SAFE, HEALTHY, AND SUSTAINABLE DIETS: ROLE OF FOOD REGULATORY BODIES AND INNOVATIONS FROM INDIA

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Health, Nutrition & Population

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Health, Nutrition, and Population (HNP) Discussion Paper

Safe, Healthy, and Sustainable Diets: Role of Food Regulatory Bodies and Innovations from India

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Abstract: The paper discusses in brief India's food regulatory system in the context of modernized frameworks and examples of well-developed and mature regulatory systems from five selected developed countries (Australia, New Zealand, Canada, the United States, and the European Union). India's food regulator, the Food Safety and Standards Authority of India (FSSAI), established in 2008, has developed a modernized regulatory system that aligns well with the most recent food safety regulatory systems model of the World Health Organization (WHO) (2018). As it continues to strengthen the regulatory system to enhance food safety, FSSAI is applying innovative approaches to address the country's unique challenges of food safety, public health, and sustainable diets. The paper discusses two of FSSAI's innovations: (i) approaches to enhance the safety of food businesses operating in India's huge informal food sector; and (ii) proactive direct engagement with consumers at scale to promote safe, nutritious, healthy, and sustainable diets by influencing behavior change, thus contributing to improvements in public health, nutrition, and environmental sustainability. The paper also describes FSSAI's regulatory leadership during the COVID-19 pandemic to promote food safety. The paper concludes that the approaches and innovations adopted by FSSAI appear promising and there are lessons that could be adopted and adapted by other low- and middle-income countries (LMICs). These approaches have not yet been evaluated but do merit a deeper study and discussion that may well lead to expanding the roles food regulatory bodies could play in promoting food safety, public health and nutrition, and sustainability. Whether food regulators are well-placed to take on wider roles may vary by country and the system of public administration, but it is not inappropriate per se for regulators to have that expanded role.

Keywords: Food Systems Approach, Eat Right India, Food Regulations, Food Safety

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List of Acronyms

APEC	Asia Pacific Economic Cooperation
CFIA	Canadian Food Inspection Agency
CNNS	Comprehensive National Nutrition Survey
DALY	Disability adjusted life year
EFSA	European Food Safety Authority
EU	European Union
GFSI	Global Food Safety Initiative
FAO	Food and Agriculture Organization of the United Nations
FBD	Foodborne diseases
FBO	Food business operator
FoSTaC	Food Safety Training and Education
FSA	Food Standards Agency (UK)
FSANZ	Food Standards Australia New Zealand
FSMA	Food Safety Modernization Act 2012
FSS Act	Food Safety and Standards Act 2006
FSSAI	Food Safety and Standards Authority of India
FSW	Food safety on wheels
GNR	Global Nutrition Report
HC	Health Canada
LMICs	Low- and middle-income countries
MIYCN	Maternal, Infant, and Young Child Nutrition
NCD	Noncommunicable disease
NCDC	National Communicable Disease Control
NFHS	National Family Health Survey
RAFT	Rapid Analytical Food Testing
RASFF	Rapid Alert System for Food and Feed
RRT	Rapid Response Team
RUCO	Repurpose Used Cooking Oil
US FDA	US Food and Drug Administration
WHO	World Health Organization of the United Nations

PART I – INTRODUCTION

1.1 The Interrelated Challenges of Food Safety, Nutrition and Public Health, and the Environment

Food impacts health in several interrelated ways. Food safety, unhealthy diets, malnutrition, and noncommunicable diseases (NCDs) are closely linked, especially given the changes experienced in food systems over the last 50 years (Branco et al. 2019). An estimated 600 million people, almost 1 in 10 in the world, fall ill after eating contaminated food, and 420,000 die every year, resulting in the loss of 33 million healthy life years or disability-adjusted life years or DALYs (WHO,2015). With increased globalization of the food supply, the road traveled by food from its origin to the plates of consumers is often long and complex, and people worldwide are exposed to increased and new hazards (Jaffee et al., 2018; WHO, 2020). Foodborne diseases obstruct socioeconomic development by straining health care systems and harming national economies, tourism, and trade(Anderson et al., 2018).

Macro changes such as globalization of the food supply, economic development, technological advances, changes in agricultural systems, and increasing urbanization and climate change have transformed diets around the world (Turner et., 2018). These factors have also influenced daily diets, promoting a transition away from grains, legumes, vegetables, and fruits to an increased consumption of processed foods, takeaway foods, animal source foods ,and refined carbohydrates (Turner et., 2018). Furthermore, in low- and middle-income countries (LMICs), while undernutrition continues to be a significant problem, the prevalence of overweight, obesity, and diet-related NCDs is increasing, resulting in the emergence of the "double-burden of malnutrition" (WHO, 2016). Globally, it is estimated that 1.9 billion adults are overweight or obese, while 462 million are underweight. It is estimated that in 2020, 149.0 million children under five were stunted (too short for age), 45.0 million were wasted (too thin for height), and 38.9 million were overweight or obese. Further, approximately 45 percent of deaths among children under five years of age were linked to undernutrition. These occur mostly in LMICs, where, along with undernutrition, rates of overweight and obesity are rising (WHO 2021). As per Food and Agriculture Organization's (FAO's) recent State of Food Insecurity report (2021), there were approximately 720 to 811 million hungry people in the world in 2020. Unsafe food makes the vicious cycle of disease and malnutrition worse, particularly affecting infants, young children, the elderly, the immune-compromised, and the sick.

Both malnutrition and unsafe food have large economic costs. FAO recognizes that the cost of unsafe food goes beyond its individual impacts, to socioeconomic development, overloading health care systems and compromising economic growth and trade. Food safety also has an economic cost attached to it. FAO/WHO on World Food Safety Day 2019, (FAO, 2019) highlighted that the price tag attached to unsafe food in low- and middle-income countries, according to the World Bank ((Jaffee et al., 2018 is "about US$95 billion in lost productivity annually." FAO/WHO also note that unsafe food not only has a cost associated with productivity, but also limits trade.

Food-related environmental impacts are a growing concern and need attention. Lloyd's Register Foundation's *Foresight Review of Food Safety: Feeding the World Safely and Sustainably* (2019) (Anderson et al., 2018) notes that there are environmental and social costs to food production too, identifying that "the global food production system is one of

the biggest contributors to greenhouse gas emissions" and that "plastic packaging is now an urgent global concern, and food cold chains, while an important part of food safety, have a negative impact on energy consumption and sustainability." Johnson (2015) highlights that "the need to incorporate environmental considerations into food choices is recognized as critical for progressing public health, food security and environmental sustainability."

1.2 About the Food Safety and Standards Authority of India

India's food regulatory system has evolved over the last decadeafter the creation of the national food regulatory body, the Food Safety and Standards Authority of India (FSSAI) in 2008 under the Ministry of Health and Family Welfare (MoHFW). The Prevention of Food Adulteration Act, 1954, was India's primary law governing food safety, along with other laws/orders specifically targeting the food sector. In 2006 the Indian Parliament consolidated and subsumed the various acts and orders into the Food Safety and Standards Act (FSS Act). FSSAI is responsible for the implementation and enforcement of food regulations as per the FSS Act, 2006.

FSSAI has statutory powers for laying down science-based standards and regulating the manufacture, storage, distribution, sale, and import of food products to ensure the availability of safe and wholesome food for human consumption. FSSAI at the national level and state food authorities at the state level are jointly responsible for the implementation and enforcement of the FSS Act. The FSSAI is organized into technical and administrative divisions such as Science and Standards, Trades and International Cooperation, Enforcement, Administration, Finance, Quality Assurance and Social Behavioral Change Development, and Informational Technology.

1.3 Food Systems Approach

A number of definitions for food systems have been put forward in a growing body of work that emphasizes the need to take a systems approach to look at a variety of food-related areas including nutrition, food safety, and environment. Wageningen Economic Research, (Van Berkum etal., 2018) for example, references a range of sources on what food systems comprise and states that *"all the processes associated with food production and food utilization: growing, harvesting, packing, processing, transporting, marketing, consuming and disposing of food remain. All these activities require inputs and result in products and/or services, income and access to food, as well as environmental impacts. A food system operates in and is influenced by social, political, cultural, technological, economic and natural environments."* FAO, in *Sustainable Food Systems: Concept and Framework* (FAO, 2018) also outlines that food systems encompass the entire range of actors and the activities involved in production right through to disposal of food products and that a food systems approach considers the food system in its totality, taking into account all the elements, their relationships, and related effects.

While not specifically defining or referring to a "food environment" or "food system," Friel et al (2014) note that "around the world, including Australia, the importance of integrating environmental considerations into people's food choices is now recognized as an important component of a policy response concerned with health, food security and environmental sustainability. It also notes the critical importance of sustainable diets which take into account whole ecosystems."

Globally, experts are moving toward promoting a systems approach to address food-related health and environment issues. In 2019, EAT-Lancet Commission's *Healthy Diets from Sustainable Systems: Food Planet Health* (Willett et al., 2019) shone a spotlight on food as a critical factor in optimizing both human health and environmental sustainability. The document clearly articulates that, "*Food is the single strongest lever to optimize human health and environmental sustainability on Earth. However, food is currently threatening both people and planet. An immense challenge facing humanity is to provide a growing world population with healthy diets from sustainable food systems. While global food production of calories has generally kept pace with population growth, more than 820 million people still lack sufficient food, and many more consume either low-quality diets or too much food. Unhealthy diets now pose a greater risk to morbidity and mortality than unsafe sex, alcohol, drug and tobacco use combined.*"

The report provides a strong call to action….

"The Commission calls for widespread multi-sector, multi-level action including: a substantial global shift toward healthy dietary patterns; large reductions in food loss and waste; and major improvements in food production practices. Food will be a defining issue of the 21st century. Unlocking its potential will catalyze the achievement of both the Sustainable Development Goals (SDGs) and Paris Agreement." It is in this context that the role of food regulatory bodies assumes great significance.

While there are clear arguments for integrating food safety, public health nutrition, and food and environment, any potential limitations and/or challenges associated with this approach need to be considered. Candel and Pereira (2017), also stated that food system outcomes are affected by many determinants and that "traditional government efforts to steer these determinants through monocentric command and control strategies get stranded in 'siloed' administrative systems" and therefore need "integrated policy approaches"; however, at the same time they note that there are policy integration challenges. These include determining an overarching policy framework that finds "wide resonance"; determining policy goals across a range of interests, politics and priorities; involving and coordinating all relevant sectors; finding the right balance between policy integration and policy specialization and the tension between those; and that in developing integrated policy that is beyond symbolic, it is critical to use a mix of policy instruments to achieve the goals.

Current advances in the work on systems leadership support the notion that undertaking change in the food environment/food systems requires a multistakeholder, collaborative approach. Dreier et al (2019) note that achieving change against complex problems like those associated with the 2030 Sustainable Development Agenda *"requires a departure from traditional top-down, hierarchical and linear approaches to implementing change. Instead it requires innovative and adaptive approaches that engage broad networks of diverse stakeholders to advance progress toward a shared vision for systemic change."*

As food systems include all the interconnected activities—right from agriculture, forestry, or fisheries involved in the *production, aggregation, processing, distribution, consumption, and disposal of food products*—it entails involvement of different actors at different levels. In India, there are various players responsible for maintaining the ecosystem and balance of this food system—from the Ministry of Agriculture (for on-farm activities), to the Ministry of Food Processing (for food industries including small and medium enterprises), Urban Development, Public Food Distribution (for provision of

subsidized food through a government food safety net program), Women and Child Development (to tackle the problem of undernutrition, anemia), Drinking Water and Sanitation (universal sanitation coverage), the Ministry of Petroleum (converting biodiesel from used cooking oil), the Ministry of Education (providing hot cooked meals to schoolchildren), and the Ministry of Health and Family Welfare—each has a dedicated role and a program to cater to the challenges of food safety, health, and environment. For more details on the roles and responsibilities of each line ministry, refer to Annex 3. In its endeavor to play a strong role in developing sustainable food systems, the food regulatory body of India (FSSAI) collaborates with other line ministries to identify areas of synergy and coordinated efforts. Some of the partnerships are mentioned in Sections 2 and 3 of the report.

To place India's food regulatory framework within the global context, the paper highlights key features of five mature, well-developed and modern food regulatory systems from Australia, New Zealand, Canada, the United States, and the European Union (EU). For India, apart from the key features of the country's food regulatory body as it fits in the global framework, the paper also discusses two innovations attempted by FSSAI: (i) efforts to improve food safety in India's large informal food sector; and (ii) proactive outreach to consumers to promote safe and healthy diets that are also environmentally sustainable to improve public health and nutrition and environmental sustainability. At the same time the paper highlights some important points and questions that will benefit from a larger discussion.

Following this Introduction, Section 2 of the paper discusses in detail India's food safety regulatory system in light of the global framework and modernized food safety systems; Section 3 discusses the innovations and actions taken by FSSAI beyond food safety laws and regulations. Finally, Section 4 summarizes the analysis and presents a few discussion points that may need more consideration not only for India's food regulator but also for other LMICs if they plan to adapt any of the discussed strategies/ interventions.

PART II – INDIA'S FOOD SAFETY REGULATORY SYSTEM

2.1 India's Unique Challenges

Every year 100 million cases of foodborne diseases (FBDs) are reported in India, and unsafe food costs India as much as US$15 billion annually—a very high economic burden (Kristkova et al, 2017). The burden of FBDs is comparable to that of malaria, human immunodeficiency virus/Acquired immunodeficiency syndrome (HIV/AIDS), and tuberculosis, (Havelaar et al, 2015) and yet it does not get the required attention. Further, India faces a triple burden of malnutrition—undernutrition (stunting, wasting, underweight), micronutrient deficiencies, and rapidly rising obesity and incidence of noncommunicable diseases. On the nutrition front, the recent *Global Nutrition Report* (Global Nutrition Report 2021) revealed that five out of six global maternal, infant, and young children nutrition (MIYCN) targets to address stunting, wasting, anemia, low birthweight, and childhood obesity are off-track for India. No progress has been made towards achieving the target of reducing anemia among women of reproductive age, with 57.0 percent of women aged 15 to 49 years being anemic (National Family Health Survey-5 [NFHS-5], 2019–2021). Although prevalence of stunting has shown a decline in the last five years, 35.5 percent of children in India under five years of age are still stunted, which is higher than the average for the Asia region (21.8 percent). On the rising burden of NCDs, one in ten school-age children and adolescents in India are prediabetic and a high percentage of them have a deranged lipid profile—major risk factors for NCDs (Comprehensive National Nutrition Survey [CNNS], 2015–2016). Six of the top-ten risk factors for burden of disease in India are food related (WHO, 2015). Similar figures are also highlighted by the Indian Council of Medical Research (2016) — more than 60 percent of deaths in the country are caused by NCDs such as diabetes, heart disease, and hypertension, to name just a few.

India also faces the challenge of regulating the food supply for over 1.4 billion people with a huge variety and diversity of food and cultural habits across the country. There are over 4.8 million (FSSAI, 2022a) licensed/registered food businesses where a large number of microlevel food businesses coexist with very modern food businesses. Given this, India, specifically FSSAI, is rising to the challenge and while developing a modernized food regulatory system for the country, it is also developing context-specific approaches to address the country's challenges, and factoring in elements to complement regulatory approaches for a larger impact. This section discusses India's regulatory system within the context of global regulatory frameworks and key features of well-developed regulatory systems from five countries.

2.2 Global Frameworks for Modernized Food Safety Systems

Seminal work by FAO and WHO in 1997 laid the foundation for establishing effective food safety control systems with several updates over time (see Box 1). Figure 1 presents the key elements of the 1997 FAO/WHO framework.

The FAO/WHO paper of 1997 defines a food control system as *"a mandatory regulatory activity of enforcement by national authorities to provide consumer protection and ensure that all foods during production, handling, storage, processing, and distribution are safe, wholesome and fit for human consumption; conform to safety and quality requirements; and are honestly and accurately labelled as prescribed by law."* (WHO, 2003). This is a top-down control system of a sort that is increasingly challenged as ineffective in establishing food safety in very large populations. Insofar as it relies on traditional enforcement with inspections, it is difficult for it to apply to more than a small percentage of the food businesses in any country. Where that country has a vast informal economy, traditional enforcement is even more inappropriate. That is not to say that the model is not applicable since it will still apply to the formal economy and to large food businesses. The model also recognizes the importance of Information, Education, and Communication (IEC) training, including for consumers, but perhaps did not foresee the potential development of that element.

Figure 1: Five Key Elements of the FAO/WHO 1997 Model

Food Law & Regulations	**Food Control Management**	**Inspection Services**	**IEC and Training**
This element provides legal authority to allow enforcement where necessary. There will always be a need for coercive action against operators who deliberately or recklessly endanger others and to support enough enforcement to provide a level playing field for compliant businesses to compete. The legal framework is necessary for the formal market to operate and will also have some leadership and guidance value on how food businesses should perform (but only a small percentage of food businesses will ever read regulations). Particularly for developing economies and for very large populations, it is no more than a framework.	Control management systems were central to the original model and remain central in developed economies, especially in the concept of "official controls" in the EU system. But this also covered the "management" as well as the "control" aspect in that it covered national food safety strategies or policies and national monitoring and sampling plans, which are still necessary.	This is perhaps where practices have changed most in the last 20 years. There has been a global trend away from a "policing" model of inspection to a more supportive and partnering model between enforcement agencies and food businesses. This is reflected in the APEC quote above which referred to "proactive and preventive measures to ensure safe food throughout the food supply chain". The emphasis is no longer on stopping unsafe food as ensuring the supply of safe (and wholesome) food. But even in 1997, this was envisaged by FAO/WHO, as seen in the definition of the control system quoted above as positively ensuring safety.	The 1997 paper recognized that this was important, not only for training officials at various levels but also consumers. What they may not have seen was how much the delivery of safe and healthy food has become a matter of persuasion and enabling, rather than enforcement.

Lab Services
The necessity for science-based research and testing is no less important than it was. If anything, developments in food science make it all the more important to keep pace with changes. Innovations like whole genome sequencing show that the relevance of this element is timeless.

Source: Food and Agriculture Organization and World Health Organization, 1997

Figure 2 presents the WHO's updated model of 2018 (WHO, 2018) which notes that the objectives of national food safety systems are to protect the health of consumers and ensure fair practices in food trade. It builds on the 2013 Codex Principles and the Codex Risk Analysis model. (Alimentarius. C, 2013)

The common enabling factors seen to be necessary include leadership, partnership, resources, and competencies. The key elements of the food safety system are very similar to those of the early FAO/WHO model but are modified according to a country's level of development.

For the purpose of this discussion paper, the elements have been summarized as follows:

Figure 2: WHO Framework for Action on Food Safety
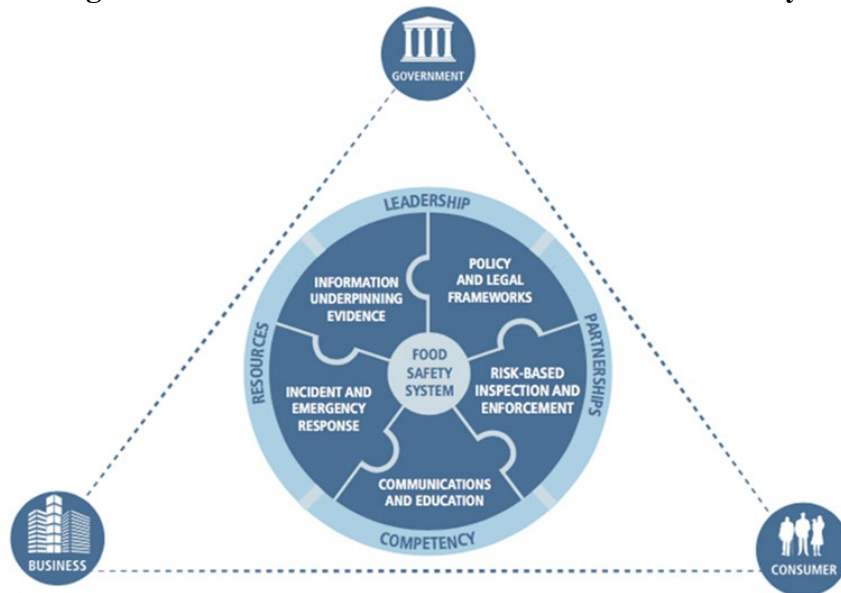
Source: WHO Regional framework for action on food safety in the Western Pacific, 2018.

- *Policy and Legal Frameworks* – Risk-based food safety laws and regulations; multisectoral food safety plan with defined roles for stakeholders; mechanisms to review performance of the system; legal measures for food safety along the supply chain in line with Codex Alimentarius and international requirements.
- *Risk-Based Inspection and Enforcement* – A system and plans for risk-based enforcement throughout the food chain; qualified food inspectors; registration system for businesses in the formal sector; access to reference food laboratories with capacity to undertake required food safety testing.
- *Information Underpinning Evidence* – A coordinated national surveillance system, including monitoring programs, total diet studies; mechanisms in place to collect laboratory-based surveillance of foodborne diseases; analyze and utilize foodborne disease surveillance data.
- *Incident and Emergency Response* – Legal authority to enforce and conduct food recalls and risk management; designated International Food Safety Authorities Network (INFOSAN) emergence contact point; documented food recall and traceability system; procedures for investigation and response to food safety incidents.
- *Communications and Education* – Platforms for food safety awareness programs and communication/education plans; mechanism to review the effectiveness of food safety communication programs.

The framework also outlines the following enabling factors:
- Leadership – Establishing a common vision, setting priorities and demonstrating commitment to strengthen food safety across sectors and stakeholders and setting an example for good food safety for all to follow.
- Partnerships – Working toward a common vision involving all relevant stakeholders, each with their own set of responsibilities, working in a coordinated manner to reduce duplication and gaps in the system and ensuring strong working relationships between government, businesses, and consumers.
- Competency – Technical skills, knowledge, attitude, and behavior to manage food safety risks.
- Resources – For allocating appropriate human and financial resources to achieve the objectives of the food safety system.

The WHO model recognizes that food safety is a shared responsibility among the following stakeholders:
- Government including all ministries and agencies involved in official food control, and any other relevant government agencies
- Businesses including food business operators along the entire food chain, as well as food industry associations that represent various sectors
- Consumers including broad society, as well as representative consumer groups

This model recognizes the need for food safety systems to be able to adapt to address ever-evolving contexts and food safety issues. It also recognizes that responsibilities regarding food safety go well beyond government, that there must be a shared approach, and that food safety is multidimensional with a range of factors to build into the system, as well as ongoing review mechanisms to manage changing situations. In implementing the framework, organizations must consider the "how," particularly in low- and middle-income countries where food regulatory systems may be at a stage of early to midlevel development.

2.3 Examples of Well-Developed Food Regulatory Systems

This section captures a snapshot of the approach taken toward food safety by five developed food regulatory systems from around the world (Australia, New Zealand, Canada, the United States, and the European Union). This provides a cursory illustration of how advanced food safety regulatory systems implement elements of a system model such as the WHO model. Although these countries represent different national and population contexts and stage of economic development relative to India, they do provide a context of elements that well-developed, modernized food regulatory systems reflect. For example, nearly all of them have largely overcome the challenge of a vast informal food sector. In terms of ranges of populations, New Zealand has 4.7 million, Australia 25.2 million, Canada 37.5 million, the United States 329.4 million, and the EU 513.0 million. All have highly developed economies and food industry sectors.

All five developed regulatory systems have dedicated bodies for setting up food-related **Policies, Standards, and Legal Frameworks**. There are vertical and horizontal linkages between the concerned authorities with clear roles and responsibilities laid out. Of the five, EU regulates 28 member states through regulations that are "directly applicable," that is, they have full legal effect in each country without any further intervention by these countries' governments.

All five countries/regions have **Incident and Emergency Responses** in place. For example, Food Standards Australia New Zealand (FSANZ) coordinates and monitors food recalls in Australia and in New Zealand. It is coordinated by the Ministry of Primary Industries; the Canadian Food Inspection Agency (CFIA) initiates food recalls with the industry and investigates foodborne illness outbreaks in Canada; and EU Traceability, supported by the Rapid Alert System for Food and Feed (RASFF), gathers and disseminates information on food hazards across the EU.

Risk-Based Inspection and Enforcement follows a different path in all the countries. While in Australia/New Zealand it is implemented by all responsible state/territory jurisdictions, in Canada CFIA provides training programs across the country to ensure key technical competencies for CFIA employees; in the United States, Food Safety Modernizing Act (FSMA) allows the Food and Drug Administration (FDA) to use risk-based prioritization to target most serious foodborne health hazards and food facilities in both domestic and foreign countries. In Australia it is the Food Standards Australia New Zealand (FSANZ), while in New Zealand, it is the Ministry for Primary Industries (MPI) that conducts food monitoring programs on food produced domestically as well as on imported foods. In Canada, the Public Health Agency of Canada (PHAC) conducts public health surveillance; in the United States it is the Centers for Disease Control and Prevention (CDC) that gathers data on foodborne illnesses and investigates foodborne illnesses and outbreaks. The details are presented in Annex 1.

Information Underpinning Evidence: While in Australia, food safety testing is undertaken by accredited government and nongovernment laboratories; in New Zealand, MPI approves all food safety testing laboratories, which must use approved methods that are validated according to international protocols. In Canada, PHAC is responsible for conducting public health surveillance; in the United States, FSMA undertakes food testing by FDA-accredited laboratories to meet high quality standards. In the European Union, the European Food Safety Authority (EFSA) has built a high international reputation for strong science, contributing to standard-setting. It is a key part of the

dynamism of the EU system whereby it regularly issues regulations resulting from food safety research, for example, minimum residue levels of certain contaminants.

On **communication and education**, the paper also examined the government initiatives that focused on nutrition and/or any other broader initiatives that may have an impact on health outcomes. The Australian government's nutrition promotion efforts fall within a broad program "*Eat for Health.*" The Office of Nutrition Policy and Promotion (Government of Canada, 2017) is the focal point for public health nutrition and leads efforts to support healthy eating, whereas the Food Directorate (Government of Canada, 2021) is the federal health authority responsible for assessing health risks and benefits; setting standards, policies, and regulations; and providing advice and information regarding the safety and nutritional quality of food in New Zealand. The Department of Health and Human Services (HHS) and the Department of Agriculture are jointly responsible for nutrition, food, and related health initiatives in the United States, and the Directorate General for Health and Food Safety (DG SANTE) has the overall responsibility for nutrition promotion and coordination activities in the European Union. The detailed table in Annex 2 provides a summary of the types of initiatives that have been undertaken along with the responsible agency; the types of initiatives implemented; and which, if any, partnerships are part of the overall effort.

2.4 WHO 2018 Framework and India's Approach

This section assesses India's food regulatory system vis-à-vis the WHO's (2018) framework. It is important to note that the Indian system has ingredients of all five elements of the WHO framework to different degrees. While policy and legal frameworks are sound; emergency response and risk-based enforcement are still emerging; and innovations are occurring under communication and education that must be evaluated for the impact they have generated. The summary is presented below:

- Policy and Legal Framework: The comprehensive legislation Food Safety and Standards Act, 2006 (FSS Act) integrates erstwhile acts/orders related to food into one unified law, moving from the narrow focus on adulteration to food safety, ensuring wholesomeness of food to consumers. To create a responsible regulatory system, FSSAI develops food standards/regulations through 20 Scientific Panels and one Scientific Committee considering the latest developments across the globe in food science and technology. FSSAI at the national level and state food authorities at the subnational level are responsible for the enforcement of this act. While the state's commissioner of food safety is the head having powers for enforcement of the act at the state level, FSSAI at the national level has the powers to monitor and issue direction in this respect to the state food safety authorities. The implementation of the act at the grassroots level is performed by the designated officers and the food safety officers of the state food safety authorities who make use of the food aanalysts' report to find out whether the food under investigation is legally compliant.

- Incident and Emergency Response: For managing food safety events, specifically foodborne illness outbreaks, FSSAI and state food authorities are working in close coordination with the National Centre for Disease Control (NCDC) and its state/district surveillance officers at the field level. Rapid Response Teams (RRTs) at the state and district levels have been established to monitor and control food safety events. In such food safety events, FSSAI and the food safety commissioner

have authority to issue a mandatory recall of unsafe food when a food business operator fails to voluntarily recall the same. The system is nascent, and efforts are ongoing to further define, refine, and institutionalize a more advanced emergency response system.

- Risk-Based Inspection and Enforcement: Given the very large ratio of food businesses to enforcement officials in the country, FSSAI has adopted a risk-based inspection plan. Food business operators (FBOs) have been categorized in three grades of risks (i.e., high, medium, and low), and the frequency of inspection of such FBOs is decided as per the need to ensure efficient and effective enforcement. FSSAI has directed states/union territories (UTs) to conduct at least one inspection per year of the FBOs falling under high and medium risk categories and to conduct inspection of at least 10 percent of FBOs every year falling under the low risk category. Further, FSSAI through its 2018 FSS (Food Safety Auditing) Regulations recognizes third-party auditing agencies. So far, 28 third-party auditing agencies have been recognized under various scopes of auditing.(FSSAI, 2018)

- Information Underpinning Evidence: There is a network of 222 laboratories across the country and 18 referral laboratories along with a fleet of Mobile Food Testing Labs, Food Safety on Wheels (FSWs) to expand the reach to consumers through as many touch points as possible for testing, training, and awareness generation. (FSSAI, 2022b) Further, FSSAI has framed a policy and process for approval of Rapid Analytical Food Testing (RAFT) kit/equipment/method for regulatory and surveillance purposes.

- Communications and Education: Apart from general communication and education, the Eat Right India program intends to bring about social and behavioral change in diets whether people eat at home, at school, at the workplace or when they eat out to prevent death and disease due to unhealthy diets. Reaching out to consumers to create awareness and promote safe, healthy, and sustainable diets is one of the major thrust areas of the program. This innovation is being taken to scale and is discussed under Innovations (Section 3).

Relative to many other food safety regulators globally (including the five assessed in the previous section), FSSAI's role or mandate allows for a broader remit than some agencies that have a role limited to "protecting public health and safety." Although, the country has a strong policy environment, the network of laboratories and monitoring and surveillance systems seem weaker considering the scale of challenges the country confronts—1.4 billion population, over 1.4 million registered food businesses, large informal food sector, and high burden of food safety and nutrition issues. Further, the analysis with the WHO model shows that FSSAI through its Information, Education, and Communication (IEC) approach goes beyond the classic food safety system approach focusing on food safety, healthy diets, and the environment. This approach is unique in that while adhering to the broad categories of the model, it goes beyond its regular mandate toward making the environment more "enabling" than "enforcing." A few more examples of how FSSAI has attempted to tackle the informal food sector in the country and reach consumers and industry though its outreach approach are discussed in Section 3 of this report.

In the countries examined (in Section 2.3), the general trend for governments is to divide the responsibilities around food, nutrition, and health across lines that generally apply to

the notion of "protecting public health and safety" versus "promoting nutrition and public health." It appears that the health portfolio (or a combination of the health and agriculture portfolio) is usually responsible for dietary guidance, nutrition information, and promotion, be it in various forms and for various audiences. From a food safety perspective, responsibilities are typically limited to protecting public health and safety through regulatory mechanisms, and the food safety regulators are responsible for this. There is an area that is arguably an interface between the two—the nutrition labeling area, where one could argue that regulatory mechanisms associated with nutrition labeling, such as nutrition information panels, nutrition claims, health claims, and materials to support such regulations, are awareness-raising and education/health promotion tools.

Box 3: Efforts by the Indian Food Regulatory System That Go beyond the Orthodox Food Regulatory Systems Approach

Nutrition Awareness and Education Campaigns – While there are nutrition principles and aspects of nutrition awareness and education that are typically encompassed in food regulation—that is, nutrition labeling, including nutrition information panels, nutrition/health claims, and fortification, and occasionally there may be related education programs—it is quite unusual for a large-scale nutrition-focused campaign to be led by the food safety regulator. This would normally be undertaken by the broader health department/portfolio.

Repurpose Used Cooking Oil (RUCO) **–** An Education, Enforcement and Ecosystem strategy to divert used cooking oil from the food value chain through collection and conversion of used cooking oil into biodiesel. Although this is at a very early stage of implementation, this unique partnership between the Ministry of Petroleum and Natural Gas and the private sector is intended to serve the dual purpose of improving safety of oil through removal of used cooking oil and the production of biodiesel, a fuel for consumer use. How this strategy evolves is something to look out for in the future.

Clean Street Food Hub – This initiative is aimed at street vendors in the informal sector and provides them with infrastructure necessary for food hygiene, for example, electricity, running water, and waste management. For petty food business operators (FBOs,) FSSAI has also launched a cluster approach. FSSAI is awarding Clean Street Food Hub certificates to the cluster of petty FBOs after upgrading the hygiene and sanitary facilities of these clusters. The petty FBOs in these clusters are being trained under the Food Safety Training and Certification (FoSTaC) program regarding hygiene and sanitary requirements.

Lal Bahadur Shastri National Academy of Administration – This is a central training establishment for Indian civil servants. FSSAI has established a center on Food, Planet, and Health—the center is responsible for training civil servants on Eat Right India (ERI) and on how the program can be mainstreamed in the health-related tasks at all levels.

Forming Partnerships with different stakeholders such as industry, professionals, government, and development leaders. Leveraging the private sector like the Confederation of Indian Industries (CII) through the Capability Harnessing Initiative with Food Safety and Sciences (CHIFSS) to strengthen capacity-building interventions and food testing infrastructure; similarly *NetProFaN* partnership with professionals is leveraged to take ERI to state and local levels. Partnerships with ongoing government programs—*Poshan Abhiyan*, National Health Mission, *Swachh Bharat* is also explored for harmonized messaging.

PART III – INNOVATIONS TO ADDRESS INDIA'S UNIQUE CHALLENGES

Thus far, the discussion paper has covered the application of regulatory systems or, more accurately, regulatory systems deriving authority from primary legislation—that is, from laws, acts, or EU regulations. But food safety and nutrition management and interventions may benefit from mechanisms or even systems that are not an integral part of the legal framework. These can operate at two very different levels in the case of food safety. This section covers the strategies adopted by food regulatory authorities to tackle informal food markets and consumer engagement for promotion of safe, healthy, and sustainable diets.

3.1 Improving Food Safety in the Informal Food Economy

Below the level of the national regulatory framework, most countries have an informal economy that exists outside the formal, regulated economy; these markets operate under commercial disciplines, but they are likely to be unregistered and operate outside enforcement systems (especially tax). Even highly developed economies will have small businesses that are growing, rearing, distributing, or catering. This includes semi-subsistence smallholders who may have a small surplus that they sell, or individuals who sell packaged snacks to drivers stopped at traffic lights. But it can also consist of a very large number of small businesses that cumulatively supply a significant, or even majority, percentage of the national diet.

"Informality" is a complex issue. It has positive elements as well as negative ones, and it even has its adherents who argue that it is not only necessary but preferable (VanderBerg, 2014). In more developed economies, it is likely to play a smaller part in the overall economy and in social structures but will still present the hard choices at the interface between barely viable formal businesses and artificially viable informal businesses. The role of regulatory agencies will more often be to "fight informality" (Dašić et al., 2021) to provide the "level playing field" that is one of the main benefits of a regulatory system.

The informal food sector is a major issue in many countries and is linked to the country's stage of development. North America and Australasia have largely left behind the socioeconomic conditions that support a large informal sector, but even the EU remains a mixture. France still has a cultural attachment to small peasant farmers producing food, especially cheese, in traditional ways. That has led to some flexibility in the EU food safety system that allows some traditional production to be unregistered. In most other countries, the informal food sector will be a source of often considerable concern. This is particularly true for India and China because of the scale of the problem, but also applies across most of Africa, Central and South East Asia, as well as Latin America.

Many countries see the informal food sector as "too difficult" to deal with and ignore it when discussing their food safety regulatory systems. It is impractical to apply conventional regulatory systems and conventional regulatory enforcement to vast numbers of informal food businesses. In Nigeria, the poultry sector has between 7 and 40 large or very large producers, but the Small Producers' Association estimates an informal sector of 200 viable smallholders with modular hatcheries, 200,000 small producers with 500 to 1,000 chicks, and 300,000 noncommercial backyard producers (personal communication). Even if they are noncommercial, they still generate food that is eaten.

Individually, each business may be low risk because of its limited impact on a large number of people, but cumulatively it can present a significant risk. It is a weakness in the system of risk-based inspection, but one-on-one inspection is not a viable option anyway. Nonetheless a lack of coercive enforcement does not mean that practice levels cannot be raised, even if they don't reach the levels required for full compliance with the formal regulatory system. In these circumstances, improvement is the goal, rather than compliance. But a 5 percent improvement across 200,000 small producers may be a much greater public benefit than a 5 percent improvement in an already largely compliant large business. Businesses in the informal sector include businesses that are hardly viable and have no capacity at all for improvement, but they also include viable businesses (within the reduced constraints of the informal sector) that are capable of improving—and that want to improve.

The evidence generally shows that foodborne disease and the incentives for enhancing food safety management capacity vary systematically with the level of economic development. Jaffee et al. (2019) present a model for the "food safety life cycle," which relates economic development of a country to the economic burden suffered as a result of food safety issues. This can be seen in Figure 3.

Figure 3: Food Safety Life Cycle with Levels of Economic Development
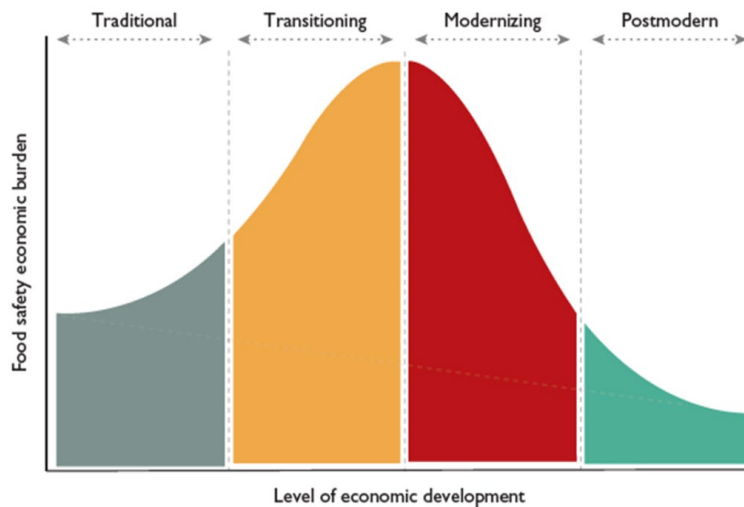
Source: Jaffee et al. 2019, p. 16.

While one may imagine that the economic burden decreases with rising economic development, World Bank data show this not to be the case. As can be seen in Figure 3, the food safety economic burden is at its highest when countries are in a stage of "transitioning" their food safety systems to the point of implementing a "modernized" food safety system, as consumers will be exposed to a wide range of foodborne hazards until the establishment of various food safety controls and the improvement in food safety capacity meets growing and changing needs. This is thought to reflect "evolving food safety challenges, and the degree of mismatch with food safety management capacity in the public and private sectors." (Jaffee et al., 2019). This highlights the need for capacity to keep up with the pace of increasing system-related needs, which is a challenge in itself.

For these countries (those in transitioning stage), diets are rapidly transforming beyond starchy staples toward a wider array of plant and animal source foods. In addition, more foods are consumed in processed form and outside the home. As populations become increasingly urbanized, the distances between food production and consumption tend to increase; and as supply chains elongate, they also tend to involve more processes and intermediaries. (Jaffee et al., 2019).

The "food safety life cycle" model is particularly relevant for India as the country is in the process of modernizing its food safety system. Not only are there challenges with modernizing an overall system, but the sheer scale of doing this for a country of 1.4 billion people, with over 2.5 million registered food businesses and a very large informal sector is immense. In modernizing its food safety system, India is attempting to improve the food safety of businesses operating in the informal food sector as they operate below the level of the national regulatory framework and hence are likely to present greater risk. FSSAI is working on enabling processes to facilitate individual food business operators to improve safety, such as in Clean Street Food Hubs, Blissful Hygienic Offering to God (BHOG) (for temples), and Hygiene Rating. Countrywide deployment in the public-private partnership (PPP) mode would help large deployment of these efforts. A few examples of this attempt are mentioned below:

- Urbanization accentuates the importance of street vendors in supplying food to tens of millions of people. The Clean Street Food Hub (FSSAI, 2020a) initiative emerged as a way of engaging with the informal sector and improving practices. The initiative approaches street food vendors in clusters rather than as individuals and provides vital infrastructure and training. Often in partnership with municipal bodies, the hubs are supplied with electricity for cold chain and heating, running water for hygiene, and waste management facility for disposal. FSSAI is engaging with relevant agencies to have these issues systematically recognized and addressed in urban planning.[1] This approach is not unique and goes back to vendors in Singapore in the 1950s. The mayor of Mandalay in Myanmar is also sensitive to the issue of street food and is developing hubs or food halls in municipal markets, again as an element in urban planning (personal communication). But FSSAI is doing it at scale, encouraging states to increase the number of certified hubs.

- FSSAI is also creating an ecosystem of Food Safety *Mitras*[2] (FSMs) to help food businesses with licensing and registration, training, and auditing hygiene at different places (e.g., school and college campuses). The FSM scheme aims to enable individuals with an entrepreneurial mindset to become certified licensing and registration professionals. This is an attempt to scale up advisory services to the informal (and formal) sector at reduced government cost.[3] It is an example of FSSAI's view of the role of government as catalyst and not as controller.

Although these are some examples of how India is engaging with the informal sector, it also insists on registration with FSSAI before an informal business can engage with the services. There is a small registration fee, but these businesses do not fall under the category of receiving licenses due to their small turnovers. If informal businesses can

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[1] The former Food Safety Commissioner in Goa is now running Urban Planning in Goa, having been one of the pioneers of these hubs.
[2] "Mitra" is Hindi for "Friend." See https://fssai.gov.in/mitra/ for background.
[3] In Nigeria, the Nigerian Institute for Animal Science is considering ways of using its network of 2,000 registered animal scientists to implement a new regulatory framework in the poultry sector, as a cross between extension workers and inspectors. It Is not a parallel to the Mitra idea but is another regulator looking to mobilize an external group and deploy it in the informal sector. (Ongoing unpublished World Bank Group Project.)

grow sufficiently to migrate themselves to the formal sector and survive, the state will receive revenues. Until then, it has an informal sector that operates slightly better and with slightly less risk than before.

While this raises expectations about beginning to manage the informal food sector in LMICs, there is bound to remain an interface with the small and medium enterprises (SMEs) end of the formal sector where formal businesses find it difficult or impossible to compete with the informal businesses that do not carry the same regulatory and tax burdens. Perhaps there is sufficient market differentiation that direct competition is less obvious, such as street traders with trollies, contrasted with food outlets with permanent structures, but there will still be some level of competition for the same market. This issue has not been explored for this paper but is perhaps an aspect of FSSAI innovation that deserves further discussion and elaboration.

3.2 Proactive Promotion of Safe Food, Healthy Diets, and Nutrition

Multiple factors influence consumers' dietary behaviors. These range from factors on a personal level such as knowledge, skills, dietary preferences, and time for food preparation; to sociocultural and/or psychological determinants including cultural background and family food habits; to those that impact at an economic, societal, and/or political level such as the cost or availability of food, policy or regulatory pricing levers and/or incentives, food industry formulations, marketing or regulatory measures, local environment, and commercial pressures.(Branca et al., 2019; Mozaffarian et al., 2018 and Johnson, 2015). The critical point with respect to the multitude of factors that have the potential to influence dietary choices is that, if not coordinated, these factors may all become barriers to "healthy" choices. However, if interventions to address these factors are implemented in a coordinated, policy-driven manner, such interventions may provide an opportunity for governments (and other stakeholders) "to support improvements in diets, health, wellbeing and equity." (Mozaffarian et al., 2018) Figure 4 illustrates the multilayered influences that alter food choices.

Figure 4: Multilayered Influences That Alter Food Choices
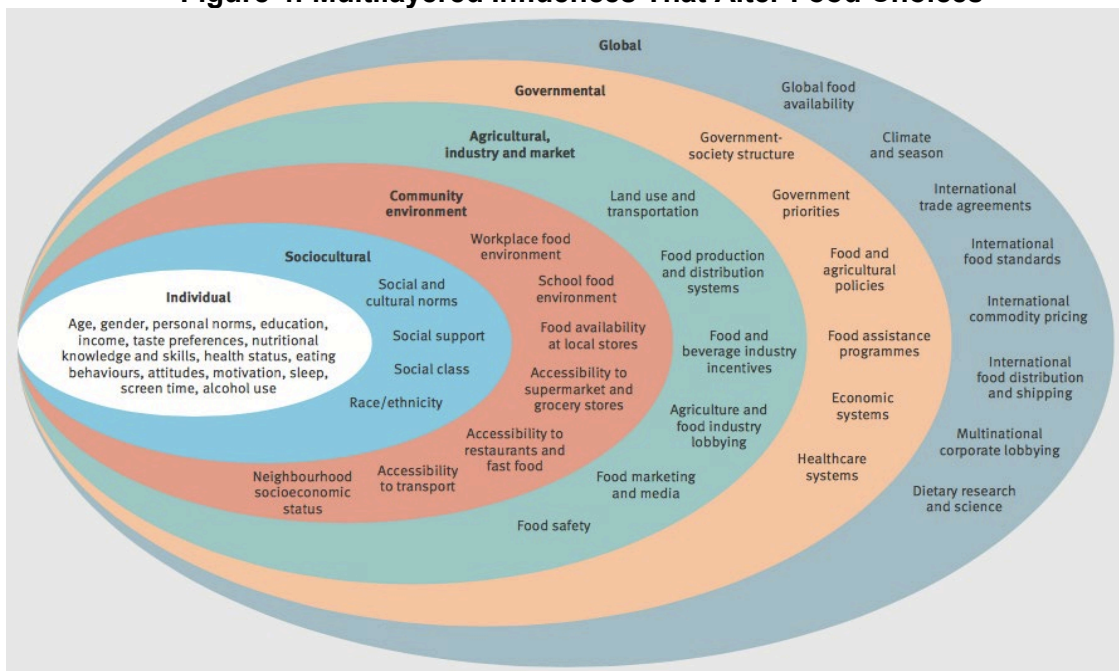
Source: Mozaffarian et al. 2018.

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Within this larger ambit of communication and education, it is important to have a legal framework for a food safety system (as set out in the FAO and WHO models [1997, 2018]), but its value is limited in delivering public goods. A legal framework is necessary for the following:

- To impose sanctions against people who present a real danger and will not otherwise change
- To establish some market rules and create the "level playing field" infrastructure for businesses in the formal sector to operate and compete
- To confer legitimacy on the regulatory regime, which may also have commercial value through rating systems
- To allow government agencies to spend public money–pursuing activities that do not otherwise require legal powers

The legal framework is not necessary to provide the following:

- Guidance to those who want to improve their businesses, including setting aspirational standards
- Voluntary codes of practice from the industry
- Support through extension services or other advisory services
- Raise awareness of various issues relating to hygiene and nutrition among the public
- Generally promote behavior change without coercion

<u>FSSAI and its Eat Right India program:</u> With a rationale to promote safe, healthy, and sustainable diets, FSSAI launched the Eat Right India program in 2018. It developed a wide range of initiatives to reach multiple audiences in a variety of ways (Kathuria et al., 2020).This is in line with the global thinking that public health issues including those associated with food are multifactorial, with any interventions having the ability to induce effects "within complex webs of interactions" (Mozaffarian et al. 2018). Conversely, "no single intervention can tackle the complexities of the current food system, and different approaches can be complementary and synergistic" (Mozaffarian et al. 2018). It is essential to have strong government leadership to deliver a "comprehensive, sustained multitarget and multilevel approach." (Mozaffarian et al. 2018).

In the countries examined, the initiatives to promote nutrition and public health include evidence-based dietary guidelines, visual tools such as food guides indicating proportions of food groups to consume daily, and a range of written materials. Campaigns also exist, but these tend to be directed at particular target groups on specific nutrition issues or as broad nutrition materials for specific target groups such as schools, infants, or the elderly. None of the countries examined have a dedicated program on the scale of Eat Right India, by either the food regulators or the nutrition/health promotion functions within the health and agriculture portfolios. To ensure healthy diets, FSSAI has mandated a reduced limit of industrially produced trans fats, to no more than 2 percent, to make the country free from industrially produced trans fats by 2022. To achieve the target, the regulator works closely with both the industry to identify and implement the ways and mechanisms to reduce the use of industrial trans fats in processed foods; simultaneously on the consumer end, it is sensitizing the general public about the sources and ill effects of trans fats through the Eat Right India program.

In addition, it appears that among the countries examined, the focus on "environment" relative to food and health is not incorporated in either the food regulatory space or the public health nutrition space. In terms of food regulation, there are examples of regulating materials such as plastics, but this is in the context of "food contact materials," where the issue is to protect food safety—that is, the potential for toxic substances to leach into food, as opposed to managing the environment with respect to impacts associated with food, such as the use of plastics. There have been various ongoing efforts in India, under the Eat Right India program, to engage industry on the issue of plastic in food packaging. It is encouraging to note that 24 food businesses have signed a pledge on becoming "Plastic Waste Neutral" by collecting, processing, and recycling 100 percent postconsumer plastic waste across sources. Furthermore, 21 companies have committed themselves to reduce the levels of virgin plastic in the food and beverage sector. Also, the draft regulation on recycling of postconsumer polyethylene terephthalate (PET) for food contact applications and acceptance criteria (FSSAI, 2022c) for recycled PET resin is now in place. FSSAI is also simultaneously working toward creating various platforms to disseminate engaging content in partnership with various stakeholders to nudge citizens on this issue. This includes creating networks of professionals in food and nutrition (NetProFaN) as well as large-scale outreach activities to engage citizens. Many other such interventions have been utilized so far to create traction in disseminating the "eat right" message.

Some examples from the world where the issue of legal remits of regulatory agencies gives rise to a debate on whether "protect" or "prevent" can include "promote" are also discussed under this section. The history of food safety legislation prior to 1997 was to stop unsafe food, originally through stopping adulteration. But closing down a bad food business does not create a good food business. Prevention has been the norm for legal remits since after 1997, including the Food Safety Modernization Act 2012 in the United States and the Chinese Food Safety Law 2014. Prevention fits well with a risk approach and it is forward-looking, further FSSAI's remit "to ensure safe and wholesome food," is now being applied in a very proactive way.

Although New Zealand supports regulatory stewardship and the United Kingdom's Food Standards Agency (FSA) has a broad remit to manage food risk, other regulators are more constrained:

- The Canadian Food Inspection Agency (CFIA) says on its website (Government of Canada, 2022a) that "Mitigating risks to food safety is the CFIA's highest priority," but its actual legal remit is far more mundane: "The Agency is responsible for the administration and enforcement [of a list of laws]" (Government of Canada, 2022b). However, the preamble to the Canadian Food Inspection Agency Act says that establishing a single food safety agency will "facilitate a more uniform and consistent approach to safety and quality standards and risk-based inspection systems.

- The US FDA states as its mission "ensuring the safety of our nation's food supply" (USFDA, 2018). This is similar to FSSAI's "ensure safe and wholesome food," but it could possibly be argued that the US FDA mission is slightly more proactive in that it does refer to "food supply." Ensuring that "food is safe" in the present is slightly narrower and arguably not as proactive as "ensuring the supply of safe food," which has a broader and a future-oriented outlook. But, to support FSSAI, a simple reference to "ensure safe food" could also be taken as ensuring future supply of safe food.

- The remit of the Netherlands Food and Consumer Product Safety Authority (NVWA) is "to safeguard human and animal health and welfare." (NVWA, 2019) That could be taken quite broadly (Box 4).

<div style="border:1px solid #2a6099; background:#dbe7f3; padding:1em;">

Box 4: "Regulatory Stewardship" in New Zealand

A wider remit for all regulatory agencies has been set in New Zealand under the concept of "Regulatory Stewardship." This has applied to all regulatory agencies since 2013 and is a duty to look out for the interests of the sector it regulates and, if appropriate, propose changes to the regulatory framework—that is, the regulators' remits are not bound just by current laws but by the interests of the sector, which will include emergent risks.

</div>

Source: The Treasury, New Zealand Government, December 2020

- One of the tenets is also that consumer demand for safe, healthy, and sustainable foods can drive the industry to produce such foods. While in theory it makes sense to have consumers drive a bottom-up demand-driven approach, this does not always play out as such. As noted in Swinburn et al. (2015), the food industry has significant power to shape consumer demand by "promoting highly palatable, affordable, and readily accessible food products". In any intervention that relies on both a wave of bottom-up consumer demand as well as the power of individual choice, factors such as this need to be considered. Consistent with this, Sharma, Teret, and Brownell (2010) recognize both the opportunities and the risks of industry self-regulation, noting industry "may be self-serving and deceptive, stall needed government action, and protect business as usual." To counter against factors such as these, it proposes following standards for self-regulation: (i) transparent self-regulatory standards created by a combination of scientists (not paid by industry) and representatives of leading nongovernmental organizations, parties involved in global governance (e.g., World Health Organization, United Nations Food and Agriculture Organization), and industry. No one party will be given disproportionate power or voting authority; (ii) specific codes of acceptable behaviors based on scientifically justified criteria; (iii) mandatory public reporting of adherence to codes, including progress toward achievement of full compliance with pledges and attainment of key benchmarks. Objective evaluation of self-regulatory benchmarks by credible outside groups and periodic assessments/audits to determine compliance and outcomes; and (iv) possible oversight by an appropriate global regulatory or health body (e.g., World Health Organization).

With sustainability and nutrition becoming more integrated in the business strategy, models have emerged where market leaders through voluntary efforts are positively influencing consumer food choices. Swinburn et al. (2015) and Sharma, Teret, and Brownell (2010) note opportunities and risks of industry self-regulation and indeed propose accountability mechanisms, while Hope et al. (2015) argue that although Australian regulators have sought collaborations with food companies, such approaches may fail because "corporations and actors within corporations are legally required to focus on the interests of the company, including profitability. The goal of providing sustainable, healthy foods is not necessarily going to align with legal requirements related to growing profitability." Even more stridently, the European Public Health

Alliance (2016) argues "evidence consistently shows that self-regulation fails to deliver benefits for public health," noting several key findings from a range of academic papers, explaining why this is the case. The reasons for this include that voluntary commitments are not based on the best evidence for improving public health; a lack of enforcement means commitments can be broken without consequence; all actors may not participate, weakening the potential impact of the regulatory measure; voluntary measures usually include actions that would have occurred anyway but with limited impact; and voluntary measures are usually vague with implementation being difficult to monitor.

Conversely, consumers can maintain a reforming position against the industry, with appropriate leadership. The United Kingdom's Food Standards Agency (FSA) ran a campaign against high salt levels in processed food starting in 2004 (Griffith et al., 2017). This was sustained over a period of years and generated strong opposition from the industry. Industry spokespersons complained that they were being forced to make expensive alterations to processing by the actions of a government agency, which was outside its remit because there was no legal limit to salt levels in food. There was no law to enforce. Had there been a law, they argued, they could have lobbied to prevent it during its passage through Parliament. The result was that salt levels have been significantly reduced and heart disease figures related to salt have improved in the United Kingdom.

There are other cases of state regulators leading campaigns to shape markets through consumer support. The most dramatic is the Brazilian technical regulator, Inmetro, which certifies products with its safety logo if they pass conformity assessment testing. That logo is trusted by Brazilian consumers and strongly influences their buying choices. Inmetro had a slot on Sunday evening television, which tested household products and rated them for safety. The results would be reflected in the market within a week. This led to other ministries working with Inmetro to promote their policies, such as the Environment Ministry promoting energy-efficient products, the Transport Ministry promoting crash helmets, and the Health Ministry promoting condoms.

This section deliberated on the question of how much to regulate or, rather, when there may be opportunities for coregulation or self-regulation, how best can food safety or nutrition issues be managed. This debate links largely to the question of whether the responsibility for food choices that affect health lies with the government in its leadership and governance role, with industry that produces the food, or with the consumer who purchases and consumes the food. For mechanisms such as coregulation or self-regulation, a trusted partnership needs to be established between government and the industry for such mechanisms to be successful. Swinburn et al. (2015) stated that "hard approaches involve government regulatory and fiscal interventions, whereas soft approaches involve educational and industry voluntary codes." It also said that "for true partnerships to be successful, goals and principles should be aligned, and a clear understanding of who is accountable to whom, for what, why, by when, and what the sanctions are for non-compliance or poor performance" (Swinburne et al., 2015). Thus, self-regulation by industry effectively involves setting up very strong accountability mechanisms between key actors, recognizing strong performance, and having the ability to deal with noncompliance issues. While in theory it makes sense to have consumers drive a bottom-up demand-driven approach, this does not always play out as such.

3.3 Leadership during the COVID-19 Pandemic

The coronavirus disease 2019 (COVID-19) pandemic presented an exceptional and unprecedented challenge for food safety control systems and authorities around the

world to continue with their routine functions in accordance with national regulations and international recommendations. The complex situation affected public health and environmental, economic, social, and other systems. Given the complex and interconnected nature of these systems, holistic and systemic approaches were required to respond effectively. As seen globally, FSSAI also responded by providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid response efforts.

As in other countries, authority staff were largely working from home, visual inspections were contained, and there was a need to maintain routine activities such as the inspection of food business operations, certifying exports, control of imported foods, monitoring and surveillance of the safety of the food supply chain, sampling and analysis of food, managing food incidents, providing advice on food safety and food regulations for the food industry, and communicating on food safety issues with the public. Further, the pandemic also exposed the vulnerabilities in the food system, impacting both production and supply. Lockdowns and containment measures caused closure of restaurants, schools, hotels, and shopping places, while the demand for food from food businesses faced a collapse.

To respond to these challenges, FSSAI leveraged its existing platforms and channels to amplify its actions to ensure safe and wholesome food for all. These included the following:

- *Development of technical resources, online capacity-building sessions, and updated regulations and notifications in response to COVID-19.* During 2020, FSSAI released 19 notifications and 16 draft amendment regulations to respond proactively during the pandemic situation. COVID-19-specific guidelines for food handlers were released in collaboration with the Indian Dietetic Association (IDA). Draft guidelines for safe reopening of school canteens/cafeterias were also released during this period. Further, a cloud-based online portal called Food Safety Compliance System (FoSCoS) was launched that replaced the existing Food Licensing and Registration System in the states/UTs. FoSCoS served as a one point stop for all engagement of food business operators (FBOs) for all sorts of regulatory compliance transactions including online licensing. This proved to be beneficial during lockdown periods as it facilitated uninterrupted communication between food businesses and the food regulator. For continuous training of food handlers, FSSAI started online Food Safety Training and Certification (FoSTaC) of food handlers to ensure safety of food not only while cooking but also while delivering during lockdowns.

- *Awareness-generation activities:* Key messages pertaining to food safety and personal hygiene were disseminated in the form of small videos through various communication channels. Renowned technical experts in the field of food safety and nutrition including doctors, nutritionists, dieticians, chefs, and sports personnel helped spread the message to all. Further, an additional module on awareness was made mandatory as part of the FoSTaC training. A detailed guidance note on "Food Hygiene and Safety Guidelines for Food Businesses during Coronavirus Disease (COVID-19) Pandemic" was released in addition to a e-handbook on "Eat Right during COVID-19" for citizens, that highlighted safe food practices to be followed diligently and included tips on health and nutrition. A separate web page was created for COVID-19 to serve as a knowledge hub for food businesses (FSSAI, 2020c). This is seen as a one-stop platform for businesses to get recent updates on guidelines, standards, and advisories pertaining to food safety during the pandemic situation.

- *Engaging with state food safety departments:* This was primarily done to communicate the emerging priorities in food safety landscape; expedite work related to licensing on the online portal; establish a licensing helpline in each state with a dedicated number and e-mail id; create a robust complaint-handling mechanism; conduct only essential inspections, etc. Several advisories were also released during this period to provide ease for businesses. FSSAI also provided rapid handheld kits/devices to states/UTs across the country to make food testing easier, faster, and cost-effective, especially during a pandemic situation. Further, import clearances of food items and national food testing laboratories were declared essential services. Food imports were expedited through provisional clearance of certain food items.

While there is enough scientific evidence that the COVID-19 virus is not transmitted by food, it has tremendous public health implications; therefore food safety remains critical in developing coping strategies for COVID-19. The impact of the virus is still unfolding, lessons are emerging, markets are volatile, and there is a constant need to keep abreast with global and national developments for evidence-based decision making. FSSAI has shown leadership and continues to do so as the apex body for ensuring safety of food at all times and to all citizens.

PART IV – CONCLUSION AND DISCUSSION POINTS FOR FURTHER CONSIDERATION

The paper agrees that the FSSAI approach is an encouragement to LMICs to develop their own solutions to their own mix of problems, rather than implement a solution constructed for highly developed economies. It also highlights the importance of maintaining a strong regulatory framework, whatever the stage of economic development. Even if there is a huge informal sector, there will still be a formal sector that needs a regulatory infrastructure for food businesses to operate in.

Tackling these new problems requires a reassessment of the role of government and the role of regulation. A regulatory framework is a necessary but insufficient government response to the problem. Proactive promotion of good practice of large numbers of people is needed, rather than reducing the bad practice of relatively small numbers. Prevention has taken over from policing, but proactive promotion of good practice has not yet been established as the new practice.

Whether regulators are best or well placed to take on wider roles may vary according to the country and its system of public administration, but it may not be inappropriate per se for regulators to have that expanded role. The example of the salt campaign by the FSA shows that regulators can act beyond exercising legal powers and deliver regulatory outcomes through campaigning with consumers. In India's case, as mentioned earlier, FSSAI's Eat Right India complements the efforts of nutrition programs implemented by other departments, including their behavior change communication (BCC) interventions.

Whether FSSAI's approach should be the new paradigm is too early to say. While it is early to evaluate its impact, it will be important to do so in due course. India is also a particularly difficult case in terms of testing a new paradigm. If FSSAI's techniques worked for 100 million people, then applying them in most countries may be the correct way forward, but in India, less than 10 percent of the population would have been affected.

The paper has highlighted several issues for deeper consideration and investigation. The following section outlines these and poses points and questions that merit further discussion.

4.1 Discussion Points for Further Consideration

Bearing in mind the recommendations of the EAT-Lancet Commission on Food, Planet, Health; changing eating habits and the rise of NCDs as a result of development, urbanization, and globalization; and the broad approach being taken by FSSAI, is there merit for both India and countries globally in considering a broader "food systems" approach, incorporating the functions of "food safety regulation," "public health nutrition promotion," and "food and the environment" through the following:
- a single government agency
- a single regulatory/policy system
- a formally coordinated joint approach

If an integrated food system approach were taken:

- What benefits could arise from this and what challenges (legislative, policy, regulatory, political, governance) would need to be considered?
- How might this vary in terms of the stage of development of the country in question?

Given the scale of the challenge of regulating the food system in India, with a population of 1.4 billion people and with a significant informal food-related economy, how does FSSAI and the Indian government balance the various available regulatory mechanisms (full regulation to self-regulation—which have their advantages and disadvantages as outlined in this paper), to ensure a safe, nutritious, and sustainable food supply, while working within the bounds of their budgets?

Is FSSAI demonstrating a viable way of managing/"regulating" the common phenomenon in LMICs of a large informal food sector? Is it effective to provide for a hybrid level of regulatory formality where small businesses are given state recognition and support for one activity or sector, but remain in the informal sector for other regulatory regimes, including tax? What is the impact on similar businesses in the formal sector?

How can a "systems leadership" approach be leveraged effectively to assist FSSAI and the Indian government to tackle the challenges associated with scale and complexity of the Indian food system?

Are there partnership approaches that could be implemented to leverage expertise and resources from the broader region, or globally, to assist FSSAI and the government of India in tackling the challenges associated with the scale and complexity of the Indian food system? If so, how and by whom could this be enacted?

What expanded role can FSSAI play in leveraging local actors and initiatives, such as local governments, schools, workplace, local media, and local champions that could have much greater influence on day-to-day consumer choices and health concerns?

By positioning India as a leader in the region, does Eat Right India provide a menu of interventions that other countries can choose from or are there interdependencies between different interventions, or is there even a need for this entire package of interventions?

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Annex 1: Snapshot of Food Regulatory Systems from the Developed World compared to WHO 2018 Elements

	Australia/New Zealand	Canada	United States	European Union
Policy and Legal Frameworks	Policy is set and food standards are approved by the Australia and New Zealand Ministerial Forum on Food Regulation, which includes ministers from all Australian States and Territories, as well ministers from the Australian and New Zealand federal governments. The forum is supported by senior officials from each jurisdiction. Food Standards Australia New Zealand (FSANZ) is a statutory authority operating under the *Food Standards Australia New Zealand Act 1991,* which develops food standards for Australia and New Zealand. The *Australia New Zealand Food Standards Code* sets legal requirements for the labeling, composition, safety, handling, and primary production and	Food safety is a shared responsibility both vertically and horizontally with responsibilities across federal, provincial, and municipal authorities as well as three key agencies at the federal level. The *Food and Drug Act* provides the overarching legislation while the *Safe Food for Canadians Regulations* provide the specific legal framework for food safety and the creation of the Canadian Food Inspection Agency (CFIA). Canada's food-related policy and regulations are all underpinned by the Codex Risk Analysis framework. Health Canada (HC) sets food standards, undertaking risk assessment, and CFIA enforces food laws and regulation.	The Department of Agriculture (USDA) and the Food and Drug Administration (FDA) share primary responsibility for overseeing the safety of the US food supply. In addition, all states have their own laws, regulations, and agencies dedicated to food safety. The Centers for Disease Control and Prevention (CDC) is mainly responsible for investigating local and nationwide outbreaks of foodborne illnesses. The FDA *Food Safety Modernization Act* implemented at the federal level, provides a strong shift toward preventive controls. States typically adopt regulations consistent with the federal food safety laws and regulations. The USDA is authorized	The EU regulatory system covers the third-largest population of consumers after China and India. It regulates 28 member states through regulations that are "directly applicable," i.e., they have full legal effect in each country without any further intervention by these countries' governments. Indeed, member state governments are not allowed to alter any of the terms of the regulations. The system was based on the FAO/WHO model of 1997 and began with the General Food Law of 2002, Regulation (EC) no. 178/2002, which established a food regulatory system based on risk assessment and management across the full food chain "from farm to fork." It has always covered feed as well as food but does not regulate issues relating

	processing of food in Australia. Under an intergovernmental agreement (1991) between the Commonwealth and states and territories, the states and territories adopt, without variation, food standards once they have been gazetted. A treaty between Australia and New Zealand gives effect to New Zealand's participation in the system and further specifies the role of FSANZ in relation to New Zealand. There is a joint food setting system between Australia and New Zealand, which aims to harmonize food standards between the two countries, but this does not cover some areas of food regulation, such as maximum residue limits and food hygiene provisions. Standards are enforced by state and territory departments, agencies, and local councils in		via *the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act,* and *the Humane Methods of Livestock Slaughter Act.*	to nutrition. It embeds risk analysis, the precautionary principle, and transparency as foundations of the system. The system has been renewed and extended on various occasions, to keep the system relevant to changing circumstances. For such a highly developed system, it is surprisingly dynamic. It was originally a market-based measure because of the nature of the EU, whose aim it was to regulate the market in food products through harmonizing legal provisions across the union while ensuring a high level of human life and sconsumers' interests. The market basis has also given it external competence to regulate EU trade in food products, effectively extending its regulatory system to foreign markets, which want to trade with the EU.

	Australia; the Ministry for Primary Industries (MPI) in New Zealand; and the Australian Department of Agriculture and Water Resources for food imported into Australia.			
Incident and Emergency Response	SANZ coordinates and monitors food recalls in Australia and in New Zealand; they are coordinated by the Ministry of Primary Industries. If a recall is required, the states/territory authorities order that; however, most recalls are initiated by food businesses. Larger-scale incident response mechanisms are undertaken through a partnership approach under a National Food Incident Response Protocol. For imported food, the Imported Food Control Act 1992 has emergency powers to enable the implicated food to be made a temporary risk food and referred for inspection at the rate of 100% of consignments—	CFIA initiates food recalls with the industry and investigates foodborne illness outbreaks. Provincial governments lead outbreak investigations. One example of a partnership among federal, provincial, and territorial governments is the Foodborne Illness Outbreak Response Protocol, which provides an integrated approach in response to national and regional foodborne illness outbreaks, causing high levels of severe morbidity or mortality. At the federal level, the Public Health Agency of Canada (PHAC), HC, and CFIA have legal responsibilities for responding to foodborne illness–related events.	FDA has the authority to issue a mandatory recall when a company fails to voluntarily recall unsafe food, and it can suspend businesses from registration if safety issues pose serious adverse effects. The Food Emergency Response Network is a cooperative network of food safety testing laboratories across all levels of government, set up to enable a coordinated response to food safety emergencies.	Traceability is another important building block of the EU system and has always been a part of the regulatory system. It is vital for recall and incident management. The emphasis on traceability is also partly attributable to the market origins of the EU system since it is such an important market mechanism. This is supported by the Rapid Alert System for Food and Feed (RASFF), which gathers and disseminates information on food hazards across the EU. It has a portal available to the public and can also be accessed by importing countries. It helps to manage incident response at an international level as well as within the EU market.

	effectively preventing the import of known unsafe food. Each state and territory's government has systems in place for recording and monitoring instances of foodborne illness. At a national level, this is monitored for possible foodborne illness outbreaks by OzFoodNet within the Department of Health. FSANZ has a role in monitoring international food safety incidents and, where appropriate, relaying information to Australian state and territory authorities when Australia's food supply may be affected.	The protocol ensures that all responsible agencies are notified promptly and work collaboratively to mitigate and contain risks.		
Risk-Based Inspection and Enforcement	A risk-based approach is implemented by all responsible state/territory jurisdictions, where there is a graduated approach to enforcement measures. In New Zealand, Ministry for Primary Industries (MPI) audits and	CFIA ensures industry compliance through inspection and compliance verification of food producers. CFIA provides training programs across Canada to ensure key technical competencies for CFIA employees. Provincial governments	Food Safety Modernizing Act (FSMA) allows FDA to use risk-based prioritization to target most serious foodborne health hazards and food facilities in both domestic and foreign countries. Importers have explicit responsibility to verify that their foreign	Although there is a single regulatory system for 28 member states, implementation is not uniform or very consistent, despite the efforts of the EU Commission. It is unusual in the extent to which a regulatory system covers

	monitors New Zealand's food safety system and enforces food safety requirements, including approval of food safety management plans for businesses.	regulate food processing within their jurisdictions. Local/regional public health authorities undertake food inspections of food establishments.	suppliers have adequate prevention controls in place to ensure the food they produce is safe. FDA-qualified third parties can certify that foreign food facilities comply with US food safety standards; for high-risk imported foods, there may be a requirement for third-party certification of meeting requirements. In addition, FDA is authorized to rely on inspections from other federal, state, and local agencies to meet its increased inspection responsibilities. USDA inspects all meat, poultry, and egg products sold in interstate commerce, and reinspects imported meat, poultry, and egg products to make sure they meet US safety standards.	implementation (foreseeing inherent problems in consistent implementation). Central to implementation is the concept of "official controls," exercised by "competent authorities." Each member state has a Central Competent Authority but may have a large number of Competent Authorities depending on their systems of government. This makes the EU system and its practice a useful comparator and model for very large populations, such as China and India, where a single system is implemented through multiple authorities. Risk is at the basis of inspection and enforcement, and expressly built into the regulations. But it is supported by an institutional infrastructure and tools that provide risk analysis to a high standard, which can cascade down to ground-level

				enforcement. The system also enforces against the enforcers. The Food and Veterinary Office (FVO) carries out inspections of the exercise of official controls throughout the EU and also provides detailed assessments of the level of compatibility of foreign food safety systems with the EU system.
Information Underpinning Evidence	FSANZ as well as other government agencies in Australia and New Zealand monitor the food supply. FSANZ routinely conducts targeted surveys and total diet studies to collect analytical data on the levels of contaminants and nutrients. In Australia, food safety testing is undertaken by accredited government and nongovernment laboratories. In New Zealand, MPI needs to approve all food safety testing laboratories, and they must use approved methods, validated	The PHAC conducts public health surveillance. The CFIA has a network of laboratories providing routine analytical services, research, methods development, accreditation, and scientific advice in support of food safety, animal health, and plant protection.	FSMA requires food testing to be done by accredited laboratories with FDA having a program for laboratory accreditation to ensure that US food testing laboratories meet high quality standards. The CDC gathers data on foodborne illnesses, investigates foodborne illnesses and outbreaks, and monitors the effectiveness of efforts in reducing foodborne illnesses.	Because of the express risk basis for the whole regulatory system, an infrastructure has been built, which supports risk assessment and risk management. The leading institution is the European Food Safety Authority (EFSA), which has built an international reputation for strong science, contributing to standard-setting. It is a key part of the dynamism of the EU system whereby it regularly issues regulations resulting from food safety research, e.g., minimum residue levels of certain

	according to international protocols. In New Zealand MPI conducts food monitoring programs for food both domestically produced and imported foods.			contaminants. Its research finds better ways of assessing old problems, e.g., through whole genome sequencing, as well as assessing new developments, e.g., lab-grown "meat." It is supported by a network of reference laboratories spread across the member states. It is also supported by 10 independent scientific panels and committees, drawn from across the EU, which carry out assessments and develop assessment methodologies. It also has scientific networks (see next).
Communications and Education	Generally speaking, Information, Education, and Communication material is provided purely to support food standards within the context of "protecting public health and safety." Broad food safety and nutrition promotion is not undertaken to "promote	Health Canada provides advice and information on food safety and provides and promotes nutritional health. Provincial governments implement food safety programs, and local public health authorities communicate food safety messages to the public.	The USDA Food Safety Inspection Service provides an extensive range of downloadable food safety information. FDA has a Strategic Plan on Risk Communication. Collaboration: Formal collaboration is	Under the FAO/WHO 1997 model, one of the three legs of Risk Analysis is Risk Communication; therefore, that is expressly covered in the EU regulatory system. EFSA takes the lead in this area and has a Communications Experts Network, which

	public health."	An example of a government-industry collaboration includes development and maintenance of food safety programs along the food chain for food safety, quality, and traceability throughout the total food chain. An example of government and academic collaboration is the existence of expert advisory committees to assist in scientific advisory.	established with other government agencies, both domestic and international.	manages risk communication, including crisis management.
	Examples of documents provided to give transparency and to communicate approaches are New Zealand MPI's Risk Management Framework and Food Standards Australia New Zealand's Science Strategy.		Capacity-building: FSMA provides for capacity-building both domestically and for foreign agencies to better meet requirements.	EFSA also produces many factsheets, infographics, and videos, as well as arcane scientific articles, to engage with a wider audience.
		Collaboration: A collaboration and partnership approach is a critical component of the Canadian food safety system, with other governments, industry, and consumers. Note the partnership approach in incident management outlined above.		

Annex 2: Snapshot of Dietary/Nutrition Guidance and Promotion Activities

	Australia	New Zealand	Canada	United States	European Union
Overall responsibility and coordination	Within the Commonwealth Department of Health lies the national leadership and coordination role in the promotion of healthy eating to all Australians. State and territory governments also undertake a similar role from a jurisdictional perspective but typically use materials available at the national level. The Australian government's nutrition promotion efforts fall within a broad program, "*Eat for Health.*" The program includes key tools that have been developed for use across Australia by health professionals, industry, and consumers. Tools include a range of information and educational material on "eating well," including nutrition and food safety information. Two of the key tools that underpin much of the other nutrition promotion activities are the Australian Dietary Guidelines and the Healthy Food Guide.	The New Zealand Ministry of Health (MoH) provides evidence-based guideline materials for health professionals and resources for the public.	the Office of Nutrition Policy and the Food Directorate have key roles. The Office of Nutrition Policy and Promotion, the focal point for public health nutrition, leads efforts to support healthy eating, whereas the Food Directorate is the federal health authority responsible for assessing health risks and benefits, setting standards, policies, and regulations, and providing advice and information regarding the safety and nutritional quality of food.	The Department of Health and Human Services (HHS) and the Department of Agriculture are jointly responsible for nutrition, food, and related health initiatives.	Directorate General for Health and Food Safety (DG SANTE)
Policies/Partnerships	The last Food and Nutrition Policy in Australia was	New Zealand has a National	Health Canada administers	Not available	While the EU had a *Strategy for Europe on*

	launched in 1992; there are currently calls for a new policy. The Healthy Food Partnership is a collaborative/partnership mechanism that forms part of a broader Australian Government Nutrition Framework for "collective, voluntary action between the government, the public health sector and the food industry" and supports and encourages Australians to eat well and live healthier lives. Note: the Food Standards Australia New Zealand is a member of the Healthy Food Partnership Executive Committee.	Healthy Food and Drink Policy that is designed to assist health sector organizations in promoting healthy food environments in public and workplaces.	Canada's Healthy Eating Strategy.		*Nutrition, Overweight and Obesity Related Health Issues*, this was published in 2007. Currently there is a partnership-based *Platform for Action on Diet, Physical Activity and Health,* which was launched in 2005, which appears to be active. It involves food business operators, public health nongovernmental organizations (NGOs), consumer organizations, and scientific and professional associations. Some of the specific activities include establishment of a database of nutritional characteristics of foods, a study on food advertising to children, a tool to help schools draft better school catering contracts and workshops on food reformulation and food taxes. One initiative is to "support Member States in a three-step approach: i) asking

					Member States about their priorities for reducing non-communicable diseases; ii) collecting validated best practices in those areas, and iii) making support available for countries to roll out those practices." The primary interest of DG SANTE in nutrition is in its interface with more mainstream food safety, i.e., nutritional claims in advertising and nutritional labeling.
Dietary Guidelines	The *Australian Dietary Guidelines,* which have information about the "types and amounts of foods, food groups and dietary patterns that aim to: • promote health and well-being; • reduce the risk of diet-related conditions, such as high cholesterol, high blood pressure, and obesity; and • reduce the risk of chronic diseases such as type 2 diabetes,	The MoH provides Nutrition Guidelines targeted for significant stages of the life cycle.	Health Canada is responsible for Canada's Dietary Guidelines, which promote healthy eating and overall nutritional well-being, and support improvements to the Canadian food environment. "The Canadian food environment" includes "aspects of the social and physical environment that affect the types of food available, the	The *Dietary Guidelines for Americans 2015–2020* is a document jointly released by the Department of Health and Human Services and the Department of Agriculture. The guidelines are designed for "professionals to help all individuals ages 2 years and	Individual member states develop their own guidance. For example, the UK government (specifically Public Health England) has produced its own "*Government Dietary Recommendations*" and "*Eat Well Guide,*" with supporting materials.

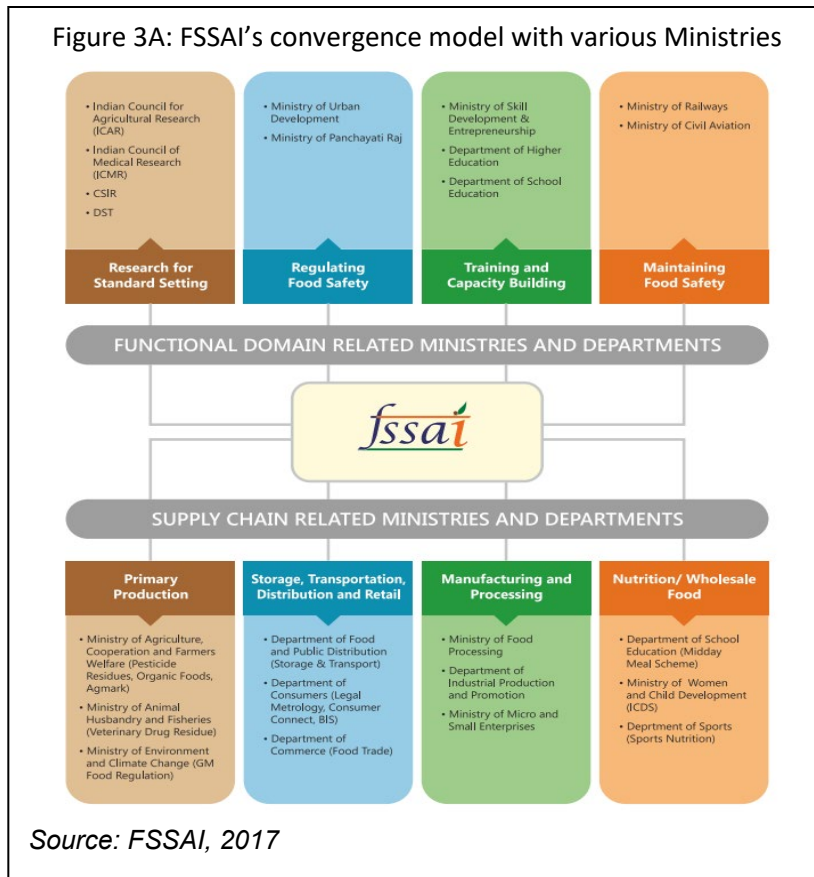|					
	cardiovascular disease and some types of cancers." The Dietary Guidelines are a tool developed by the National Health and Medical Research Council, with the Australian Commonwealth Health portfolio. They are based on scientific evidence and their development is a result of input from prominent scientists and consultation with relevant stakeholders.		accessibility of food, and the nutrition information that people are exposed to, including food marketing. All these aspects of the food environment can influence food choices." The intended audience for the guidelines are health professionals and policy makers so they can be a resource for developing nutrition policies, programs, and educational resources for members of the Canadian population two years of age and older. Canada's Dietary Guidelines were released in conjunction with Canada's Food Guide outlined below.	older and their families consume a healthy, nutritionally adequate diet and the information is used in developing federal food, nutrition, and health policies and programs. It also is the basis for federal nutrition education materials designed for the public and for the nutrition education components of HHS and USDA food programs."	
Food guide and related materials; other awareness-	*The Australian Guide to Healthy Eating* is a visual representation of the	A range of resources are available to	Under Canada's Health Eating Strategy, there are	To support the *Dietary Guidelines*, there	UK government (specifically Public Health England) has

raising/educational initiatives or campaigns	proportion of the five food groups recommended for consumption each day. The *Health Star Rating System* was developed by the Australian, state, and territory governments, in collaboration with industry, public health, and consumer groups. The Health Star Rating Calculator was developed in consultation with Food Standards Australia New Zealand and other technical and nutritional experts. It is a voluntary front-of-pack labeling system that rates the overall nutritional profile of packaged food and assigns it a rating from ½ star to 5 stars with the intent to provide an easy way to compare similar packaged foods. The more stars, the healthier the choice. The system commenced in 2014. If the health star rating system is used, it triggers various regulatory (nutrition labeling) requirements.	support the guidelines. The "Four Food Groups" are promoted with supporting materials, but without a visual guide.	tools, information, and education materials. This includes Canada's Food Guide, a visual representation of recommendations on the proportion of food choices on a daily basis. It also includes information about nutrition labeling.	is also a set of resources called "*MyPlate*," which provides both a visual representation of the proportion of food types to include on a plate, as well as other information and education resources.	produced the "*Eat Well Guide*," with supporting materials.

Annex 3: Convergence with Other Stakeholders on Issues related to Food Safety and Nutrition

Over a period of time, FSSAI has identified key stakeholders and has adopted a collaborative approach to address the interlinked aspects of food safety and healthy, nutritious, and sustainable diets. Given that mandates of most of the ministries/departments relate to food in one way or another, there is enhanced focus on adopting a "*whole government approach*." Figure 3A provides a schematic of various ministries/departments and research institutes that have collaborated in some way to complete the cycle of this food systems approach.

To limit residues of pesticides, veterinary drugs and antibiotics, heavy metals, and aflatoxin in food, intervention is required at the primary production stage itself. Since, primary production is outside the remit of the food authority, involving the *Ministry of Agriculture Cooperation and Farmer's Welfare, and the Ministry of Animal Husbandry, Dairying and Fisheries* is identified as an important stakeholder to promote good practices for agriculture, dairying, poultry, and aquaculture. Similarly, synergies with ongoing flagship programs have been leveraged— for instance, special cleanliness drives in fruit and vegetable markets and street food vending areas in cities/towns could be taken up jointly under the *Swachh Bharat Abhiyan.* Under *Ayushman Bharat,* as a part of a preventive and promotive health care strategy, frontline health workers in the health and wellness centers could be trained on food safety and nutrition. For this, FSSAI has already developed the "Eat Right Toolkit" and online courses. Promotion of fortified staples in safety net programs like Integrated Child Development Services, Mid Day Meal, and Public Distribution System is already part of the government's stated policy. This could be accelerated under Eat Right India. *Jal Shakti Abhiyan* could have a special focus on potable water supply in petty food vendor clusters in places such as street food hubs and vegetable, fruit, and meat markets. Recognizing these synergies and enabling cross-departmental collaboration would ensure a coherent approach to the food system.

Figure 3A: FSSAI's convergence model with various Ministries

Source: FSSAI, 2017

The paper discusses in brief India's food regulatory system in the context of modernized frameworks and examples of well-developed and mature regulatory systems from five selected developed countries (Australia, New Zealand, Canada, the United States, and the European Union). India's food regulator, the Food Safety and Standards Authority of India (FSSAI), established in 2008, has developed a modernized regulatory system that aligns well with the most recent food safety regulatory systems model of the World Health Organization (WHO) (2018). As it continues to strengthen the regulatory system to enhance food safety, FSSAI is applying innovative approaches to address the country's unique challenges of food safety, public health, and sustainable diets. The paper discusses two of FSSAI's innovations: (i) approaches to enhance the safety of food businesses operating in India's huge informal food sector; and (ii) proactive direct engagement with consumers at scale to promote safe, nutritious, healthy, and sustainable diets by influencing behavior change, thus contributing to improvements in public health, nutrition, and environmental sustainability. The paper also describes FSSAI's regulatory leadership during the COVID-19 pandemic to promote food safety. The paper concludes that the approaches and innovations adopted by FSSAI appear promising and there are lessons that could be adopted and adapted by other low- and middle-income countries (LMICs). These approaches have not yet been evaluated but do merit a deeper study and discussion that may well lead to expanding the roles food regulatory bodies could play in promoting food safety, public health and nutrition, and sustainability. Whether food regulators are well-placed to take on wider roles may vary by country and the system of public administration, but it is not inappropriate per se for regulators to have that expanded role.

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