by improving access to critical micronutrients.
- Contribution: The piece by GAIN will serve as an advocacy tool demonstrating the importance of food fortification in addressing harmful diseases in low- and middle-income countries. The data can be used to show the way in which food fortification programs have helped achieve reductions in anaemia and reductions in risk of mortality in low- and middle-income countries.

Tackling Malnutrition in Haiti: Challenges, Resilience and Hope (GAIN, 2018[156])

- Description: GAIN addresses the RANFOSE project, a joint initiative by GAIN and the Partners of the Americas, which "aims to increase availability of high-quality, fortified staple foods across the country and expand the local production and importation of fortified foods." The GAIN piece addresses the process undertaken by the initiative in implementing fortification and the key objectives they hope to achieve.
- Contribution: The GAIN piece will be helpful in providing guidance for implementation of a project similar to the RANFOSE project. In particular, the piece addresses the initiative's early priority of developing an oversight and enforcement system to monitor food vehicles to ensure that they meet fortified standards.

Guidance Note on Food Fortification in Development Cooperation (European Commission, 2020[42])

- Description: This guidance memo addresses the consequences of micronutrient deficiencies on human health and national economics. The memo emphasizes food fortification as an effective solution to address food insecurity. The memo further discusses engaging the private sector to encourage private funding in fortification efforts and emphasizes that specific fortification measures should be tailored to local contexts after conducting situational analysis.
- Contribution: The guidance memo will serve as an advocacy tool, as it emphasizes the way in which food fortification meets EU political priorities.

Guideline: Fortification of Food-Grade Salt with Iodine for the Prevention and Control of Iodine Deficiency Disorders (WHO, 2014[157])

- Description: The purpose of the guideline is to help Member States and partners to make decisions on nutrition-related action to achieve the Millennium Development Goals (MDG). WHO emphasizes the importance of iodine in the growth, development, and control of metabolic processes in the body, in reproductive functions, and in a child's ability to learn. Finally, the guideline addresses the way in which salt is the appropriate vehicle for fortification with iodine, as (i) it is widely consumed, (ii) it is limited to production in a few centres, facilitating quality control, (iii) the necessary technology is well-established, (iv) fortification of iodate does not impact the taste of salt, (v) iodine remains in processed foods that contain salt as the main ingredient, and (vi) iodization is expensive.
- Contribution: The guideline will serve as an effective advocacy tool for advocating for salt as a fortification vehicle to address iodine deficiency disorders.

Guideline: Fortification of rice with vitamins and minerals as a public health strategy (WHO, 2018[158])

- Description: The guideline discusses how decisions about the types and amounts of nutrients to add to rice are based on a number of factors, including: (1) the nutritional needs of target populations, (2) the typical amount of rice consumption, (3) the impact of fortification on rice, and

(4) the level of fortification of other staple food vehicles. The guideline provides evidence-informed recommendations on the fortification of rice with micronutrients. These recommendations include fortification of rice with iron, vitamin A, and folic acid.

- Contribution: The guideline will serve as an advocacy tool for the fortification of rice with iron, vitamin A, and folic acid. The guideline also serves as an informational tool in determining how much of a particular micronutrient to add to a fortified food vehicle.

Guidelines on Food Fortification with Micronutrients (WHO and FAO-UN, 2006[25])

- Discussion: The guideline discusses food fortification as a solution for micronutrient malnutrition. It emphasizes the prevalence and harms of micronutrient deficiencies. The guideline provides technical information on the chemical forms of micronutrients that can be used to fortify foods. Finally, the guideline recommends important steps in “designing, implementing and sustaining” fortification programs. These key recommendations include determination of the amount of nutrients integrated into a food vehicle, establishment of monitoring systems for quality assurance, international harmonization, consumer marketing, and public education.
- Contribution: The guideline serves as practical guidance in determining the technical steps in designing, implementing, and sustaining food fortification programs.

WHO guideline: Fortification of Maize Flour and Corn Meal with Vitamins and Minerals (WHO, 2016[26])

- Discussion: WHO recommends fortification of flour and maize with certain micronutrients, such as iron, to address deficiencies in vulnerable populations, including children and women. The guideline provides information pertaining how to determine which nutrients, and the amount of those nutrients, to integrate into flour.
- Contribution: The guideline serves as a recommendation for fortification of flour and corn with iron. The guideline provides information pertaining to the process of determining which nutrients, and the amount of those nutrients, to add to a fortified food vehicle.

WHO Guideline: Use of Multiple Micronutrient Powders for Point-Of-Use Fortification of Foods Consumed by Infants and Young Children Aged 6-23 Months and Children Aged 2-12 Years (WHO, 2016[159])

- Discussion: The guideline discusses the high rates of anaemia in children in Saharan Africa and in South Africa. These high rates of anaemia are caused by deficiencies in Vitamin A and iron. The guideline recommends “point-of-use fortification of complementary foods with iron-containing micronutrient powders” to reduce anaemia. Point-of-use fortification refers to fortification occurring in the home, at schools, nurseries, refugee camps or other places.
- Contribution: The guideline serves as an effective advocacy tool for point-of-use fortification.

A Blueprint for the Design and Implementation of Large-Scale Food Fortification Programs (Nutrition Internatinal and Food Fortification Initiative, 2021[160])

- Discussion: The blueprint provides a guide for governments and agencies supporting large-scale fortification programs. The blueprint aims to inform these parties on how to scale and sustain effective fortification initiatives and outlines recommended fortification practices. These recommendations include demonstrating feasibility of such initiatives with stakeholders, establishing guiding structures with respect to legislation and monitoring guidelines, operationalizing, and creating a system for monitoring and enforcement.
- Contribution: This blueprint serves as guidance for critical steps organizations should take in (1) engaging and advocating with key stakeholders and (2) implementing fortification efforts to ensure effectiveness and efficiency.

Scaling up Rice Fortification in Latin America and the Caribbean (Sight and Life and World Food Programme, 2017[161])

- Description: The report outlines the prevalence and severity of micronutrient deficiencies, including iron, iodine, zinc, and Vitamin D deficiencies, in Latin America and the Caribbean. The report further provides a list of nutritional programs that aim to provide micronutrients in Latin America countries, along with the target group for those programs. The report concludes that the prevalence of micronutrient deficiencies has declined in Latin America, but that in several countries, micronutrient deficiencies remain a problem in populations with more substantial economic, geographical, or social vulnerability. The report further concludes that strategies like rice fortification can be used to address these micronutrient deficiencies.
- Contribution: The report is helpful in understanding the state of micronutrient deficiencies in Latin America countries. The report will serve as an advocacy tool for rice as a fortification vehicle.
- Gaps: The report explicitly acknowledges that there is "a significant gap in terms of the available data."

Summary of findings

This portion of the literature review examines existing guidelines and reports by international organizations (intergovernmental organizations and international non-governmental organizations) relevant to food fortification and provides high-level summaries of the content of these reports and of their primary potential contributions to this project. There are three key takeaways from the aforementioned reports and guidelines. First, micronutrient deficiencies pose a severe problem that contributes to serious health issues, particularly in economically and socially disadvantaged communities. Second, food fortification is widely recognized as one of the most effective and cost-efficient tools to address this malnutrition. Third, key challenges within the realm of food fortification pertain (1) to determining the proper vehicle of fortification, (2) to determining how that food vehicle can be efficiently distributed to the populations suffering the most from micronutrient deficiencies, and (3) to determining how to effectively implement a fortification program in a given region. Aggregately, these reports and guidelines from international organization serve (1) as an advocacy tool in demonstrating the effectiveness and efficiency of food fortification in addressing malnutrition and (2) as a guide in developing recommendations that take into account the key lessons learned and challenges faced by international organizations that have undertaken food fortification initiatives.

Two significant gaps within the reports that should be noted. First, GAIN's review of data from a Nigerian fortification program revealed risks that fortification standards could result in the harmful over-consumption of micronutrients. However, the other reports did not address the risk of over-consumption of micronutrients caused by food fortification. As such, additional information pertaining to ensuring that standards are appropriately set to ensure neither over- nor under-consumption of micronutrients is critical. Second, it would be helpful to understand which food fortification recommendations can be generally applied to most regions and which recommended measures must be tailored to meet the particular needs of communities. For example, the European Commission's *Guidance Note on Food Fortification in Development Cooperation* report mentioned that situational analyses should be undertaken to determine whether a population-based program or a targeted program is needed in a particular region. It would be helpful to understand if there are any other additional fortification recommendations that need to be informed by and altered based on situational analyses conducted prior to their implementation in either particular regions or within specific demographics, like women and children for certain micronutrients.

Databases on food fortification standards, policies, and regulation

Global Fortification Data Exchange (GFDx, n.d.[31])

- Description: The GFDx provides maize flour, oil, rice, salt, and wheat flour fortification data for 196 countries. GFDx includes food fortification legislation for fortification standards, health status before/after mandatory fortification, percent of fortified products, legislation scopes, proportions of industrially processed food, availability of regulatory monitoring protocols, and fortification quality. GFDx also includes nutrient intake for different minerals (like Folate, Iodine, Iron, Niacin, Riboflavin, Thiamine, Vitamin A, Vitamin B12, Vitamin B6, and Zinc).
- Contribution: This database is a helpful resource for analysing legislative materials and food fortification data on maize flour, oil, rice, salt, and wheat flour. The site allows to generate custom charts. So, it could be used for comparative studies on normative frameworks and determining potential steps forward based on a country's current policies.

Food Fortification Initiative (FFI, n.d.[124])

- Description: This database provides wheat flour, maize flour, and rice fortification data. The database also includes various annual reports, and has profiles for Zimbabwe, Uganda, South Africa, Namibia, Mauritius, Mozambique, Morocco, Ethiopia, Egypt, Angola, Tajikistan, Mongolia, Bangladesh, Sri Lanka, Malaysia, Indonesia, Viet Nam, Solomon Islands, Papua New Guinea, and India. Each country profile includes information on grain practices, legislation status, grain available for human consumption, milling industry information, and nutrient deficiency indicators.
- Contribution: This database is a helpful resource for food fortification data as well as voluntary and mandatory legislative materials on wheat flour, maize flour, and rice.

Global Alliance for Improved Nutrition (GAIN, n.d.[125])

- Description: GAIN provides reports, publications, and data sets on large-scale food fortification. It includes different country reports. These reports cover topics like Vitamin A fortification for oil and wheat flour in Senegal (Centre de Recherche pour le Développement Humain, GAIN and Westat, 2013[126]), and Vitamin A fortification for oil in Pakistan (Institution of Home and Food Science and GAIN, 2016[127]).
- Contribution: GAIN is a helpful resource for finding country reports. It can be used for comparative studies of fortification practices and lend insight on food fortification developments in specific countries.

Push! (Push!, 2018[123])

- Description: This database provides folic acid fortification data and folic acid fortification legislation. The database uses a scorecard system to evaluate the effectiveness of folic acid fortification.
- Contribution: While PUSH! is aimed at preventative care for Spina Bifida and Hydrocephalus, this resource provides helpful information on folic acid fortification. The country reports can be used to evaluate folic acid fortification strategies, compare approaches by different countries, and analyse best practices for folic acid fortification based on demonstrated success in other countries.

Food and Agriculture Organization of the United Nations (FAOLEX) (FAO, n.d.[121])

- Food and Agriculture Organization of the United Nations (FAOLEX)
- Description: FAOLEX is a food, agriculture and natural resources management database that includes national legislation, policies, and bilateral agreements for over 200 countries, territories, and regional economic integration organizations. To use the database, type "food fortification" in the search engine to pull up different country resources.

- Contribution: This database is a helpful resource for finding national regulations and legislative materials. Since the database is constantly updated, it is a great resource for finding the latest food fortification policies from different countries. Therefore, it could be used for comparative studies on normative frameworks and the determining the direction of food fortification legislation.

eCatalogue of indicators for micronutrient programmes (WHO and CDC, 2015[119])

- Description: The eCatalogue of indicators is a repository of standards and impact indicators for food fortification legislation. The standards and indicators largely relate to regulatory overview and monitoring of the implementation and impact of food fortification programs. Strengths, limitations, and examples are given for each indicator. The target audience for the catalogue is advisors or program managers who monitor the impact of micronutrient programs. The purpose of the catalogue is to help program managers track the implementation performance of micronutrient programs, and to see whether the programs are achieving their objectives. The catalogue includes a logic model, which gives a systematic overview of how a fortification project should be monitored and evaluated effectively and denotes specific indicators as evidence for each specific level of implementation. The logic model can be downloaded and adapted to specific programs. The model shows the relationship between input theories of effective implementation, and the desired outputs of a program. The data used to create the indicators comes largely from practice-based evidence (i.e., from program manuals, literature, country reports and expert opinions).
- Contribution: The indicators are largely related to best practices for monitoring and implementation, however there are specific and technical indicators included on how to best measure the level of micronutrients. The logic model is also a good overview of how to carry out effective monitoring of fortification programs. However, a drawback is that the catalogue has not been updated since 2015.

Global database on the Implementation of Nutrition Action (GINA) (WHO, n.d.[120])

- Description: GINA is a repository for sharing nutrition policies, guidelines, and actions. It contains the legislation, nutrition policies and action plans for each country, including an interactive world map. The WHO claims that GINA can be used to link policies and actions to nutrition status indicators, to monitor implementation, and to identify overlaps and gaps in nutrition policy. Users can also submit and share experience on implementation. The database appears to be regularly updated also.
- Contribution: The database relates to nutrition policies overall. However, it can be used to identify the legislation, policies, and action plans regarding fortification in any given country. It also contains the names of the monitoring mechanisms for fortification published by each country. However, it does not include link to or a copy of the mechanism, which makes it hard to find.

Summary of findings

This section of the literature review examined existing databases on food fortification standards, policies, and regulations to provide a high-level summary of the main documents and their contributions to this project. There are several key takeaways from the aforementioned databases on fortification standards, policies, and regulation. First, there are adequate options for tracking maize flour, oil, rice, salt, and wheat flour fortification data and legislation in specific countries. Second, country reports are available for tracking specific food fortification implementation strategies. However, the information is spread across various resources. Therefore, in the future, it would be helpful to aggregate all the information across these databases and reports. That way, data from individual country reports can be compiled into comprehensive guides that provide more detailed information for each country. After aggregating all this information, it would be helpful to set up a standardized set of charts and assessments to input all this information. This would enable more detailed country analyses, allow for direct comparisons between countries, and provide

the groundwork for assessing best practices, pinpointing individual areas of improvement. Finally, databases containing information on the regulatory frameworks in place are available along with performance indicators, which are of high relevance to the development of the OECD's index.

Assessments of food fortification programmes

Food Fortification: The Advantages, Disadvantages and Lessons from Sight and Life Programs (Olson et al., 2021[52])

- Description: This is a reflection on lessons learned from various Sight and Life fortification programs in low- and middle-income countries (LMIC). The article draws on a large body of Sight and Life research but specifically focuses on programs in India, Rwanda, and Ghana. It finds that fortification programs "are most successful when partnerships are formed that include the public and private sector as well as other parties that can provide support in key areas such as advocacy, management, capacity building, implementation and regulatory monitoring." The report also notes several challenges including (i) difficulty with engaging small to medium businesses, (ii) having insufficient technological capabilities, and (iii) lack of fortification and food regulations. The report highlights specific country programs:
    - ***India**:* In 2018, the Indian government began a fortification program called the National Nutrition Mission which focuses on fortifying staple foods like rice. The program funnels fortified foods to the population through three government programs all designed to supplement the population's food intake.
    - ***Rwanda***: Rwanda runs its fortification program through its Food and Drug Administration (FDA). The FDA in Rwanda established the Rwanda National Fortification Alliance through which various stakeholders meet to discuss the progress of and challenges with the country's fortification program. The article specifically highlights findings from the alliance which "identified VAT taxation as one of their biggest challenges" and subsequently petitioned the Rwandan Ministry of Finance to decrease or eliminate such taxation on fortified flour.
    - ***Ghana***: A joint partnership between the governments of Ghana and Germany and NGOs produced a seal called the OBAASIMA seal which is a "front-of-package seal that guarantees nutrition quality, while easily identifying fortified food products that provide a good source of 18 vitamins and minerals designed for women of reproductive age."
- Contribution: This article reviews the successes and challenges faced by fortification programs in a number of countries, specifically in India, Rwanda and Ghana. These findings include information on implementation of fortification programs. Specifically, the article identifies a number of best practices which are of interest to the OECD, in particular relating to: (1) the need for labels on fortified products to display the added micronutrients and have a recognizable logo on fortified foods (2) the benefits of public distribution of fortified foods, and (3) the need for elimination of tax barriers and use of government subsidies.

Enablers and Barriers of Zinc Fortification; Experience from 10 Low- and Middle-Income Countries with Mandatory Large-Scale Food Fortification (Tarini et al., 2021[63])

- Description: This is an academic study exploring zinc fortification in ten LMICs. These ten countries include Cameroon, Guatemala, Haiti, Indonesia, Malawi, Togo, Burkina Faso, Mali, Côte d'Ivoire, and the Philippines. The study notes that despite the high prevalence of zinc deficiency worldwide, zinc does not form part of many LMIC fortification programs. The identified "enablers" to the inclusion of zinc in fortification plans include the low cost of zinc, the existence of mandatory regional standards, and the receipt of advice from development partners. The "barriers" identified include the "the absence of zinc from regional fortification standards, limited available data on the

efficacy and effectiveness of zinc fortification, and the absence of national objectives related to the prevention of zinc deficiency."

- Contribution: This article is a recent deep dive exploring the factors that hinder and enable fortification with a particular micronutrient, zinc While some factors identified are zinc-specific, they may also be generalizable to other micronutrients. For example, some factors are of general relevance to the OECD: (1) advice from international organizations often initiates food fortification programs (2) governments must collect scientific data on micronutrients lacking in the population, and must also assess and reevaluate the implementation of the program (3) Regional fortification standards guide national fortification standards, and (4) the long term success of a fortification program requires commitment from the national government and international organizations. It is important to note that the findings are only based on the ten LMICs previously identified, so may not be applicable to all countries.

The Unfinished Agenda for Food Fortification in Low- and Middle-Income Countries: Quantifying Progress Gaps and Potential Opportunities (Mkambula et al., 2020[74])

- Description: The report examines the Global Fortification Data Exchange (GFDx) to identify countries that could benefit from new or improved LSFF programs. The study identified the following 84 countries as countries that either currently have a voluntary fortification program in place which should be mandatory or do not have a fortification program in place and could benefit: Bangladesh, Belize, Brazil, China, Colombia, Egypt, India, Korea (DPR), Maldives, Nigeria, Saint Vincent and the Grenadines, Sri Lanka, Thailand, Timor-Leste, Albania, Algeria, Angola, Armenia, Azerbaijan, Belarus, Bosnia and Herzegovina, Botswana, Bulgaria, Eswatini, Ethiopia, Gabon, The Gambia, Georgia, India, Iraq, Lebanon, Lesotho, Libya, Macedonia, Mauritius, Montenegro, Namibia, Pakistan, Romania, Russia, Sao Tome and Principe, Serbia, Sri Lanka, Ukraine, Vanuatu, Lesotho, Moldova, Namibia, Zambia, Afghanistan, Argentina, Benin, Brazil, Cabo Verde, Central African Republic, Congo, Korea (DPR), Dominican Republic, Ecuador, Fiji, Grenada, Guatemala, Guinea, Guinea-Bissau, Honduras, Indonesia, Iran, Jamaica, Jordan, Kazakhstan, Kiribati, Kyrgyzstan, Lebanon, Macedonia, Malaysia, Mali, Mauritius, Mexico, Mongolia, Montenegro, Morocco, Myanmar, Namibia, Nepal, Niger, Paraguay, Romania, South Africa, Sudan, Suriname, Tajikistan, Thailand, Timor-Leste, Tunisia, Turkey, Turkmenistan, Ukraine, Uzbekistan, Democratic People's Republic of Korea, Samoa, South Sudan, Vanuatu. The report lays out a four-pronged strategy: (i) establish new LSFF programs in regions in need; (ii) implement systems innovation informed by implementation research to address coverage and quality gaps; (iii) emphasize advocacy to form new partnerships and create access to new resources, especially with the private sector; and (iv) explore potential new fortificants and vehicles. The report identifies that the potential for fortification of oil, ghee, rice, wheat, and maize is not being met due to low coverage of adequately fortified goods. To address poor coverage, the report urges the generation and use of data for decision making during program design and implementation. The report furthermore urges use of innovations in ingredients, product mixes, technology, and systems/business models in order to boost coverage and quality. The report also details characteristics a country might have that would preclude implementation or strengthening of LSFF programs within that particular country. These reasons include: (i) political instability or lack of political support(ii) no strong motivators that would bring industry on board, (iii) small-scale production of commonly consumed good, (iv) an unwillingness to use regional and global data as evidence of impact, and (v) a reliance on the government, rather than the private sector, to finance the cost of premix. Premix is a blend of vitamins and minerals added to foods during the fortification process.
- Contribution: The report is useful in understanding (i) how to identify countries that could benefit from new or improved LSFF programs, (ii) how to engage with the private sector (iii) solutions to address poor coverage and (iv) what characteristics may impede a strong LSFF program in a

particular country. In all, the report serves as evidence for a number of important LSFF elements: (1) Evidence is needed to identify appropriate fortificant vehicles (2) The use of subsidies/tax breaks are desirable to incentivise private industry (3) LSFF should be integrated with food control (4) Involvement of private industry/consumers and conducting satisfaction survey/polls for government initiatives is key, and (5) ongoing political commitment is paramount to LSFF success.

Food Fortification in West Africa: Progress and Lessons Learnt (2018) (Frederick Grant, Becky L. Tsang and Greg S. Garrett, 2018[39])

- Description: The report reviews food fortification in West Africa and examines lessons learned in the implementation of LSFF programs in the region. While the report generally discusses West Africa broadly, it also looks more specifically at the fifteen countries that make up the Economic Community of West African States ("ECOWAS"). These fifteen member countries are Benin, Burkina Faso, Cabo Verde, Côte d'Ivoire, the Gambia, Ghana, Guinea, Guinea-Bissau, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo. Specifically, the report identifies key stakeholders and discusses (i) the role of these stakeholders and (ii) the processes at both the national level and the regional level that serve to advance LSFF. Key stakeholders include the West African Health Organization ("WAHO"), the West African Monetary and Economic Union ("UEMOA"), and ECOWAS. Further, the report emphasizes that LSFF programs have improved through "regional commitment and leadership complemented by national level action." The report details regional efforts in support of food fortification, including the harmonization of regional fortification standards and regional quality assurance and quality control guidelines. In addition, the report emphasizes that LSFF programs are an evolving, ongoing, and dynamic process requiring frequent review and revision. The report details efforts pertaining to both private-sector industry and government capacity-building, especially with respect to fortification processes, quality assurance and control, food safety, and quantitative and qualitative analytical techniques. The report concludes by emphasizing the importance of (i) regional political will be complemented by national-level action, (ii) clear roles and responsibilities between agencies and organizations, and (iii) the fact that the passage of LSFF legislation is only the beginning of the process and that continuous monitoring and reassessment is critical in ensuring that the program meets the population's micronutrient needs.
- Contribution: The report provides guidance in understanding how to harmonize fortification standards across regions and how to build both private-sector and government capacity to implement an LSFF program. It supports (1) clearly delineated responsibilities for supervision of fortified food (2) right level of regulation mandating fortification, and other policy instruments (3) clearly delineated responsibilities for supervision (4) political commitment to LSFF, and (5) assessing the impact of food fortification periodically.

Coverage and Utilization in Food Fortification Programs: Critical and Neglected Areas of Evaluation (Neufeld et al., 2017[67])

- Description: This article uses the FACT survey instrument which is designed to assess "coverage and utilization of fortified foods." There are several takeaways from the study, but the most relevant is that fortification programs should set "clear and achievable goals to assess programs" over time and "ensure complementarity" with other strategies to control micronutrient deficiencies. More specifically, the researchers assert that on average, it takes a government about 3-5 years to get a fortification program up and running, including the time it takes to prepare industry to meet the standards. Furthermore, this article recognizes the lack of information available about the implementation process for fortification programs and encourages further study. The researchers do suggest that "program assessments that identify and improve procedures aligned with good practice, such as integration of fortification into existing food safety and control inspections and

continual financing to support such actions, the use of an incentive and penalty schemes to ensure compliance" would likely improve program compliance and effectiveness.

- Contribution: This article identifies several gaps in the existing food fortification research and literature, such as information on the implementation process for fortification programs and makes recommendations for how to improve program compliance and effectiveness. For example, it suggests enhanced data collection during the LSFF implementation process. With regard to controls, the report identifies across LMICs a "lack of resources, capacity, tools, and processes to routinely and systematically monitor nutrient concentrations in fortified foods and act on that information to enforce compliance with food fortification standards". The report urges "concrete actions" but does not specify actions in this regard. Nonetheless, these results are relevant to the elements of (1) the need to report and store results of supervision (2) inclusion of food fortification supervision in food safety programs (3) the importance of a designated budget allocation to supervision (4) the impact of food fortification should be assessed periodically, and (5) micronutrients which are added address deficiencies of the population that are verified based on scientific evidence.

The Prevalence of Micronutrient Deficiencies and Inadequacies in the Middle East and Approaches to Interventions (Hwalla et al., 2017[95])

- Description: The report reviews current approaches to micronutrient deficiencies in the Middle East. While the report discusses the Middle East broadly, the studies reviewed in the report tend to focus on Egypt, the United Arab Emirates, and Saudi Arabia. The report emphasizes that LSFF in the Middle East is "sporadic and ineffective." The report attributes the ineffectiveness of LSFF in the Middle East to the fact that ongoing monitoring programs are small and outdated. The study finds that Middle Eastern countries need to update their national fortification data, to better inform policy decisions regarding the development of LSFF programs. The report emphasizes developing public-private partnerships in implementing micronutrient fortification programs. The main conclusions of the report are that governments in the Middle East need to better educate vulnerable members of the population (women of childbearing age, the elderly, children) who are vulnerable to malnutrition. Nationwide nutrition surveillance systems need to be established. Healthcare workers should have better diagnostics in place for malnutrition and collect data. This data can be used to inform further initiatives.
- Contribution: The report is helpful in understanding the monitoring characteristics that render an LSFF program ineffective. Specifically, LSFF programs need up-to-date national data that can be used to (i) analyse the effectiveness of current policies and (ii) inform any changes in LSFF policies. The report can also be helpful in understanding the importance of developing strong partnerships with the private sector to aid in the sustainable execution of an LSFF program. The recommendations and conclusions of this report are related to the core elements identified of (1) the need to add micronutrients based on scientific data from the population, and (2) public education campaigns on food fortification.

Coverage of Large-Scale Food Fortification of Edible Oil, Wheat Flour, and Maize Flour Varies Greatly by Vehicle and Country But Is Consistently Lower Among the Most Vulnerable Results from Coverage Surveys in 8 Countries (Aaron et al., 2017[53])

- Description: The report presents LSFF coverage survey findings from eighteen programs conducted in eight countries between 2013 and 2015. The eight countries studied were Bangladesh, Côte d'Ivoire (Abidjan), India (Rajasthan), Nigeria, Senegal, South Africa, Tanzania, and Uganda. The survey focuses on the three stages of coverage that are important in ensuring that a region's population is effectively covered. The first stage is consumption of the vehicle, meaning that the household consumes the vehicle. The second stage is consumption of the fortifiable vehicle, meaning that the food vehicle is consumed by households and is "processed

industrially and hence is well-suited to large-scale food fortification." The third stage is consumption of the fortified vehicle, meaning that the vehicle consumed in the household is fortified. All three stages must be true for the population to be effectively covered, and each stage "depends on all the preceding stages being true." The results of the report find that only two of the eight LSFF programs met all three performance criteria. In general, across the eight countries, poor choice of food vehicle and a failure to fortify a fortifiable food vehicle were two of the main problems that hindered the success of programs. The report emphasizes the importance of thoughtful program design and frequent monitoring. Finally, the report emphasizes that mandatory programs typically achieve higher coverage levels than voluntary fortification programs. However, this finding requires that regulatory standards pertaining to fortification are followed and that food producers are compliant with said fortification regulations. The report furthermore emphasizes the inclusion of food fortification as one tool part of an overall comprehensive nutrition strategy. Finally, the report notes the importance of "field-friendly" testing kits in order to assess fortification status such as iron spot tests and iodine rapid test kits, as more elaborate quantitative tests are costly, time-consuming, and can be subject to degradation in improper storage.

- Contribution: This report is useful in comparing the impact of a voluntary fortification program as compared to a mandatory fortification program. It shows the necessity of choosing the appropriate fortification vehicle. Further, this report provides guidance in understanding how to develop an effective routine and evaluation system, wherein information is collected to inform future decision-making. This is in line with the idea that reporting, storing, and disseminating monitoring results is important for the effective implementation of LSFF programs

The Rise and Fall of Universal Salt Iodization in Viet Nam: Lessons Learned for Designing Sustainable Food Fortification Programs with a Public Health Impact (Codling et al., 2015[70])

- Description: The report discusses how, in 2005, more than 90% of households in Viet Nam were using iodized salt but that household coverage declined to 45% in 2011, resulting in inadequate iodine intake among women of reproductive age. The article explores why achievements made by Viet Nam in the universal salt iodization program in 2005 were not sustained. The report concludes that the salt iodization program was unsustainable, as salt iodization was not an industry norm but rather a government-funded activity. The report found that a new, effective, and sustainable program needs to include mandatory legislation, mandatory iodization of all food grades of salt, industry responsibility for the cost of the fortificant, uniform and clear authorizations for all producers of salt, government commitment for enforcement through routine food control systems, and intersectoral collaboration and management of the program.
- Contribution: This report is useful in understanding how a change in a nation's fortification policies can result in dramatic changes in the consumption of a particular micronutrient. A number of identified core elements intersect with this report: (1) ongoing political commitment is key to successful LSFF policy (2) right level of regulation mandating fortification and policy tools are required (3) clearly delineated responsibilities for supervision of fortified food and premixes (including supervision by the producers themselves) (4) a transparent, efficient and predictable authorization process needs to be in place The report is also useful in providing guidance pertaining to mandatory versus voluntary fortification programmes.

Food Fortification as a Complementary Strategy for the Elimination of Micronutrient Deficiencies: Case Studies of Large-Scale Food Fortification in Two Indian States (Bhagwat et al., 2014[49])

- Description: The report reviews LSFF efforts in two Indian states, Rajasthan, and Madhya Pradesh. The report specifically details selection of micronutrients for fortification, choice of food vehicles, determination of the ideal levels of fortification, and selection of appropriate delivery channels. The report highlights that in India there are two major delivery channels for staple foods. These two channels are the commercial channel and the government-supported public distribution system.

The report states that voluntary fortification through commercial channels was implemented in both Indian States. Further, in Rajasthan, which is located in northern India, the public distribution system also provided for fortification. The report also discusses use of social marketing and communication as critical tools in creating public awareness pertaining to micronutrient deficiencies. In addition, the report examines internal and external quality control measures pertaining to LSFF. Internal quality control is implemented through "strict adherence to standard operating procedures and further validated through simple laboratory tests at the production level." Production staff were trained on fortification processes and quality control. Further, an independent evaluation of fortified food samples from each partnering food processing industry is carried out in both Indian states by external laboratories. The report also discusses India's approach to mandatory versus voluntary fortification. The government mandates fortification only with respect to salt with iodine and hydrogenated fats with vitamin A. The report highlights the challenges of voluntary programs. These challenges pertain primarily to the cost differences between fortified and non-fortified products and the consumers' willingness to pay for the increased cost due to fortification.

- Contribution: The review is useful in understanding implementation policies that are necessary in a successful LSFF program. Specifically, the review provides guidance on: (i) quality control measures, (ii) governmental communication with the public, (iii) delivery channels, and (iv) mandatory versus voluntary fortification. The discussion on mandatory fortification relates to the core element of having the right level of legislation mandating fortification. Further elements are supported by this report, including (1) public education on fortification (2) the necessity of a public distribution for fortified foods, along with (3) private industry incentives, through subsidies and the like (4) Clearly delineated responsibilities for supervision of fortified food and premixes (including the producers themselves), and (5) adequate professional training of inspectors.

Legislative frameworks for corn flour and maize meal fortification (Makhumula et al., 2014[72])

- Description: This article reviews national standards and regulations for corn flour and maize meal fortification and finds that minimum content ranges cause confusion. The report reviewed countries adding micronutrients to corn flour or maize meal. The countries reviewed were Venezuela, Brazil, the United States, Kenya, Malawi, Nigeria, South Africa, Tanzania, Uganda, the eastern, central, and southern Africa region (""ECSA"), Costa Rica, El Salvador, Guatemala, Honduras, and Nigeria, Guatemala, and Mexico. The report proposes a model for fortification legislation and recommends content and the expected average nutrient content as quality control and enforcement parameters, with the label of the final product displaying the average content. It also recommends including clear sampling and testing procedures in regulations. The report recommends increasing standardization, including standardized measurements and acceptable levels of variance, having adequate QC/QA documentation and guidelines available, and having adequate training of inspectors and producer staff. Producer staff should be trained to be able to self-regulate and correct any deviations.
- Contribution: This resource offers helpful information on sampling and testing procedures for regulators. The information and the recommendations of the report overlap with some core elements for food fortification: (1) requirements to produce fortified foods should be transparent and publicly available/accessible (2) appropriate legislation/other policy instruments mandating fortification are necessary.

Summary of findings

This section of the literature review looked at a variety of food fortification programs around the world, giving a high-level summary of the main conclusions and recommendations from these reports. These recommendations serve as evidence for the OECD's best practice principles for food fortification. The

country-specific examples are useful in understanding the factors that led to individual country's success or failure with food fortification.

Many of the results and recommendations are however of wider applicability and relevance to other countries. Common themes emerge from the recommendations, including great emphasis on the essential role that the private sector plays in fortification policies. Educating and incentivizing the private sector to partake in fortification was key in India's food fortification plan. International organizations have played a significant role in food fortification policies, as they often provide data and jumpstart the food fortification initiative in LMIC countries. Further, education campaigns play an essential role in educating the public and industry members about food fortification. Ongoing political commitment at the national and supranational level is essential to food fortification. Sustainable, long-term policy frameworks for food fortification are essential to ensure continuation of the fortification program, as demonstrated by the cessation of salt iodization in Viet Nam. This also involves having adequate legislation and other necessary policy tools which mandate fortification. Finally, sufficient resources must be allocated to the monitoring of food fortification, and both inspectorate staff and production staff must be trained to an adequate and standardized level. Self-correction for detected deviancies is preferred for production staff, and the availability of guidelines and specifications can help with this. These common recommendations support the OECD's best practices and principles for food fortification.

Regulatory control and monitoring

Firm's compliance behaviour towards food fortification regulations: Evidence from oil and salt producers in Bangladesh (Saha et al., 2021[105])

- Description: This article discusses how to improve monitoring of fortification programs. It recognizes that frequent qualitative testing of micronutrient levels is expensive for countries to implement, resulting in lower monitoring and reporting. With this premise in mind, the researchers developed a scoring system that assesses compliance at various stages of a normal compliance process. For instance, they look to see if firms possess required fortification technology and whether they have implemented processes for monitoring. After applying this score to oil and salt producers in Bangladesh, the researchers find that the following factors are important in increasing compliance: (i) education of industry, (iii) more in-person interactions with industry groups, and (iii) explaining to industry why it is important to comply (reinforcing incentives and penalties at stake). The distrust of some firms towards the effectiveness of incentives and penalties was also found to be a barrier to compliance. Greater engagement with fortification regulation had the effect of reducing distrust. The report also found inconsistencies in inspections, wherein large producers faced more inspections at the retail and wholesale level, whereas small and medium sized producers faced more inspections at the point of production. Further, it was found that the frequency of inspections needed to be tailored. Oil factories benefitted from more than one inspection a year, whereas salt factories did not. It was also found that a risk-based approach to inspections was not applied in Bangladesh, and in fact, larger, more compliant factories were more likely to be inspected.
- Contribution: This article presents a new way to measure compliance that limits expensive testing of micronutrient levels. It also identifies several concrete actions that increase compliance with fortification standards, such as increasing companies' awareness of and education on regulations The article also calls for a more prudent compliance, enforcement, and inspections policy. These findings may be useful for OECD in trying to understand best practices for implementation of fortification programs. In all, this article supports: (1) a risk-based approach to supervise businesses needs to be applied (2) enforcement agencies should have appropriate-proportionate compliance mechanisms including provision of information, guidance, imposing sanctions, etc., and (3) enforcement agencies need a clear mission and performance indicators.

Voluntary Food Fortification Policy in Australia: Did "Formal" Stakeholder Consultation Influence the Outcome? (Ashton et al., 2021[61])

- Description: This article discusses the voluntary food fortification policy which was developed by the Australia and New Zealand Food Regulation Ministerial Council (2002-2012). The article found that the formal consultation process did not meaningfully affect the final fortification policy. Competing narratives emerged. Public health officials framed voluntary food fortification as a public health problem, whereas industry stakeholders framed it as a problem of commercial benefit. The latter narrative won out at the outset. Evidently, the formal consultation came too late in the process because "the policy debate was fought and won at the initial framing of the problem in the earliest stages of the policy process." The authors also attribute corporate lobbying and influence as a contributor to this problem, with governments being more focused on trade rather than public health.
- Contribution: This article presents an interesting take on the role of stakeholder involvement in fortification policy making. A consideration for OECD could be trying to involve stakeholders earlier in the policy making process (before the formal consultation process) to avoid repeating the results in Australia. Furthermore, governments must strive to ensure that public health concerns are not drowned out by corporate lobbying and interests.

Understanding drivers of private-sector compliance to large-scale food fortification: A case study on edible oil value chains in Bangladesh (Ebata et al., 2021[46])

- Description: The report discusses how the success of LSFF in LMICs is often hindered by limited private sector compliance with fortification mandates. Because the private sector is responsible for supplying fortified food, limited compliance is highly harmful to the effectiveness of LSFF programs. The report specifically examines a case study of edible oil in Bangladesh to conduct an analysis of the factors that either facilitate or impede compliance by private, for-profit entities. The report identifies four bottlenecks that disincentivize the private sector from complying with fortification mandates: (i) fortified and non-fortified foods co-exist in the market, disincentivizing producers to invest in fortification – consumer awareness of the benefits of fortified food is low, thus they choose cheaper, non-fortified bulk oil. (ii) lack of traceability reduces risk for producers' non-compliance with fortification regulations, (iii) small-scale producers face economic pressures that prevent them from adequately fortifying oil products, and (iv) enforcement of regulation and standards is inconsistent, which allows for the supply of under-fortified oil in the market. Based on these findings, the report recommends strengthening the control of bulk item fortification through greater surveillance at the production level. The authors recommend better enforcement of oil fortification at the refinery level to deal with these issues. This is because there are a small number of large oil refineries, and it removes the need to educate consumers. The authors suggest simple, low-cost measures for better enforcement, such as checking that the amount of premix used correlates to the food produced. Accountability needs to be increased by ensuring traceability through labels, with sufficient penalties in the case of non-compliance. The final suggestion the authors make is that regulators should aim for better dialogue with industry members to increase trust and confidence in the regulatory/fortification process.
- Contribution: The report is useful in identifying bottlenecks to private industry fortification, and how to incentivize private sector compliance with fortification regulations. Private sector compliance is deemed critical in a successful LSFF program, thus this report can provide crucial guidance in formulating and developing LSFF policies.

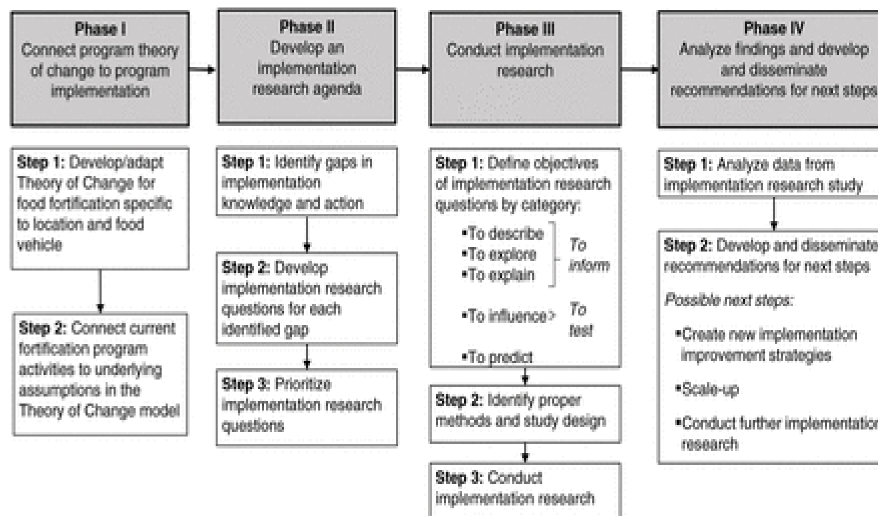
Monitoring Flour Fortification to Maximize Health Benefits: A Manual for Millers, Regulators, and Program Managers (WHO, 2021[102])

- Description: This manual focuses on regulatory and consumption monitoring in countries where wheat and maize flours are industrially processed. The manual is directed towards fortification program stakeholders interested in setting up monitoring systems in their countries. The manual includes information on the following: quality management systems, quality assurance procedures for fortified flour, quality control measures for fortified flour, quality control and quality assurance by millers, external, import, and commercial monitoring, and consumption monitoring.
- Contribution: This manual offers a helpful resource on best practices for quality management for monitoring mills and insights for industry stakeholders.

Systematic Process Framework for Conducting Implementation Science Research in Food Fortification Programs (Teachout et al., 2021[162])

- Description: This article establishes a framework for locating implementation gaps in existing fortification programmes. The framework is summarised in Figure 4.2:

Figure 4.2. Systematic Process Framework for Conducting Implementation Science Research in Food Fortification Programs



Note: See Emily Teachout et al., Systematic Process Framework for Conducting Implementation Science Research in Food Fortification Programs,9(2) Global Health: Science & Practice 412, (2021), https://www.ghspjournal.org/content/9/2/412.

- Contribution: This could serve as a useful tool for countries to use when monitoring implementation of fortification programs, as it is aimed at low-resource countries. As the framework concerns implementation, one limitation however is that the framework assumes that food fortification already occurs.

Conventional and food to food fortification: An appraisal of past practices and lessons learnt (Chadare et al., 2019[54])

- Description: This resource reviews 100 articles and reports to analyse reducing malnutrition through food fortification. The review concludes that a mix of many food-based approaches is needed to tackle undernutrition, especially in developing countries. The findings determine fortified food must be frequently consumed by the population, centrally processed, and affordably processed. The report highlights the importance of continuous production, monitoring, labelling, and consumer education.
- Contribution: This resource offers a helpful overview of the fortified foods, outcomes, and limitations of existing reports. Limitations include a need to determine “contextually feasible and sustainable

mechanisms for premix supply, quality control, and cost recovery." Finally, databases need to be consistently updated to adequately estimate population intakes of micronutrients.

Large-Scale Food Fortification and Biofortification in Low- and Middle-Income Countries: A Review of Programs, Trends, Challenges, and Evidence Gaps (Osendarp et al., 2018[48])

- Description: This article focuses broadly on LMICs as a whole and describes elements of a successful fortification program. It also tables the effects and results of food fortification programs in some LMIC countries. It also identifies issues with monitoring that led to poor performance of fortification programs. The article lists several takeaways for successful programs: (i) choice of food vehicle is extremely important; (ii) programs must clearly identify the population affected by a particular micronutrient deficiency, (iii) the programs should be one part of a comprehensive strategy to combat micronutrient deficiencies, (iv) programs should work to strengthen industry capacity/resources in order to ensure quality control, and (v) the government must periodically reevaluate the assumptions about micronutrient deficiencies in target populations to ensure that the program remains effective and is tailored to evolving needs. Furthermore, successful programs typically involve public/private partnerships (involving civil society, NGOs, government agencies, industry) and will have strong monitoring and evaluation strategies. Conversely, programs which are unsuccessful share the following characteristics: (i) weak enforcement (in part due to conflicting or piecemeal laws), (ii) underfunded/under-resourced quality control regimes, (iii) political pushback from private entities, (iv) private industry which is unable to sustain the costs of the program, and (vi) insufficient funding/budget.
- Contribution: This article lays out several best practices for the implementation of fortification programs. It also highlights some characteristics that are common among less successful programs. As OECD works to develop the index, it will be important to keep these findings in mind.

Regulatory Monitoring of Fortified Foods: Identifying Barriers and Good Practices (Luthringer et al., 2015[47])

- Description: This paper outlines the effectiveness of regulatory monitoring systems and compliance barriers in national fortification standards. By conducting interviews and a literature overview, it highlights the lack of consistent regulatory monitoring as a key barrier to the implementation of a successful fortification programme because producers are not held accountable for lack of compliance in 12 LMIC countries. The paper shows the challenges to fortification along different levels of the supply chain.

Figure 4.3. Critical challenges along the food value chain that present barriers to consistent compliance against national fortification standards

Source: (Luthringer et al., 2015[101]).

When interviewing industry members, the top barriers to compliance were identified (in order of importance): price of premix, competition from non-fortifying competitors, poor lab capacity, lack of fortification equipment, lack of market demand, and lack of technical capacity. Regulators were also interviewed, and the following factors were seen to be the greatest challenges to creating a high-compliance legal and regulatory environment: perceived political risk of action, lack of trained inspectors, poor government coordination, limited industry capacity, lack of budget, and industry composition and geography. The results also showed that regulatory agencies and industry did not often share the same values on food fortification. It also lists a large number of recommendations to improve compliance including (i) increasing technological capabilities of industry, (ii) making funding available to both the private and public sector, and (iii) addressing the political barriers that prevent strict enforcement.

- Contribution: This paper is an excellent resource for identifying strategies to model and avoid with respect to food fortification monitoring mechanisms. It identifies the core barriers facing both regulators and producers and offers key solutions to increase coverage of fortified foods. This paper should be read in its entirety to understand the large number of recommendations. It also highlights political risk as a key barrier to effective implementation which OECD should keep in mind when creating the index. Overall, the lessons learned from this paper align with a large number of core elements, including: 1) governments should incentivize private industry through the use of subsidies, provisions of equipment, and tax breaks 2) Conducting satisfaction survey/polls for government initiatives 3) Enforcement agencies have clear mission and performance indicators 4) designated budget allocated to supervision 5) appropriate-proportionate compliance mechanisms including provision of information, guidance, imposing sanctions etc., and (6) inspectors should have adequate professional training.

External mill monitoring of wheat flour fortification programs: an approach for program managers using experiences from Jordan (Wirth et al., 2013[90])

- Description: This report provides an analysis of food fortification monitoring systems in Jordan. Mowahad wheat flour is the most commonly consumed wheat flour in Jordan. The fortification of all Mowahad wheat flour with iron, zinc, folic acid, zinc, and Vitamins A, B1, B2, B3, B6, and B12 is mandatory, and the process is subsidized by the government. Specifically, the report places emphasis on Jordan’s robust monitoring and reporting system. It notes that unlike most regulatory systems in which a government agent inspects fortification facilities, the Jordan regulatory program also uses the data collected during inspections to create an “external monitoring system” which allows regulators to make data-driven decisions about the effectiveness of the fortification program overall and to adjust the levels of micronutrients required to be added. Regularly, data is collected to assess whether an individual mill has failed or passed, and data is collected on all mills to make broader analyses. Clear, standard but simple indicators are used, but quantitative testing is also carried out. In the case of technical difficulties
- Contribution: This report provides helpful insights on regulatory monitoring systems that could be put in place in other countries. The external monitoring system used by the Jordanian regulators is a good example of data-informed decision making by regulators. Jordan is an example of (1) sharing data between relevant regulatory agencies, (2) assessing the impact of fortification regularly, (3) having appropriate legislation to mandate fortification and (5) enforcement agencies having clear performance indicators.

Legal framework for food fortification: Examples from Viet Nam and Indonesia (Dijkhuizen et al., 2013[45])

- Description: This article reviews Indonesian and Viet Namese food fortification efforts and legislation. It analyses the process of creating a legal framework in Viet Nam and Indonesia. For Viet Nam, it identifies strengths in the process such as clearly define roles and responsibilities, and clear timeframes. The biggest weakness in the Viet Namese legislative process is the lack of consideration for monitoring and enforcement. By contrast, in Indonesia the process is weakened by a slow and complicated policy process, and unclear demarcations of responsibilities. Indonesia also suffers from a lack of motivation to enforce at all levels, lack of public health awareness of fortification, and a preference for voluntary fortification over mandatory. Indonesia’s strengths are its simple and inclusive legal framework, and the integration of enforcement in the legal structure. As suggestions, the report finds that legal frameworks should specify the fortificants, fortification levels, food vehicles, and fortification procedures. It also finds that legal frameworks should regulate cost, include product labelling, integrate social marketing, and provide monitoring and enforcement provisions. In addition, the article recommends setting clear public health objectives to optimize food fortification strategies.
- Contribution: This resource provides a helpful analysis of mandatory fortification approaches for sustainable food fortification programs. The report is of high relevance to the OECD as it covers Indonesia and Viet Nam. The recommendations also relate to a number of core elements for food fortification: (1) food fortification policy should be integrated in public health policy (2) right level of legislation mandating fortification is needed (3) legislation should clearly delineate responsibilities for fortification (4) legislation should clearly specify fortification levels, and (5) governments should enact public education campaigns on fortification.

Guidelines on HACCP, GMP, and GHP for ASEAN Food SMEs (EC-ASEAN Economic Cooperation Program on Standards, 2005[163])

- Description: This report outlines best practices for pest control, relationships with suppliers, on-site hygiene, monitoring systems, and auditing.
- Contribution: This guide could help create an effective quality control system for food fortification. However, it would help to determine whether this model was successful when put into practice

before basing decisions on this guide. Further, this document is from 2005 and so may be in need of updating.

Wheat Flour Fortification Current Knowledge and Practical Applications (Flour Fortification Initiative, 2004[73])

- Description: This report offers information on wheat flour fortification, specifically with iron and folic acid. It recommends considering iron status, dietary intake of bioavailable iron, dietary factors, and at-risk groups. It also recommends premix suppliers certify the type, source, and manufacturing process for iron fortificants. The report suggests implementing premix standards, clear regulatory guidance, accreditation of premix suppliers, and public dialogue.
- Contribution: This is a helpful resource for cost and quality control considerations, wheat flour fortification, iron fortification, and folic acid fortification.

Dietary reference intakes: guiding principles for nutrition labeling and fortification (2003) (Institute of Medicine (US) Committee on Use of Dietary Reference Intakes in Nutrition Labeling, 2003[51])

- Description: This book provides a historical overview of U.S. and Canadian food fortification practices, policies, and labelling. Although the U.S. system and Canadian systems differ, they both use Dietary Reference Intake (DRI) reports (which specify the amount of nutrients a given population should consume) to set fortification policy and to avoid the over or under-consumption of micronutrients. It also offers some guiding principles for regulators to consider when overseeing the creation of voluntary fortification programs. For example, the book suggests that public health officials create a set of metrics to use in determining (i) whether there is a micronutrient deficiency in the population that requires attention and (ii) whether the need is widespread enough for fortification to be the proper solution. The book also suggests establishing an upper intake level (the highest amount of a micronutrient which a person can tolerate) for each micronutrient being added to foods to avoid overconsumption by the population. However, the book notes that this may only be relevant for micronutrients which when consumed in high amounts may be dangerous like Vitamin A.
- Contribution: This resource is more focused on the technical aspects of fortification programs such as how to identify a micronutrient deficiency among the population and how to determine what levels to use when fortifying foods. Furthermore, it is only focused on voluntary/discretionary fortification programs rather than mandatory programs.

The History of Food Fortification in the United States: Its Relevance for Current Fortification Efforts in Developing Countries (Bishai and Nalubola, 2002[24])

- Description: The article provides an overview of the history of U.S. food fortification programs and identifies the main waves of food fortification programs in the United States. The article focuses on the social, economic, and political issues surrounding LSFF programs. Bishai and Nalubola emphasize that the primary distinguishing factor of food fortification as compared to other public health initiatives is that a successful LSFF program requires significant involvement and cooperation from the private sector. While the report acknowledges that the private sector is motivated by profit and remaining competitive in the market, the report also underscores instances of "corporate public spiritedness and concern for the well-being of the American consumer in the historical record." This article recommends advertising in the private and public sector. The article suggests that successful fortification programs have strong food-processing industries, effective legislation, and monitoring mechanisms.
- Contribution: This article provides a detailed historical overview of decades of fortification program development in the United States. This article can serve as an advocacy tool to demonstrate how consumer demand for micronutrients can be sufficient to make private sector involvement in fortification self-sustaining and profitable. Finally, the article identifies helpful insight into advertising

strategies for launching successful food fortification programs, including emphasizing the superiority of fortified foods and large-scale government purchases of fortified foods. The primary limit of the review is that characteristics that made fortification programs successful in the United States may not be applicable to low- and middle-income countries.

Summary of findings

The preceding section has identified several case studies of best practices of food fortification. It has also highlighted the many pitfalls encountered in these programs. A common barrier identified was the lack of engagement with and support for private industry. Private industry cooperation is essential to the success of food fortification programs. Industry must be incentivized economically to engage in fortification, for which the use of subsidies and supply of equipment is useful. Critical to this also is increasing education on fortification benefits and establishing trust and dialogue with regulatory bodies, as demonstrated by the Bangladesh case study.

Insufficient enforcement by regulatory bodies was also identified as a common barrier to adequate food fortification coverage. The literature overview has revealed that perceived political risk can be a barrier to effecting penalties. The literature has identified best practices to deal with this. Enforcement bodies must engage in cooperation and dialogue with industry, while also carrying out risk-based inspections and issuing proportionate sanctions (e.g., from guidance documents to high fines). A legal framework which incorporates enforcement and clearly demarcates responsibilities is a necessary base, as demonstrated by Indonesia and Viet Nam respectively. Consistent and standardized reporting by regulatory bodies is also key to informing future policy choices, as demonstrated by report on Jordan. These lessons are highly relevant for LMIC governments with little budget, who must tailor and strategize their enforcement priorities. For example, Bangladesh dealt with the dual problems of lack of consumer awareness and high levels of non-fortified oil on the market by mandating all refineries to fortify oil, and by increasing traceability.

Overall, the literature identifies best practices which support the OECD’s measurement framework for food fortification regulatory indicators. Specifically, the report on legal frameworks of Indonesia and Viet Nam are an excellent resource to inform the OECD’s work on these countries. Some limitations are present in the literature. For example, not all recommendations are suitable for every country, but many of the principles are applicable to other nations. Furthermore, some reports near the end of this section are quite technical in nature, which may make them of less relevance to the OECD from a regulatory and monitoring standpoint.

References

(n.a.) (2016), *Guideline: Fortification of Maize Flour and Corn Meal with Vitamins and Minerals*. [164]

Aaron, G. et al. (2017), "Coverage of Large-Scale Food Fortification of Edible Oil, Wheat Flour, and Maize Flour Varies Greatly by Vehicle and Country but Is Consistently Lower among the Most Vulnerable: Results from Coverage Surveys in 8 Countries", *The Journal of Nutrition*, Vol. 147/5, pp. 984S-994S, https://doi.org/10.3945/jn.116.245753. [53]

Alavi, S. et al. (2008), *Rice Fortification in Developing Countries: A Critical Review of the Technical and Economic Feasibility Edited by*, http://www.a2zproject.org (accessed on 8 March 2024). [56]

ASEAN (2017), *ASEAN Leaders' Declaration on Ending All Forms of Malnutrition*. [147]

ASEAN and UNICEF (2016), *Regional Report on Nutrition Security in ASEAN*. [149]

Ashton, B. et al. (2021), "Voluntary food fortification policy in Australia: did 'formal' stakeholder consultation influence the outcome?", *Health Promotion International*, Vol. 36/5, pp. 1393-1402, https://doi.org/10.1093/heapro/daab003. [61]

Astrup, A. and S. Bügel (2018), "Overfed but undernourished: recognizing nutritional inadequacies/deficiencies in patients with overweight or obesity", *International Journal of Obesity*, Vol. 43/2, pp. 219-232, https://doi.org/10.1038/s41366-018-0143-9. [7]

Backstrand, J. (2002), "The History and Future of Food Fortification in the United States: A Public Health Perspective", *Nutrition Reviews*, Vol. 60/1, pp. 15-26, https://doi.org/10.1301/002966402760240390. [27]

Bailey, R., K. West Jr. and R. Black (2015), "The Epidemiology of Global Micronutrient Deficiencies", *Annals of Nutrition and Metabolism*, Vol. 66/Suppl. 2, pp. 22-33, https://doi.org/10.1159/000371618. [12]

Baldwin, R. (1990), "Why Rules Don't Work", *The Modern Law Review*, Vol. 53/3, pp. 321-337, https://doi.org/10.1111/j.1468-2230.1990.tb01815.x. [96]

Bhagwat, S. et al. (2014), "Food fortification as a complementary strategy for the elimination of micronutrient deficiencies: case studies of large scale food fortification in two Indian States", *Asia Pac J Clin Nutr*, Vol. 23, pp. 4-11, https://doi.org/10.6133/apjcn.2014.23.s1.03. [49]

Bhattacharya, S., V. Falcao and R. Puri (eds.) (2017), "The Public Distribution System in India: Policy Evolution and Program Delivery Trends", in *The 1.5 Billion People Question: Food, Vouchers, or Cash Transfers?*, The World Bank, https://doi.org/10.1596/978-1-4648-1087-9_ch2. [113]

Bhutta, Z. (ed.) (2012), "Estimating the Global Prevalence of Zinc Deficiency: Results Based on Zinc Availability in National Food Supplies and the Prevalence of Stunting", *PLoS ONE*, Vol. 7/11, p. e50568, https://doi.org/10.1371/journal.pone.0050568. [18]

Bird, J. et al. (2017), "Risk of Deficiency in Multiple Concurrent Micronutrients in Children and Adults in the United States", *Nutrients*, Vol. 9/7, p. 655, https://doi.org/10.3390/nu9070655. [9]

Bishai, D. and R. Nalubola (2002), "The History of Food Fortification in the United States: Its Relevance for Current Fortification Efforts in Developing Countries", *Economic Development and Cultural Change*, Vol. 51/1, pp. 37-53, https://doi.org/10.1086/345361. [24]

Blanc, F. (2018), *From chasing violations to managing risks : origins, challenges and evolutions in regulatory inspections*, https://www.e-elgar.com/shop/gbp/from-chasing-violations-to-managing-risks-9781788112482.html (accessed on 5 March 2024). [93]

CDC (n.d.), *Adult Obesity Facts*, https://www.cdc.gov/obesity/data/adult.html. [8]

Centre de Recherche pour le Développement Humain, GAIN and Westat (2013), *Fortification Assessment Coverage Toolkit (FACT) Survey in Senegal*, https://www.gainhealth.org/resources/datasets/fortification-assessment-coverage-toolkit-fact-survey-senegal (accessed on 6 March 2024). [126]

Chadare, F. et al. (2019), "Conventional and food-to-food fortification: An appraisal of past practices and lessons learned", *Food Science & Nutrition*, Vol. 7/9, pp. 2781-2795, https://doi.org/10.1002/fsn3.1133. [54]

Codex Alimentarius Commission (2018), "General Standard for the Labelling of Prepackaged Foods". [84]

Codex Alimentarius Commission (2012), "Draft Codex Strategic Plan 2014-2019". [33]

Codex Alimentarius Commission (1987), *General Principles For The Addition Of Essential Nutrients To Foods*, https://www.google.com/search?client=firefox-b-d&q=Codex+Alimentarius+Commission+General+Principles+For+The+Addition+Of+Essential+Nutrients+To+Foods+CAC%2FGL+9-1987 (accessed on 5 March 2024). [34]

Codling, K. et al. (2015), "The Rise and Fall of Universal Salt Iodization in Vietnam", *Food and Nutrition Bulletin*, Vol. 36/4, pp. 441-454, https://doi.org/10.1177/0379572115616039. [70]

Condes, S. and J. Dahdah (2018), "Delivering high-quality, locally produced and fortified blended food products in West AfricaNutrition Exchange 10, -", *Nutrition Exchange 10*, p. 28, http://www.ennonline.net/nex/10/blendedfoodwestafrica (accessed on 8 March 2024). [116]

CSIR Summer Research training team (2021), "Micronutrient's deficiency in India: a systematic review and meta-analysis", *Journal of Nutritional Science*, Vol. 10, https://doi.org/10.1017/jns.2021.102. [16]

Cyriac, S. et al. (2020), “High Coverage and Low Utilization of the Double Fortified Salt Program in Uttar Pradesh, India: Implications for Program Implementation and Evaluation”, *Current Developments in Nutrition*, Vol. 4/9, p. nzaa133, https://doi.org/10.1093/cdn/nzaa133. [55]

da Cunha, D. et al. (2016), “Inspection Score and Grading System for Food Services in Brazil: The Results of a Food Safety Strategy to Reduce the Risk of Foodborne Diseases during the 2014 FIFA World Cup”, *Frontiers in Microbiology*, Vol. 7, https://doi.org/10.3389/fmicb.2016.00614. [91]

Darnton-Hill, I. et al. (2005), “Micronutrient deficiencies and gender: social and economic costs”, *The American Journal of Clinical Nutrition*, Vol. 81/5, pp. 1198S-1205S, https://doi.org/10.1093/ajcn/81.5.1198. [64]

Dary, O. and B. Imhoff-Kunsch (2012), “Measurement of Food Consumption to Inform Food Fortification and Other Nutrition Programs: An Introduction to Methods and Their Application”, *Food and Nutrition Bulletin*, Vol. 33/3_suppl2, pp. S141-S145, https://doi.org/10.1177/15648265120333s201. [60]

Diasso, D., M. Halidou Doudou and A. Savadogo (2020), “Multisectoral Nutrition Implementation in Burkina Faso: Organization, Collaboration and Support of Contributing Sectors at Regional Level”, *Acta Scientifci Nutritional Health*, Vol. 4/10, pp. 26-36, https://doi.org/10.31080/asnh.2020.04.0762. [62]

Dijkhuizen, M. et al. (2013), “Legal Framework for Food Fortification: Examples from Vietnam and Indonesia”, *Food and Nutrition Bulletin*, Vol. 34/2_suppl1, pp. S112-S123, https://doi.org/10.1177/15648265130342s113. [45]

Ebata, A. et al. (2021), “Understanding drivers of private-sector compliance to large-scale food fortification: A case study on edible oil value chains in Bangladesh”, *Food Policy*, Vol. 104, p. 102127, https://doi.org/10.1016/j.foodpol.2021.102127. [46]

EC-ASEAN Economic Cooperation Program on Standards, Q. (2005), *Guidelines on HACCP, GMP and GHP for ASEAN Food SMEs*. [163]

ECOWAS (2007), “The West Africa Quality System Reaching Excellence Through Quality”. [40]

ECSA-Health Community (n.d.), *NCDs, Food Security and Nutrition Programme*, https://ecsahc.org/ncds-food-security-and-nutrition-programme/#1627573471008-dcb08153-ae93 (accessed on 6 March 2024). [142]

European Commission (2020), *Guidance Note on Food Fortification in development cooperation*, https://www.who.int/news-room/fact- (accessed on 6 March 2024). [42]

FAO (2024), *Codex Alimentarius*, https://www.fao.org/fao-who-codexalimentarius/about-codex/en/ (accessed on 6 March 2024). [129]

FAO (n.d.), *FAOLEX Database*, https://www.fao.org/faolex/en/ (accessed on 6 March 2024). [121]

FAO (n.d.), *FAOSTAT*, https://www.fao.org/faostat/en/#data/FS (accessed on 8 March 2024). [122]

FAO et al. (2023), *The State of Food Security and Nutrition in the World 2023*. [10]

FAO, A. et al. (2002), *The World Food Summit Five Years Later: Mobilizing the political will and resources to banish world hunger*, Food and Agriculture Organization of the United Nations. [133]

FAO and WHO (2019), *Food control system assessment tool: Introduction and glossary*, http://www.fao.org/ (accessed on 6 March 2024). [148]

FFI (n.d.), *Food Fortification Initiative*, https://www.ffinetwork.org/ (accessed on 6 March 2024). [124]

Flour Fortification Initiative (2004), *Wheat Flour Fortification: Current Knowledge And Practical Applications*. [73]

Food and Agriculture Organization (FAO) (1997), *Preventing micronutrient malnutrition: A guide to food-based approaches - A manual for policy makers and program planners*, Food and Agriculture Organization (FAO), https://www.fao.org/3/x5244e/x5244e03.htm. [4]

Frederick Grant, Becky L. Tsang and Greg S. Garrett (2018), "Food Fortification in West Africa: Progress and lessons learned", in *Scaling up Rice Fortification in West Africa*, http://www.jonathansteffenlimited.comwww.sightandlife.org (accessed on 6 March 2024). [39]

Friesen, V. et al. (2019), *Fortification Assessment Coverage Toolkit (FACT) Manual*, http://www.gainhealth.org. (accessed on 8 March 2024). [69]

Friesen, V., M. Ojo and M. Mbuya (2021), *Food fortification – the devil in the detail*, https://www.gainhealth.org/media/news/food-fortification-devil-detail (accessed on 6 March 2024). [107]

FSSAI (2021), *Food Safety and Standards (Labelling and Display) Regulations*. [89]

FSSAI (2020), *Food Safety and Compliance System (FoSCoS) Guidance Document*. [94]

FSSAI (n.d.), *Food Safety and Standards Authority of India, Food Safety Compliance System (FoSCoS)*, https://foscos.fssai.gov.in/ (accessed on 8 March 2024). [82]

FSSAI (n.d.), *Food Safety on Wheels*, https://fsw.fssai.gov.in/home (accessed on 8 March 2024). [99]

FSSAI (n.d.), *FoSCoS Condition of License*. [83]

Fulgoni, V. et al. (2011), "Foods, Fortificants, and Supplements: Where Do Americans Get Their Nutrients?", *The Journal of Nutrition*, Vol. 141/10, pp. 1847-1854, https://doi.org/10.3945/jn.111.142257. [23]

GAIN (2021), "Fortified Porridge in Mozambique: Application of the Supply Chain Analysis for Nutrition (SCAN) Tool", https://doi.org/10.36072/bp.5. [151]

GAIN (2021), *Staple Food Fortification: A Commitment Guide for the UN Food Systems Summit and Tokyo Nutrition for Growth Summit*, https://pubmed.ncbi.nlm.nih.gov/30997493/ (accessed on 6 March 2024). [152]

GAIN (2021), *Thinking regionally about industrial food fortification*, https://www.gainhealth.org/events/thinking-regionally-about-industrial-food-fortification (accessed on 6 March 2024). [144]

GAIN (2021), *Verifying Laboratory Performance and Quality Control in the Context of Micronutrient Testing of Fortified Food - A Guidance Document*. [153]

GAIN (2020), *COVID-19 Is Making It Harder for Vulnerable People to Access Healthy Food*. [154]

GAIN (2018), *Tackling malnutrition in Haiti: challenges, resilience and hope*, https://www.gainhealth.org/media/news/tackling-malnutrition-haiti-challenges-resilience-and-hope (accessed on 6 March 2024). [156]

GAIN (2017), *Assessment Of Consumption Monitoring Systems Fortified And Nutritious Foods In The East, Central, And Southern Africa (Ecsa) Region - Final Report*. [41]

GAIN (n.d.), *The Global Alliance for Improved Nutrition (GAIN)*, https://www.gainhealth.org/ (accessed on 6 March 2024). [125]

Garrett, G. et al. (2019), *Doubling down on food fortification to fortify the future*, https://www.gatesfoundation.org/ideas/articles/food-fortification-to-fortify-the-future (accessed on 6 March 2024). [155]

GCNF (2022), *Results from the 2021 Global Survey of School Meal Programs ©*. [115]

GFDx (n.d.), *Global Fortification Data Exchange*, https://fortificationdata.org/ (accessed on 6 March 2024). [31]

Global Alliance for Improved Nutrition (GAIN) et al. (2018), *Regulatory monitoring of national food fortification programs*, https://www.gainhealth.org/resources/reports-and-publications/regulatory-monitoring-national-food-fortification-programs (accessed on 5 March 2024). [44]

Government of Viet Nam (2017), *Decree No. 43/2017/ND-CP dated April 14th, 2017, on good labels - LawNet*, https://lawnet.vn/en/vb/Decree-43-2017-ND-CP-on-good-labels-55057.html (accessed on 8 March 2024). [87]

Government of Viet Nam (2016), *Decree 09/2016/ND-CP of Government providing for food fortification with micronutrients*, https://english.luatvietnam.vn/decree-no-09-2016-nd-cp-dated-january-28-2016-of-the-government-providing-for-food-fortification-with-micronutrients-102647-doc1.html (accessed on 5 March 2024). [30]

Government of Viet Nam (n.d.), *National Business Registration Portal*, https://dangkykinhdoanh.gov.vn/en/Pages/default.aspx (accessed on 8 March 2024). [77]

Gupta, S., A. Brazier and N. Lowe (2020), "Zinc deficiency in low- and middle-income countries: prevalence and approaches for mitigation", *Journal of Human Nutrition and Dietetics*, Vol. 33/5, pp. 624-643, https://doi.org/10.1111/jhn.12791. [17]

Hwalla, N. et al. (2017), "The Prevalence of Micronutrient Deficiencies and Inadequacies in the Middle East and Appr oaches to Interventions", *Nutrients*, Vol. 9/3, p. 229, https://doi.org/10.3390/nu9030229. [95]

Institute of Medicine (US) Committee on Use of Dietary Reference Intakes in Nutrition Labeling (2003), *Dietary Reference Intakes: Guiding Principles for Nutrition Labeling and Fortification*, National Academies Press, Washington, D.C., https://doi.org/10.17226/10872. [51]

Institution of Home and Food Science, G. and GAIN (2016), *Market assessment on the presence of vanapspati/ghee and cooking oil brands in Pakistan*, https://www.gainhealth.org/resources/datasets/market-assessment-presence-vanapspatighee-and-cooking-oil-brands-and-their (accessed on 6 March 2024). [127]

International Conference on Nutrition (1992), *World Declaration and Plan of Action for Nutrition*. [131]

Ittermann, T. et al. (2020), "Standardized Map of Iodine Status in Europe", *Thyroid*, Vol. 30/9, pp. 1346-1354, https://doi.org/10.1089/thy.2019.0353. [21]

Jarvis, M. (2007), "Faire Tache d'Huile: Cooking Oil Fortification in West Africa", http://www.who.int/vmnis/vitamina/data/en/index.html, (accessed on 8 March 2024). [111]

Katwan, E. et al. (2021), "Creating a Global Legal and Policy Database and Document Repository: Challenges and Lessons Learned From the World Health Organization Sexual, Reproductive, Maternal, Newborn, Child and Adolescent Health Policy Survey", *International Journal of Health Policy and Management*, https://doi.org/10.34172/ijhpm.2021.153. [118]

Khanh Van, T. et al. (2014), "Organoleptic qualities and acceptability of fortified rice in two Southeast Asian countries", *Annals of the New York Academy of Sciences*, Vol. 1324/1, pp. 48-54, https://doi.org/10.1111/nyas.12506. [57]

Lowe, C. et al. (2021), "The double burden of malnutrition and dietary patterns in rural Central Java, Indonesia", *The Lancet Regional Health - Western Pacific*, Vol. 14, p. 100205, https://doi.org/10.1016/j.lanwpc.2021.100205. [103]

Luthringer, C. et al. (2015), "Regulatory Monitoring of Fortified Foods: Identifying Barriers and Good Practices", *Global Health: Science and Practice*, Vol. 3/3, pp. 446-461, https://doi.org/10.9745/ghsp-d-15-00171. [47]

Luthringer, C. et al. (2015), "Regulatory Monitoring of Fortified Foods: Identifying Barriers and Good Practices", *Global Health: Science and Practice*, Vol. 3/3, pp. 446-461, https://doi.org/10.9745/GHSP-D-15-00171. [101]

Makhumula, P. et al. (2014), "Legislative frameworks for corn flour and maize meal fortification", *Annals of the New York Academy of Sciences*, Vol. 1312/1, pp. 91-104, https://doi.org/10.1111/nyas.12349. [72]

MFI (n.d.), *Micronutrient Fortification Index by Technoserve*, https://mfi-ng.org/ (accessed on 8 March 2024). [106]

Micronutrient Initiative (2003), *Fortification Rapid Assessment Tool (FRAT)*. [59]

Ministry of Budget and National Planning of Nigeria (2016), *National Policy on Food and Nutrition in Nigeria*. [65]

Ministry of Consumer Affairs, Food & Public Distribution of India (2021), "Centrally Sponsored Pilot Scheme on Fortification of Rice & its Distribution under Public Distribution System", https://pib.gov.in/PressReleasePage.aspx?PRID=1731144 (accessed on 8 March 2024). [114]

Ministry of Finance, B. (2020), *National Multi-sectoral Plan of Action for Food and Nutrition (NMPFAN) 2021-2025*, MINISTRY OF FINANCE, BUDGET AND NATIONAL PLANNING, http://ngfrepository.org.ng:8080/jspui/handle/123456789/3255 (accessed on 8 March 2024). [66]

Ministry of Health and Family Welfare of India (2021), *National Family Health Survey (NFHS-5) 2019-21*. [14]

Ministry of Industry of Indonesia (2021), *Regulation Number 1 of 2021 on Enforcement of Indonesian National Standards of Wheat Flour as Staple Food*. [98]

Ministry of Women and Child Development of India (2022), *Guidelines of 'Saksham Anganwadi and Poshan 2.0' - an Integrated Nutrition Support Programme*. [68]

Mkambula, P. et al. (2020), "The Unfinished Agenda for Food Fortification in Low- and Middle-Income Countries: Quantifying Progress, Gaps and Potential Opportunities", *Nutrients*, Vol. 12/2, p. 354, https://doi.org/10.3390/nu12020354. [74]

NAFDAC (2021), *Food Fortification Regulations*. [79]

NAFDAC (2019), *Pre-Packaged Food, Water, and Ice (Labelling) Regulations*, http://extwprlegs1.fao.org/docs/pdf/nig188319.pdf (accessed on 8 March 2024). [86]

NAFDAC (2018), "Guidelines For Inspection & Requirements For Pre-Packaged Food Manufacturing/Packaging Facilities In Nigeria", http://www.remita.netto (accessed on 8 March 2024). [78]

Nathan, R. (1999), *Regulation of Fortified Foods to Address Micronutrient Malnutrition: Legislation, Regulations, and Enforcement*. [71]

Neufeld, L. et al. (2017), "Coverage and Utilization in Food Fortification Programs: Critical and Neglected Areas of Evaluation", *The Journal of Nutrition*, Vol. 147/5, pp. 1015S-1019S, https://doi.org/10.3945/jn.116.246157. [67]

News Agency of Nigeria (2022), "FG restates support for fortification of foods with micronutrients", https://guardian.ng/news/fg-restates-support-for-fortification-of-foods-with-micronutrients-minister/ (accessed on 8 March 2024). [109]

Nucleus India (n.d.), *NABL Accreditation (ISO 17025) – Nucleus*, https://www.nucleus-india.com/nabl-accreditation-iso-17025/ (accessed on 8 March 2024). [100]

Nugent, R. et al. (2020), "Economic effects of the double burden of malnutrition", *The Lancet*, Vol. 395/10218, pp. 156-164, https://doi.org/10.1016/s0140-6736(19)32473-0. [13]

Nutrition Internatinal and Food Fortification Initiative (2021), "A Blueprint for the Design and Implementation of Large-Scale Food Fortification Programs". [160]

Oddo, V. et al. (2012), "Predictors of maternal and child double burden of malnutrition in rural Indonesia and Bangladesh", *The American Journal of Clinical Nutrition*, Vol. 95/4, pp. 951-958, https://doi.org/10.3945/ajcn.111.026070. [3]

OECD (2018), *OECD Regulatory Enforcement and Inspections Toolkit*, OECD Publishing, Paris, https://doi.org/10.1787/9789264303959-en. [75]

Olson, R. et al. (2021), "Food Fortification: The Advantages, Disadvantages and Lessons from Sight and Life Programs", *Nutrients*, Vol. 13/4, p. 1118, https://doi.org/10.3390/nu13041118. [52]

Osakwe, F. (2020), "Nigeria loses $1.5bn in GDP annually to micro-nutrient deficiencies — Features — The Guardian Nigeria News – Nigeria and World News", https://guardian.ng/features/health/nigeria-loses-1-5bn-in-gdp-annually-to-micro-nutrient-deficiencies/ (accessed on 8 March 2024). [108]

Osendarp, S. et al. (2018), "Large-Scale Food Fortification and Biofortification in Low- and Middle-Income Countries: A Review of Programs, Trends, Challenges, and Evidence Gaps", *Food and Nutrition Bulletin*, Vol. 39/2, pp. 315-331, https://doi.org/10.1177/0379572118774229. [48]

OSS (n.d.), *Indonesia OSS (One Single Submission) System - Electronically Integrated Business Licensing System*, https://oss.go.id/ (accessed on 8 March 2024). [80]

OSS (n.d.), *Indonesia OSS Integrated BPOM RI SPPIRT application*, https://sppirt.pom.go.id/Home (accessed on 8 March 2024). [81]

Purcell, T. (2012), "Linking the Poor with Rice Value Chains", http://www.markets4poor.org (accessed on 8 March 2024). [112]

Push! (2018), *PUSH! Global Report Card Scoring Criteria & All Recommendations for Each of the Indicators*. [123]

Push! (n.d.), *Global Report Card for Spina Bifida and Hydrocephlaus Prevention and Care*, https://perma.cc/XJY6-D46B (accessed on 8 March 2024). [128]

Rhoda Peace, H. (2016), "The Arusha Statement on Food Fortification", *Sight and Life Magazine: The #Future Fortified Global Summit on Food Fortification*, Vol. 2016/2, https://doi.org/10.52439/jrny9010. [138]

Rogers, L. et al. (2018), "Global folate status in women of reproductive age: a systematic review with emphasis on methodological issues", *Annals of the New York Academy of Sciences*, Vol. 1431/1, pp. 35-57, https://doi.org/10.1111/nyas.13963. [15]

SADC (2020), *SADC Minimum Standards for Food Fortification*, https://www.sadc.int/sites/default/files/2022-10/English_SADC_fortification_minumum_standards_Final.pdf (accessed on 6 March 2024). [143]

Saha, A. et al. (2021), "Firm's compliance behaviour towards food fortification regulations: Evidence from oil and salt producers in Bangladesh", *Food Policy*, Vol. 104, p. 102143, https://doi.org/10.1016/j.foodpol.2021.102143. [105]

Second International Conference on Nutrition (2014), *Conference Outcome Document: Framework for Action*. [136]

Sight and LIfe and Global Alliance for Improving Nutrition (GAIN) (2015), *The #FutureFortified Global Summit on Food Fortification Event Proceedings and Recommendations for Food Fortification Programs*, http://www.who.org/nutrition/topics/ida/en. (accessed on 5 March 2024). [37]

Sight and Life and World Food Programme (2017), *Scaling Up Rice Fortification in Latin America and the Caribbean*. [161]

Simpong, D. (2017), "Addressing the Challenge of Iodine Deficiency in Developing Countries", *MOJ Public Health*, Vol. 5/3, https://doi.org/10.15406/mojph.2017.05.00129. [19]

Standards Authority of Indonesia (2018), *National Standard for Wheat Flour as Foodstuff 3751:2018*. [97]

Stevens, G. et al. (2022), “Micronutrient deficiencies among preschool-aged children and women of reproductive age worldwide: a pooled analysis of individual-level data from population-representative surveys”, *The Lancet Global Health*, Vol. 10/11, pp. e1590-e1599, https://doi.org/10.1016/s2214-109x(22)00367-9. [6]

Tarini, A. et al. (2021), “Enablers and Barriers of Zinc Fortification; Experience from 10 Low- and Middle-Income Countries with Mandatory Large-Scale Food Fortification”, *Nutrients*, Vol. 13/6, p. 2051, https://doi.org/10.3390/nu13062051. [63]

Tarini, A. et al. (2021), “Enablers and Barriers of Zinc Fortification; Experience from 10 Low- and Middle-Income Countries with Mandatory Large-Scale Food Fortification”, *Nutrients*, Vol. 13/6, p. 2051, https://doi.org/10.3390/nu13062051. [32]

Tazhibayev, S. (2016), *USAID/GAIN Micronutrient Fortification in Central Asia, Afghanistan, and Pakistan Analysis and Justification of the Possibility of Harmonizing Standards for High Extraction Wheat Flour Fortification*, https://www.researchgate.net/publication/332171890_Kazakh_Academy_of_Nutrition_USAIDGAIN_MICRONUTRIENT_FORTIFICATION_PROJECT_IN_CENTRAL_ASIA_AFGHANISTAN_AND_PAKISTAN_ANALYSIS_AND_JUSTIFICATION_OF_THE_POSSIBILITY_OF_HARMONIZING_STANDARDS_FOR_HIGH-EXTRA (accessed on 6 March 2024). [145]

Teachout, E. et al. (2021), “Systematic Process Framework for Conducting Implementation Science Research in Food Fortification Programs”, *Global Health: Science and Practice*, Vol. 9/2, pp. 412-421, https://doi.org/10.9745/ghsp-d-20-00707. [162]

Thuy, P. et al. (2003), “Regular consumption of NaFeEDTA-fortified fish sauce improves iron status and reduces the prevalence of anemia in anemic Vietnamese women”, *The American Journal of Clinical Nutrition*, Vol. 78/2, pp. 284-290, https://doi.org/10.1093/ajcn/78.2.284. [28]

Turk, T. and R. Spohrer (2016), “Using Formative Research to Increase Purchase Intention of Fortified Foods to Prevent Micronutrient Deficiencies in Vietnam”, *Journal of Nutrition & Food Sciences*, Vol. 6/4, https://doi.org/10.4172/2155-9600.1000540. [88]

UN Food Systems Summit (2021), *Technical Note on Sustainable Food Systems*, https://summitdialogues.org/explore-dialogues/. (accessed on 8 March 2024). [38]

UN General Assembly (2016), *Resolution 70/259. United Nations Decade of Action on Nutrition (2016– 2025)*. [137]

UN Library (n.d.), *UN Milestones - Food Security and Nutrition - A Global Issue - Research Guides at United Nations Dag Hammarskjöld Library*, https://research.un.org/en/foodsecurity/un-milestones (accessed on 6 March 2024). [130]

UN Secretary-General (2012), *Zero Hunger Challenge (ZHC)*, https://sdgs.un.org/partnerships/zero-hunger-challenge-zhc (accessed on 6 March 2024). [134]

UNICEF (2021), “Advancing Large Scale Food Fortification: UNICEF’s Vision and Approach”. [43]

UNICEF, WHO and World Bank Group (2021), *Joint Child Malnutrition Estimates – Levels and Trends in Child Malnutrition*, https://www.who.int/publications/i/item/9789240025257. [11]

United Nations (2021), *Food Systems Summit*, https://www.un.org/en/food-systems-summit (accessed on 6 March 2024). [139]

United Nations (2021), *Food Systems Summit Action Track 1: Ensure Access to Safe and Nutritious Food for All Potential Game Changing and Systemic Solutions: A Second Compilation*. [140]

United Nations Secretary-General's High-Level Task Force on Global Food and Nutrition Security (2015), *Advisory Notes by the HLTF Working Groups to Respond to the 5 "Zero Hunger Challenge" Elements*. [135]

Unnevehr, L. (2015), "Food safety in developing countries: Moving beyond exports", *Global Food Security*, Vol. 4, pp. 24-29, https://doi.org/10.1016/J.GFS.2014.12.001. [92]

US Food and Drug Administration (2015), *Questions and Answers on FDA's Fortification Policy Guidance for Industry*, http://www.fda.gov/FoodGuidances (accessed on 8 March 2024). [85]

USAID (2016), "Partnership for Sustainable Food Fortification in West Africa (Fortify West Africa)", http://www.usaid.gov/west-africa-regional (accessed on 6 March 2024). [146]

Van Thuy, P. et al. (2005), "The Use of NaFeEDTA-Fortified Fish Sauce Is an Effective Tool for Controlling Iron Deficiency in Women of Childbearing Age in Rural Vietnam", *The Journal of Nutrition*, Vol. 135/11, pp. 2596-2601, https://doi.org/10.1093/jn/135.11.2596. [29]

Vietnam National Institute of Nutrition (2023), *National Report: Review of the LSFF Framework in Vietnam*. [50]

VOICE (n.d.), *Consumer Voice*, https://consumer-voice.org/resources/ (accessed on 8 March 2024). [104]

WAHO (2008), *Regional Harmonization for Sustainable Food Fortification Program (ECOWAS Regional Feasibility Study)*. [150]

WFP and GAIN (2022), *Towards the adoption of rice fortification in Nigeria Landscape Analysis Report*. [110]

WHO (2022), *Guideline: Fortification of Wheat Flour with Vitamins and Minerals as a Public Health Strategy*. [58]

WHO (2021), *Monitoring Flour Fortification to Maximize Health Benefits: A Manual for Millers, Regulators, and Program Managers*. [102]

WHO (2018), *Guideline: Fortification of Rice with Vitamins and Minerals as a Public Health Strategy*. [158]

WHO (2016), *Guideline: Fortification of maize flour and corn meal with vitamins and minerals;*. [26]

WHO (2016), *WHO guideline: use of multiple micronutrient powders for point-of-use fortification of foods consumed by infants and young children aged 6–23 months and children aged 2–12 years* . [159]

WHO (2014), *Guideline: Fortification of Food-Grade Salt with Iodine for the Prevention and Control of Iodine Deficiency Disorders*. [157]

WHO (n.d.), *Global database on the Implementation of Nutrition Action (GINA)*, https://extranet.who.int/nutrition/gina/en/home (accessed on 6 March 2024). [120]

WHO (n.d.), *Maternal, Newborn, Child and Adolescent Health and Ageing Data Portal*, https://platform.who.int/data/maternal-newborn-child-adolescent-ageing/indicator-explorer-new (accessed on 8 March 2024). [117]

WHO and CDC (2015), *eCatalogue of indicators for micronutrient programs*, https://extranet.who.int/indcat/Default.aspx (accessed on 6 March 2024). [119]

WHO and FAO-UN (2006), *Guidelines on food fortification with micronutrients*. [25]

WHO and UNICEF (2018), "WHO and UNICEF call on Vietnamese authorities to enforce food fortification regulations", https://www.who.int/vietnam/news/statements/07-06-2018-who-and-unicef-call-on-vietnamese-authorities-to-enforce-food-fortification-regulations (accessed on 8 March 2024). [76]

WHO and UNICEF (2007), *Iodine deficiency in Europe: a continuing public health problem*, https://www.who.int/publications/i/item/9789241593960. [20]

Wirth, J. et al. (2013), "External Mill Monitoring of Wheat Flour Fortification Programs: An Approach for Program Managers Using Experiences from Jordan", *Nutrients*, Vol. 5/11, pp. 4741-4759, https://doi.org/10.3390/nu5114741. [90]

World Business Council for Sustainable Development (2021), *Business backs Zero Hunger Private Sector Pledge led by WBCSD and partners*, https://www.wbcsd.org/Programs/Food-and-Nature/News/Business-backs-Zero-Hunger-Private-Sector-Pledge-led-by-WBCSD-and-partners#:~:text=The%20Zero%20Hunger%20Private%20Sector%20Pledge%20is%20a%20multistakeholder%20platform,state%20governments%2C%20and%20international%20organizations (accessed on 6 March 2024). [141]

World Food Summit (1996), *Technical Background Document: Food Security and Nutrition*, https://www.fao.org/3/w2612e/w2612e05a.htm (accessed on 6 March 2024). [165]

World Food Summit (1996), *World Food Summit Plan of Action*, https://www.fao.org/3/w3613e/w3613e00.htm#PoA (accessed on 6 March 2024). [132]

World Health Organization (n.d.), *Malnutrition Q & A*, A' https://www.who.int/news-room/questions-and-answers/item/malnutrition. [2]

World Health Organization (WHO) (1992), *National strategies for overcoming micronutrient malnutrition' A45/17*, World Health Organization (WHO), https://apps.who.int/iris/handle/10665/175581. [5]

World Health Organization (WHO) (n.d.), *Malnutrition*, https://www.who.int/health-topics/malnutrition#tab=tab_1. [1]

World Health Organization (WHO) (n.d.), *Nutritional Landscape Information System (NLiS) - Vitamin A Deficiency*, https://www.who.int/data/nutrition/nlis/info/vitamin-a-deficiency#:~:text=Vitamin%20A%20deficiency%20is%20a,women%20in%20low%2Dincome%20countries. [22]

World Trade Organization (1995), *Agreement on Technical Barriers to Trade*, https://www.wto.org/english/docs_e/legal_e/17-tbt_e.htm. [35]

World Trade Organization (1994), *Agreement on the Application of Sanitary and Phytosanitary Measures*, https://www.wto.org/english/tratop_e/sps_e/spsagr_e.htm. [36]