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IFC Scan Guide:

Policy *and* Regulatory Dimension *of* Food Safety, Food Fortification, Food Loss *and* Waste, Livestock Production (Animal Welfare *and* Use *of* Antibiotics)

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Foreword

Dear Readers,

I am happy to present a new tool developed by the IFC Food Safety Advisory team to support the analysis of the policy and regulatory dimensions of four aspects of a country's national food system: food safety, food fortification, food loss and waste, animal welfare and use of antibiotics in livestock production. The publication provides a list of assessment questions in these four areas to allow users to identify challenges and transformations. Identifying the challenges and transformations could increase efficiency in protecting consumers, improving national food safety while supporting and creating a sustainable food industry.

At IFC, we strongly believe that food safety is a key element of any national food system. The food system is comprised of a complex network of interlinked and interdependent elements that impact public health, the environment including climate change, the economy, and other spheres. The IFC Scan Guide starts with an assessment of food safety and covers other areas that are tightly linked to food safety. For instance, when strong food-safety practices are effectively implemented across the food value chain, this can help to substantially reduce food loss and waste from farm to fork. Reducing food waste, in turn, not only has a positive impact on food security, but also can help to address climate change concerns by reducing greenhouse gas emissions.

Food fortification, or the addition of vitamins and minerals to everyday foods, is one of the most cost-effective strategies to address micronutrient deficiencies and malnutrition. Every dollar spent on fortification results in nine dollars in benefits to the economy. Unfortunately, fortification has not reached its potential in emerging markets as many countries have not made it a mandatory policy. A related issue to consider is the safety of fortified food, as risk of overdose, under-fortification, or contamination by environmental, chemical, or biological hazards at various points in the chain will affect consumers.

IFC and the World Bank have partnered with other organizations with a deep understanding of the roles that different disciplines play in securing safe and nutritious food. This is directly relevant to the One Health approach, which recognizes that the health of humans, animals, plants and crops, and their shared environment are interconnected. This is an important reason why the IFC Scan Guide addresses animal welfare and use of antimicrobials in livestock production.

Initially developed at the request of IFC teams engaged in the food sector across emerging markets, the IFC Scan Guide incorporates years of experience of IFC specialists working in different regions and contexts. I am confident that this Scan Guide will become a useful and practical assessment tool for everyone who is involved in developing, maintaining, or improving national food systems.

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The IFC Scan Guide is a compilation of efforts of dedicated professionals from both the World Bank Group and external organizations.

The Guide is authored by Kateryna Onul, Policy Lead in IFC Food Safety Advisory, with support from World Bank Group colleagues, external partners, and independent international experts.

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[1] The views expressed in the review process are those of the expert and do not necessarily reflect the views or policies of the Food and Agriculture Organization of the United Nations.

Introduction

Food safety is an imperative that underpins the transformation of food systems. It is an integral part of food security, health, competitiveness, and climate change mitigation. It thus promotes food systems that are more fit for purpose, deliver better nutrition, and support individuals who base their livelihoods on such systems by fostering healthy people, a healthy economy, and a healthy planet. To realize this outcome, the old concept of food safety as food that is free of hazard must be transformed to embrace a multifactorial paradigm that considers food production as a continuum and safe food as the result of steps taken throughout. IFC Scan Guide: Policy and Regulatory Dimension of Food Safety, Food Fortification, Food Loss and Waste, Livestock Production (Animal Welfare and Use of Antibiotics) (the IFC Scan Guide) of the International Finance Corporation (IFC) supports this transformation by applying a whole food approach to the food value chain to enable steady improvement of a national food safety control system to include consumer protection and better agribusinesses.

Stakeholders in national food safety control systems should pause, take a step back, and look at the foodscape as a whole. They will then be able to shift away from the focus on individual critical points in the value chain and connect these points by recognizing that food safety is the result of a complex succession of interrelated actions. It also soon becomes clear that the foodscape is composed of a myriad of actors and actions aimed at raising food safety and enhancing health systems.

Ensuring food safety requires initiatives far beyond the food production value chain. Food can dramatically affect human health either negatively, through foodborne disease or food contamination, or positively, by fostering good health through nutritious foods of high quality. Poor safety can lead to greater food loss and waste, which may have a dramatic impact on greenhouse gas emissions and the environment. The health of the animals that are consumed as food is directly related to the safety and quality of the food they consume. Ensuring that the food and feed of these animals are safe is therefore important for the health of the animals and the environment, but also for the health and productivity of people.

Food safety is a health challenge that benefits from One Health, an integrated approach that reflects a recognition that the health of animals, plant health and the health of humans are interdependent and linked to the health of the environment. One Health represents a call on all sectors and disciplines to work together to achieve the optimal health of animals, the environment, and humans and to strengthen health systems at their interface, thereby shifting the paradigm focus from reaction to prevention. Under a One Health approach, the scope of food safety actions may be extended across sectors in an embodiment of the realization that only along multidisciplinary avenue that intersects approaches cutting across human, animal and environmental health systems, and the issues lying at their interface, will we strengthen national and regional food control systems and reduce the burden of foodborne diseases.[2]

In this endeavor, IFC and the World Bank have been joined by numerous partners with a global reach and a deep understanding of the roles that different disciplines play in securing safe and nutritious food. Awareness of the many available mechanisms is fundamental to discovering and benefiting from synergies in a manner that is dynamic, effective, and efficient. The interaction among these partners frames the food safety conversation and shapes the global architecture that supports the development of research and the adoption of initiatives to improve food safety systems.

The IFC Scan Guide is a fundamental tool to help users determine, in practical terms, when and where to leverage their support in the identification and assessment of needs and to design tailored investments to fill gaps and build stronger national, regional, and global food safety systems.

[2] For more details, see World Bank, 2021, "Safeguarding Animal, Human and Ecosystem Health: One Health at the World Bank" https://www.worldbank.org/en/topic/agriculture/brief/safeguarding-animal-human-and-ecosystem-health-one-health-at-the-world-bank

The development of the IFC Scan Guide originated from the demand of IFC teams for a resource that could quickly provide information on how to identify appropriate interventions to support IFC clients and the national food industry and to improve the national framework to enable and catalyze investments.

The IFC Scan Guide aims to support experts from both public and private sectors in assessing specific elements of national food systems, including food safety, food loss and waste, food fortification, and animal welfare and the use of antimicrobials in food producing animals, by focusing on policy, regulatory management, and institutional dimensions, as well as on capacity-building activities in countries in which the teams plan interventions or are already seeking to areas where changes are required.

The Scan Guide will be useful in accomplishing the following:

- Understanding how national food systems operate
- Identifying ways to address issues, including using limited resources to confront problems
- Designing or redesigning projects aimed at strengthening national food systems
- Developing relevant recommendations for governments
- Assessing food safety and other food system issues, designing and implementing solutions, and monitoring the related progress

A difference between the IFC Scan Guide and other assessment tools is the purpose. Other tools are exhaustive, which has the benefit of helping in undertaking thorough assessments, for instance, of national food safety control systems. However, to achieve their full potential, the deployment of these tools is time and resource intensive. The IFC Scan Guide is tailored to the needs of IFC. It is closely targeted on identifying issues that hinder the development of food industries and businesses in a manner that is both competitive and protects the health of consumers, thus contributing to stronger health systems.

Notwithstanding this clear distinction, the IFC Scan Guide is equipped to interact with other tools and offers a sound dataset that may inform and become the foundation of the application of the other tools where governments about to continue on the road to a deeper assessment of the selected subject.

To understand current capacities and assess gaps, the IFC Scan Guide provides a list of assessment questions in four areas—food safety, food fortification, food loss and waste, and animal welfare and the use of antimicrobials in food producing animals—following an approach that can be easily replicated if there is a need to assess other food system elements. The checklists and tables in the IFC Scan Guide have been developed based on the practical experience of IFC teams that have been involved in assessments of national food safety systems worldwide.

These checklists and tables are recommended for collecting critical information to help in understanding the following:

- How a system works
- How the model of a system differs from the system realized according to national policies
- How a system may not comply with international standards
- The main barriers to improvement and to harmonization with best practice
- Why the private sector may not be sufficiently active in ensuring compliance with best practice
- Who current and potential champions may be in reform and in harmonization with best practice

The IFC Scan Guide may be considered another element in a series with the Food Safety Toolkit developed by the World Bank in 2014 to illuminate the basics of food safety systems and the tools that can be used to assess market potential, build capacity, and assist in reducing the barriers to the realization of food safety at the national level. A review of the Food Safety Toolkit is recommended before commencing any assessment relying on the IFC Scan Guide.[3] The toolkit is also helpful if readers need to clarify guiding principles in food safety reform, legislative reform, institutional reform, food safety management, and food safety inspections. In addition, in developing the Scan Guide, the team learned

[3] For more details, see World Bank, 2014, "Food Safety Toolkit: Institutional Structure," March, Investment Climate Department, World Bank, Washington, DC, https://documents1.worldbank.org/curated/en/200341471590393837/pdf/107902-v4-WP-TAG-TOPIC-investment-climate-PUBLIC.pdf.

from and built upon existing tools by examining publicly available resources focused on the assessment of food systems that are within the scope of the Scan Guide. Consultations were conducted with the World Bank and experts at AGHealth, the Global Alliance for Improved Nutrition, the Standards and Trade Development Facility, and the United Nations Industrial Development Organization as well as independent experts whose feedback was considered in developing the Scan Guide.

The IFC Scan Guide has been developed primarily to aid in conducting assessments in food safety, food fortification, food loss and waste, animal welfare and the use of antimicrobials in food producing animals. Such assessments can be carried out either simultaneously or progressively, depending on needs and available resources. National food systems are established within a framework of policy setting and system design, implementation, and monitoring to maintain continuous improvement. In the early stages, the focus is on determining system objectives. Following implementation, the effectiveness and appropriateness of the national food system should be assessed regularly against the objectives, the results produced by control programs, and regulatory requirements. During these stages, the IFC Scan Guide provides solid advice, counseling the application of the principles of situational awareness, so system developers are duly informed by accurate, current information and can proactively realize continuous improvement. This is accomplished through a strong operational and results-oriented focus. The Scan Guide also complements other tools by supplying information to assist in making food businesses more viable.

Another strength of the IFC Scan Guide is that it facilitates remote assessments by presenting methods for performing secondary research, working with databases, and conducting telephone or online interviews with stakeholders. The need for in-person engagement may be reduced.

The approach proposed in the IFC Scan Guide requires the involvement of national experts who have practical experience in cooperating with public authorities on specific issues related to national food systems, in understanding and interpreting relevant national polices and legislation, and in mastering the operations of local food businesses.

Using the Scan Guide, expert team will be able to achieve the following:

- Establish a clear perspective on elements of a national food system, such as food safety, food fortification, food loss and waste, and animal welfare and the use of antimicrobials, including the specification of the roles and responsibilities of public agencies and other stakeholders
- Understand changes that may be required to upgrade relevant national food policies and regulations to address challenges linked to the globalization of the food trade and technical advances that impact the food industry and food consumers
- Identify existing and emerging risks deriving from duplication and overlap in responsibilities among public agencies or a vague regulatory framework on food-related issues and on food safety
- Develop recommendations on issues that should be addressed to help strengthen national food systems in selected areas depending on the agenda to ensure better consumer protection and create an environment that facilitates a healthy national food industry

The IFC Scan Guide is not aimed at comparing countries or providing benchmarks. Rather, it is designed to be used as an assessment tool by expert teams or as a self-assessment tool by national authorities in identifying areas in which change may be required. The IFC Scan Guise may also be used if necessary changes are identified during assessments or monitoring implemented to track progress.

Teams should note that confidentiality should be considered and clarified prior to initiating an assessment, particularly in terms of the results and how data will be managed and stored. This is a potentially sensitive area of the assessment because there may be cases in which governments are not willing to share publicly the status of food safety within the country and with trading partners, especially of the issue involves food safety control or the national capacity to tackle sanitary and phytosanitary measures. The reasons for the unwillingness to share information vary, but the most common reason is that countries want to avoid possible problems with food trading partners. Therefore, the issue of the public availability of the results of assessments should be clarified and be the subject of an agreement.

The IFC Scan Guide may also be useful among national authorities, including food safety authorities, public health ministries, agricultural ministries, and food standards agencies, engaged in the public management of various elements of a food system, particularly in assessing the efficiency of national food systems in food safety, food fortification, food loss and waste, and animal welfare and the use of antimicrobials in livestock production.

Tools such as the IFC Scan Guide help in understanding issues that should be addressed to ensure better consumer protection and the sustainable development of the food industry, especially considering the enormous challenges involved in increasingly complex food systems. Rising population, climate change, trade, globalization, and the existential threat of infectious disease and pandemics mean that efforts must be stepped up to improve food safety. IFC and the World Bank have the necessary capacity to engage across the many sectors involved in tackling these challenges. They have the global reach and the country depth to enable the deployment of the efforts needed to strengthen food systems to achieve food safety and security, a global public good.

Section I

Country Profile

Prior to the launch of an assessment of any element of a national food system, data on the food sector in the country should be collected and analyzed, including data on primary and processed food production, the domestic food trade, the trade in food for export and import, and data focused on the element of the food system that is being assessed.

During the collection of data on the country profile, check the information available on the websites of government financial institutions, including the ministry of finance, the ministry of the economy, and the government statistics service. Also check the websites of the ministry of agriculture, the ministry of the environment, the ministry of health, the food safety authority, state veterinary and phytosanitary services, the food standards agency, consumer and exporter associations, and the chamber of commerce.

Collect and analyze the results of needs assessments of sanitary and phytosanitary (SPS) measures carried out in the country by national, regional, and international organizations, donor funded projects, and any other relevant projects. These materials may become a great resource of the required information.

If the country has applied the prioritizing SPS investments for market access (P-IMA) framework, SPS documents should have already been collected.[4] Some of these documents may be available in the library of the Standards and Trade Development Facility (STDF) and on the websites of the United Nations Industrial Development Organization (UNIDO) and the World Bank.[5] A review of Performance of Veterinary Services (PVS) reports of the World Organisation for Animal Health (OIE) is recommended if these are available; they should provide useful information on livestock production and food safety in the country.[6]

The scope and the type of the data collected and analyzed should be guided by the project goal, for example, facilitating food exports, strengthening the domestic market, promoting the engagement of value chains in food, including in primary food production, food processing, the retail trade, and so on, or in specific types of food processing, for instance, food fortification or improving the use of antimicrobials in livestock production and the implementation of best practices to reduce food loss and waste.

The country profile might include basic facts about the population, geographical factors, bordering countries, administrative divisions, and the legislative system. The information on this last should cover the individuals who control legislative initiatives and how regulations are developed and issued.

In lower-middle-income countries, the share of women is often high in agricultural activities, where they have little decision-making power or control over inputs and outputs. Women may also have limited access to financing and resources, which create barriers for them to develop their own businesses and apply innovative approaches in the areas that are the focus of this Scan Guide. In working with population data, one should therefore consider the gender angle and analyze the population shares by gender in farming, food production, food distribution, and other areas relevant to the assessment. These data will also help in understanding whether food policies are socially inclusive and in considering gendered roles and responsibilities, resources, and constraints among both women and men.

[4] For more on the P-IMA framework, see P-IMA (Prioritizing SPS Investments for Market Access) (dashboard), Standards and Trade Development Facility, World Trade Organization, Geneva, https://www.standardsfacility.org/prioritizing-sps-investments-market-access-p-ima.

[5] See Browse SPS Resources (dashboard), Standards and Trade Development Facility, World Trade Organization, Geneva, https://www.standardsfacility.org/library.

[6] See PVS Pathway (Performance of Veterinary Services Pathway) (dashboard), World Organisation for Animal Health, Paris, https://www.oie.int/en/what-we-offer/improving-veterinary-services/pvs-pathway/.

Data on the following will be especially helpful in completing the country profile:

- Population shares by gender
- The number of people living in urban and rural areas
- Food imports and exports and whether the country is a net food importer or exporter

The information on food exports and imports should include any available statistics maintained by public and private entities, such as industry associations and chambers of commerce, on the most common issues in food imports and exports.

If the country exports food products to the European Union (EU), it is important to check the latest information on food recalls and public health warnings through the Rapid Alert System for Food and Feed (RASFF) concerning food exports and list any issues detected in recent years.[7] Data should also be provided on any approved national exporters of food of animal origin in the EU.[8] The same approach is recommended relative to the main food export markets if any information is available, especially on the following:

- Share of imported versus exported foods
- Key exported and imported foods
- Key food export and import markets
- Data on food industries, including formal and informal entities, for example, street vendors, home production, and so on[9]
- The geography of food production: farming, primary food production, food processing
- Data on food production, including the types and number of establishments in general, entities that handle food of animal origin, such as slaughterhouses, meat processing facilities, and dairy processors, processing capacity, and the value of production at the various stages of primary production and food processing
- The main food distribution channels in the country, including retail chains, informal or traditional markets, and public agricultural markets[10]
- Food consumption data and common health issues linked to food, such as malnutrition among various groups in the population[11]
- Information on food habits and food preferences linked to culture, religion, and traditional practices, with the possible consideration of a gender angle
- Statistics on food-borne diseases (FBDs), death, and outbreaks, including types of hazards[12]
- The number of border rejections associated with food safety issues

[7] See RASFF Window (version 2.0.5), European Commission, Brussels, https://webgate.ec.europa.eu/rasff-window/portal/?event=SearchForm&cleanSearch=1.

[8] See "Non-EU countries establishment lists," European Commission, Brussels, https://ec.europa.eu/food/safety/biological-safety/food-hygiene/non-eu-countries-authorised-establishments_en

[9] Depending on the needs of the assessment, gender considerations, including data disaggregated by gender in formal and informal food-related activities, could be added.

[10] In collecting this kind of data, one should consult with experts from the national competent authorities responsible for the registration of food business operators and food safety control in the country.

[11] Malnutrition includes overweight, obesity, undernutrition, and micronutrient deficiencies. See FAO (Food and Agriculture Organization of the United Nations), IFAD (International Fund for Agricultural Development), UNICEF (United Nations Children's Fund), WFP (World Food Programme), and WHO (World Health Organization). 2020. The State of Food Security and Nutrition in the World 2020: Transforming Food Systems for Affordable Healthy Diets. Rome: FAO.

[12] Statistics often fail to include or massively underestimate FBDs and are thus misleading. If this is the case in the assessment country, a literature review should be undertaken and discussions should be conducted with consumer organizations.

The list above may be reduced or expanded based on more specific data depending on the needs of the assessment. For instance, besides the assessment of the general food safety regulatory and policy framework, there may be a demand for an additional focus on specific subsectors or topics, for instance, the production of red meat, the export of food of animal origin, food waste management, food fortification, food distribution, or the cold chain.

In developing a list of data for the country profile in relation to the assessment of the food system, consider how accessible the data are. In cases in which there are issues with data collection or if the data are outdated, determine the "must have data" and the "it would be nice to have data" for your project.

To determine any additional information that may be required for the country profile, quickly scan issues in the area to be analyzed for the assessment of the national food safety system. For example, in assessing the regulatory and institutional framework for cold chain logistics, it will be useful to draft a brief description of the current conditions of transport infrastructure and the main food transportation routes, the average distance from primary production sites to processing facilities or agricultural markets, and statistics on food loses if these statistics are available. For instance, in assessing the efficiency of the regulation and control of aflatoxin contamination, it will be illustrative and helpful to add data on the number of samples taken in the country to detect aflatoxin contamination, the number of positive cases, and information on existing state monitoring programs.

Section II

Food Safety

I. Assessment of the policy and regulatory framework

a. Food safety policy

National food safety policy reflects basic principles that guide the development of national food (safety) laws and regulations. The assessment of national food safety policies should be undertaken through the lens of the operation of the national food safety system.

There may be cases in which there is no national food safety policy in the country. However, relevant issues could be covered in national food policies, national nutrition policies, national action plans for antimicrobial resistance, national agricultural policies, policies linked to agricultural exports, or animal or public health policies. All such relevant policies need to be identified and considered in assessing the national food safety system in the country because they may include basic principles that guide the food safety system. Basic principles may also be addressed at the subnational level. In that case, relevant subnational documentation should be analyzed.

Even a quick scan of relevant policies will reveal whether food safety concerns are prioritized and addressed in the country and if there is a balance across the interests of stakeholders. The absence of a national food safety policy or an outdated policy may reflect the low priority of food safety on the government agenda.

Best practice requires that national food safety policies clearly indicate the need (1) to protect public health by reducing the risk of food-borne diseases, (2) to protect consumers from unsafe foods, and (3) to contribute to economic development by creating a sound regulatory system for domestic food production and the food trade internally and internationally.

The national strategic plan is a tool aimed at operationalizing the national food safety policy by specifying the interventions that are needed to achieve the goals set in the national food safety policy. A good approach is one in which a strategic plan provides information on (1) areas for intervention, (2) the competent authorities (CAs) who are responsible, (3) the budgetary requirements, (4) the time frame, and (5) the reporting mechanisms to monitor progress.

Analysis of the consistency of the national food safety policy with international treaty obligations is one of the must steps of the assessment. To carry out this analysis, it is recommended that the international treaties and other mechanisms to which the country is bound be checked. It is recommended to check the following:

- Is the country a member of the Codex Alimentarius Commission (CAC), the Commission on Phytosanitary Measures of the International Plant Protection Convention, the World Organisation for Animal Health, or the World Trade Organization (WTO), and, if so, what is the level of its participation?
- Does the country participate actively in any Codex committees?
- Does the country notify the WTO about initiatives it is undertaking related to sanitary and phytosanitary (SPS) measures, including food legislation?

The assessment should also include a list of the country's regional obligations and cover regional food laws. If such laws are being developed, this should be mentioned in the assessment, along with the level of the country's involvement in any drafting of implementation process. To describe national food safety policies, use checklist 1 as a guide.

Checklist 1. Food Safety Policy

- Is there a national food safety policy? What policies have been developed and adopted?
- When was the policy formulated? Has it been updated and, if so, when?
- Is there a reference to the collaborative development of the food safety policy with the involvement of other stakeholders, for example, industry and academia?
- Does the policy set out the goals and objectives of food safety? Which indicators are used?
- Are national food safety policies based on the following guiding principles?[13]
  - Safe food is a public good and a fundamental right
  - Sound science and the application of risk analysis principles where risk assessment and risk management are clearly separated
  - The application of a traceability system
  - The utilization of preventive and precautionary principles
  - The cost-effective use of resources
  - Transparency
  - Cost recovery for sustainability
  - Food safety is the shared responsibility of the national government, the food industry, and consumers
- Does the policy define the appropriate level of protection to be attained through the application of food safety requirements and related measures?
- How consistent is the national food safety policy with international treaty obligations?
- Who among stakeholders are involved in the development and updating of national food safety policies?
- Are there any externalities or unwanted and unintended consequences of the policy?[14]
- Is there a strategic plan to improve food safety in the country?
- Does the national food safety policy provide details on the following elements?
  - Food legislation
  - The institutional structure and coordination of food safety functions
  - The application of evidence-based risk analysis principles
  - Participation in international meetings and the implementation of agreements
  - Surveillance and epidemiology
  - Laboratories for food safety control
  - The monitoring of food production and distribution systems
  - The safety of imported food for consumption
  - National food safety emergency response systems
  - Scientific capacities
  - International collaboration
  - Public awareness
  - Educational programs
- How does the food safety policy promote collaboration at the national and international levels?

[13] See FAO (Food and Agriculture Organization of the United Nations), 2013, "Jamaica: National Food Safety Policy," January, FAO, Rome, http://extwprlegs1.fao.org/docs/pdf/jam166453.pdf.

[14] Before answering this question, it is recommended that a literature review and consultations with national food policy experts (if possible) be undertaken.

b. The food safety regulatory framework

The assessment of the food safety regulatory framework involves scrutinizing the complete body of legal texts on food legislation and food law. Such legal texts include both basic (or general) and specific laws and regulations (that is, the subsidiary legal tools required for the implementation of the provisions in laws).

Ideally, to ensure the precise understanding of the legal texts, the legal texts should be examined by an expert with a legal background who knows how to read and analyze the texts and who is a native speaker.

Food law is managed most efficiently if it has two components: (1) basic food acts that set out fundamental principles for food safety systems and (2) regulations that provide detailed provisions governing the various aspects of the national food safety system.[15]

[15] See Orriss, Gregory D., 1998, "Food Fortification: Safety and Legislation," Food and Nutrition Bulletin 19 (2): 109–16, https://journals.sagepub.com/doi/pdf/10.1177/156482659801900204.

The proposed approach to the assessment is a sum of steps, whereby each step clarifies issues critical for the regulatory framework and allow a clear vision to be obtained of how the food safety regulatory framework is organized and how it *operates.*

Step 1 Determine the legal definitions of food and food derivatives in national legislation

In working on the list of food-related laws, identify the legal definitions of food and food derivatives in national legislation, such as food of animal origin, plant food, organic food, novel food, and so on. These definitions will help determine the scope of research by indicating the areas that should be covered in assessing the food safety regulatory framework.

Step 2 Compare the definitions of food and food derivatives with Codex terminology

The analysis of the definitions of food and food derivatives in national food law should determine the extent to which these definitions employ Codex terminology. The harmonization of key definitions in national food law and the definitions in the Codex will simplify international trade negotiations because the Codex standards are the basis for national food legislation in many countries, including the developed economies. Thus, if the definitions of food and food derivatives in national food law are different from those in the Codex, the harmonization of national terms with Codex terminology might be a first recommendation in the country where the assessment is taking place.

> Based on the Codex, food is "any substance, whether processed, semi-processed or raw, which is intended for human consumption, and includes drink, chewing gum and any substance which has been used in the manufacture, preparation or treatment of 'food' but does not include cosmetics or tobacco or substances used only as drugs."[16]

Step 3 Learn the hierarchy of legal acts in the country

In developing a legal inventory, begin by learning the hierarchy of legal acts in the country. This will show the starting point for the assessment of the regulatory framework and the proper sequence in the analysis of food laws.

> Depending on the legislative system in the country, food laws (1) may be detailed or (2) only adopt basic principles and norms that form the basis of the system and leave food handling procedures undefined. In the second case, food laws typically refer to subsidiary legal instruments that regulate most of the mandatory requirements on various aspects of food handling along the food chain. Thus, in work involving food laws and the analysis of the efficiency of the laws, the associated legal acts should be examined to confirm to extent to which they have been established and are properly developed. For instance, there may be a requirement in the law that food traceability be implemented. The implementation procedures should be detailed in the norms and regulated by relevant subsidiary provisions. The appropriate subsidiary provisions may not have been developed.

The next suggested step is the revision of a country profile in the FAOLEX database that provides information on national legislation, policies, and bilateral agreements on food, agriculture, and natural resource management.[17] It is recommended that this information be used as a guideline in determining the direction the research might take because the FAOLEX database cannot guarantee that the

[16] Page 23, FAO (Food and Agriculture Organization of the United Nations) and WHO (World Health Organization), 2015, *Codex Alimentarius Commission: Procedural Manual*, 24th ed., Rome: FAO, http://www.fao.org/3/i5079e/i5079e.pdf.

[17] FAOLEX Database, Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/faolex/en/.

information is correct, complete, and up-to-date. To ensure accurate assessment results, work should be focused on original valid legal texts only.

Develop a list of key elements of the national food safety system and identify the legal acts that govern these elements

Step 4

If the structure of national food law is vague and if it is not clear which laws should be analyzed to obtain a full picture of the operation of the national food safety system, the regulatory assessment might begin with the development of a list of key system elements and the identification of the legal acts that govern these elements. This list will also be useful in cases in which the structure of national food law is clear. The list of key elements of the system could help in analyzing whether all critical issues in the food safety system are covered by national legislation. The list might include the following:

- Food definitions
- The rights and responsibilities of food business operators (FBOs)
- Food safety requirements
- Food production
- Food labeling and information for consumers
- Food control
- Food exports and imports

The hierarchy of legal acts is different in civil law and common law.[18] This needs to be considered in developing the list of food legislation.

Develop an inventory of the key laws that regulate food safety

Step 5

It is recommended that the assessment of food legislation involve the development of an inventory of the key laws that regulate the various aspects of food production and distribution, including food exports and imports, food safety control, food laboratory services, and consumer protection. In the inventory, the date of the adoption of each law and the dates of amendments should be specified. This exercise will clarify whether the basic law—if there is one—and the rest of the laws and regulations are harmonized and if they are consistent. For instance, there may be inconsistency if specific laws and regulations were adopted before the basic act was adopted, but were not subsequently amended. Likewise, differences in the dates of the most recent amendments in specific laws may suggest that there is a need to check for consistency in the relevant approaches to food safety.

A well-executed inventory of national food legislation will result in a list of laws starting with the general food law and followed by laws governing specific issues. If there is no general law, the inventory will start with a list of laws that govern common food safety issues. Each law will be followed by a list of subordinate legal acts that are mentioned in the law. A subsequent section should be focused on other relevant legal acts, such as executive orders, administrative directives, and ministerial decrees adopted by the government.

Determine whether national food law complies with international standards

Step 6

Once the inventory has been completed, appropriate legal acts should be identified and examined to determine if national food legislation complies with international standards. The use of the internationally

[18] See "Key Features of Common Law or Civil Law Systems," Public-Private Partnership Legal Resource Center, World Bank, Washington, DC, https://ppp.worldbank.org/public-private-partnership/legislation-regulation/framework-assessment/legal-systems/common-vs-civil-law#Common_Law_System.

accepted benchmarks for food legislation will show whether national food legislation meets the following criteria:[19]

- Provides an enabling framework for the implementation of a science-based food safety control system that is founded on risk analysis

  There should not be any compromise in implementing food safety because food safety has a direct effect on human health. At the same time, a well-considered balance between consumer protection and the creation of a food business–enabling environment is required. Otherwise, there is a risk of jeopardizing the development of the national food industry and food trade. This will have a negative impact on domestic consumers.

- Clearly defines the roles and responsibilities of control authorities (CAs) and the mechanism for interactions among CAs

  The revision of provisions on the roles and responsibilities of CAs will show if there are duplications, overlaps, contradictions, or gaps in mandates. It is critical that the analysis of the provisions on cooperation mechanisms among CAs determine whether the declared mechanisms are efficient and all necessary implementing procedures are identified and established.

- Includes clear definitions to ensure consistency and legal security

  Best practice is promoted if the list of key definitions in the food area forms part of the general food law. The definitions should be based on the definitions in the Codex and harmonized through national food legislation. It is also important to check that smuggling, food adulteration, and food fraud are clearly defined.

- Ensures transparency in the development of food regulations and standards, as well as access to information
- Clearly defines enforcement powers and procedures, for example, prohibition orders, improvement notices, closures, and other orders
- Provides for appropriate enforcement and control measures, including efficient, proportionate, and dissuasive sanctions and penalties

The more specific criteria in checklist 2 below offer guidance on the level of correspondence of national food legislation and international standards developed by the Joint Food and Agriculture Organization of the United Nations (FAO)–World Health Organization (WHO) Food Standards Program. It is recommended that the checklist be used when assessing national food safety law.

In addition, in examining how the national food law is organized, it is critical that the analysis identify whether national food legislation is primarily based on standards or primarily reflects a risk-based scientific approach to food safety. This is important because it might reveal one reason for any slow pace in the progress toward the development of a national food industry.

The standards-based or technical standards system will typically stipulate technological processes, product characteristics (size, shape, nutrient content, additive content, weight, type of packaging), microbiological and chemical contaminants, and labeling. However, this is often not flexible, can produce problems in international trade, and requires the intervention of experts, for example, in managing legislative documents and identifying the appropriate standards for a certain type of production.

The risk-based scientific approach focuses on managing risks and usually involves general regulatory legislation setting out the principles of food safety and hygiene, along with sector-specific legislation on areas where the risks are greater. A risk-based scientific approach is an international best practice in food safety legislation, *promoted* by the Codex. The European Union (EU), the United States and other developed countries have legislative frameworks that embed a risk-based approach to food safety control.[20]

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[19] FAO (Food and Agriculture Organization of the United Nations), 2006, *Strengthening National Food Control Systems: Guidelines to Assess Capacity Building Needs*, Rome: FAO, http://www.fao.org/3/a0601e/a0601e.pdf.

[20] See World Bank, 2014, "Food Safety Toolkit: Legislative Reform," March, Investment Climate Department, World Bank, Washington, DC, http://documents1.worldbank.org/curated/en/905911471588854058/pdf/107902-v3-WP-TAG-TOPIC-investment-climate-PUBLIC.pdf.

Checklist 2. The Food Safety Regulatory Framework

- Is national food legislation based on the principles of the WTO agreements on SPS measures and on the technical barriers to trade (TBT)?
- What is the scope of national food legislation? Is it focused on food only? Or does it cover feed-related issues relative to food-producing animals or issues related to agricultural inputs, or any other issues?
- Does national food legislation apply from production to consumption?
- Is there a clear distinction between food safety and food quality in national food legislation?
- Is national food legislation standards-based or risk-based?
- Does national food legislation include obligations to ensure that only safe and fairly presented foods are placed on the market?
- Does national food legislation establish the responsibilities of CAs and FBOs clearly?
- Does national food legislation include clear provisions that indicate that the primary responsibility for food safety and quality rests with FBOs? If so, what is the level of awareness among FBOs about this?
- Does national food legislation identify a list of responsibilities of FBOs and CAs?
- Does national food legislation include provisions for accurate and sufficient information on food products placed on the market?
- Does national food legislation regulate food traceability, food recall, and withdrawal, including responsibilities in case of imported food products?
- Are there any specific regulations on the following?
  - Food for infants and young children (baby food), novel food, organic food, street food
  - Food for special dietary purposes
  - Genetically modified organisms
  - Food additives
  - Food contaminants, such as toxins, metals, and radionuclides
  - E-commerce in relation to food distribution?
- How is the issue of the maximum levels of different substances in food regulated?
  - When were the maximum levels of different substances in food adopted and updated?[21]
  - Are maximum residue levels (MRLs) harmonized with Codex standards?
  - If there are regional standards, are national MRLs harmonized with these standards?
  - How do MRLs in the assessment country differ from MRLs in target export markets?

> **!** The Codex Alimentarius database contains Codex maximum levels for pesticides and veterinary drug residues. The database is huge. However, there is no need to analyze the entire database for the purpose of this assessment. Instead, it is necessary to check if the legal documents governing national maximum levels have been developed based on the Codex and when they were updated.[22]

- How prescriptive and detailed are food safety requirements, including on food hygiene?
- Are there provisions on the possibility of the flexible implementation of food safety requirements depending on the type of food (for example, traditional food) or geographical location (for instance, FBOs located in remoted areas)?
- Is the hazard analysis critical control point (HACCP) mandatory or voluntary for FBOs?
- Is there a possibility of flexible implementation of HACCP?
- Does national legislation provide provisions for the flexible implementation of food hygiene requirements and the HACCP for defined groups of FBOs?
- Is water considered food? How are issues of drinking water and the water used in food production regulated?

> **!** If there is a food law in the country and an assessment must be made of how well this law is written and if its scope covers all elements that are critical for the national food safety system, it will be useful to check Vapnek and Spreij 2005.[23]

- How does the food safety policy promote collaboration at the national and international levels?

[21] While answering this question requires reference to that national legal database and legal documents, answering other questions about the maximum levels of different substances in food requires a literature review and consultations with national food safety experts and the CAs responsible for monitoring the relevant issues.

[22] See Codex Pesticides Residues in Food Online Database, Joint Food and Agriculture Organization of the United Nations–World Health Organization Food Standards Programme, Rome, http://www.fao.org/fao-who-codexalimentarius/codex-texts/dbs/pestres/en/.

[23] Vapnek, Jessica, and Melvin Spreij, 2005,. *Perspectives and Guidelines on Food Legislation, with a New Model Food Law*, FAO Legislative Study 87, Rome: Development Law Service, Legal Office, Food and Agriculture Organization of the United Nations, http://www2.ecolex.org/server2neu.php/libcat/docs/LI/MON-079891.pdf.

II. Institutional framework

The assessment of the institutional framework is aimed at (a) identifying all stakeholders in the public and private sectors and in the international community who are involved in the public management of food safety in the country, (b) analyzing the efficiency of the structure and level of cooperation among stakeholders, and (c) identifying gaps in the current structure and areas of improvement in the short- and long-term perspective.

a. Stakeholder analysis and mapping

The assessment of the structure of the food safety system might begin with a stakeholder analysis. This could commence with the identification of the public agencies that are responsible for issues linked to food safety, from the development and adoption of food safety–related regulations to the registration of food, official control, import and export operations, and other, associated activities. The assessment should also include the identification of the private sector players who are involved in the development of the national food safety agenda, the relevant active representatives of civil society, and the international community.

In identifying key stakeholders in the national food safety system, it is critical not to overlook those who perform quality control and laboratory testing, as well as academia and consumer associations and organizations if they perform any significant role in the development or formulation of the food safety agenda in the country.

The analysis of stakeholders should encompass an assessment of actors who are involved in any stage of the food chain, from primary production to the processing industry, wholesalers and retailers, input supply, restaurants, markets, waste management, and others who are present in the country. Table 1 might serve as a tool in picking out appropriate stakeholders for the purpose of this assessment.

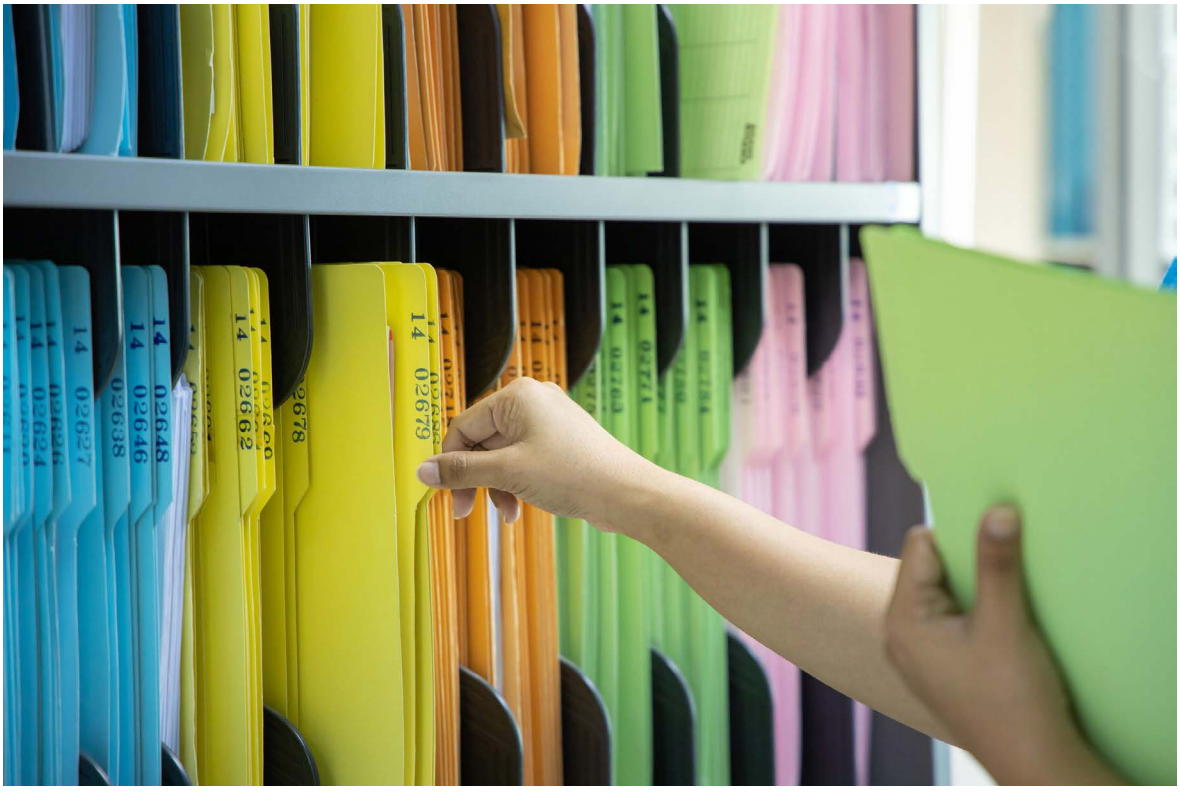
Table 1. Stakeholders through the Food Chain

Stage of the food chain	Stakeholders involved
Primary production (agriculture, livestock, aquaculture)	*Public sector:* CA involved in official control and CA involved in other forms of public food safety management
	Private sector: key players (farms, cooperatives, suppliers of required inputs and support materials, chemicals, services, and so on), industry associations
	Civil society: nongovernmental organizations (NGOs), consumer groups, research institutes
	International players, including donor-funded projects
Food processing: primary (onfarm, dairies, abattoirs, grain mills, and so on) and secondary (fermenting, baking, canning, freezing, drying, and so on)	*Public sector:* CA involved in official control and CA involved in other forms of public food safety management
	Private sector: aggregators, processors, manufacturers, brewers, key players, industry associations. Might also include suppliers of required inputs and support materials, chemicals, services
	Civil society: NGOs, consumer groups, research institutes
	International players, including donor–funded projects
Distribution: domestic production, exporters and importers, transporters on service contracts	*Public sector:* CA involved in official control and CA involved in other forms of public food safety management
	Private sector: key players, industry associations
	Civil society: NGOs, consumer groups, research institutes
	International players, including donor–funded projects
Retail: traditional markets, supermarkets, and food service and hotel industries	*Public sector:* CA responsible for official control and CA involved in other forms of public food safety management
	Private sector: key players, industry associations
	Civil society: NGOs, consumer groups, research institutes
	International players, including donor–funded projects
Consumers	*Public sector:* CA responsible for consumer protection associated with food products
	Civil society: NGOs, consumer groups, media
	International players
Food waste management	The need to analyze this part of the food chain depends on the purpose of the assessment and might not be needed

Once all stakeholders have been identified, the next step is to analyze their roles in and value to the national food safety system. A list of key criteria are usually used for this purpose (table 2). The list is not exhaustive and may be extended depending on the objective of the assessment.

Table 2. Criteria for the Analysis of Stakeholders in the Stakeholder Profile

Who is the stakeholder? Public agency, private sector company, private sector association, civil society organization, international organization, donor-funded project, and so on
Stakeholder's mandate and mission in relation to the national food safety system Official control, policy development, public management, exports and imports, quality assurance, lab testing, and so on
Stage of the food chain where the stakeholder is engaged The entire food chain/primary production/food processing/distribution/retail/consumer/food waste management
Level of influence on the system High, medium, low
Contribution Expertise, financial support, management, other
Possible views on the national food safety system Reforms are required; against any changes; support changes only in the specific sector in relation to particular issues; other
Collaboration with other stakeholders Participation in private, public-private, or public initiatives, partnerships, or platforms, and so on
Contact details Website, accounts in social media



Stakeholder mapping facilitates the visualization of the results of the stakeholder analysis and the identification of key players. Table 3 may be helpful in organizing the data and determining how many public agencies are engaged in food safety public management and how well the private sector is represented. This exercise will also help determine the role of social and international communities.

Information resources for the stakeholder analysis and stakeholder mapping include internet searches, interviews with sectoral experts, and legal documents that define the mandates of public agencies.

Table 3. The Stakeholder Inventory

Public sector				
Agency, legal document defining the mandate	Stage of the value chain	Official control (+/-)	Other functions beyond official control	Stakeholder website and contacts
Example: food safety authority	*Control across the food chain; food exports and imports*	+	*Drafting of secondary legislation; development and adoption of food safety regulations; consumer protection; and so on*	
Example: national laboratory in the area of food safety	*Used for official control across the value chain*	-	*Provides testing services to the private sector on a fee basis*	
Private sector and international community, including donor-funded projects				
Stakeholder	Areas of involvement in food safety		CA and private sector entity with which the stakeholder works	Stakeholder website and contacts
Example: IFC advisory services project	*Capacity-building activities on the hazard analysis critical control point*		*National food safety agency and a list of selected food processors*	
Example: private laboratory "LAB"	*Provides testing services to the private sector; performs sample testing on behalf of the CA for official control*		*National food safety authority, food processors*	

An effective stakeholder analysis and stakeholder mapping will provide many data on the structure of the national food safety system and reveal issues that may be a cause of inefficiency in the system. More specifically, the analysis is expected to answer the selected questions listed in checklist 3.

Checklist 3. Analysis of the Stakeholder in Food Safety

Part I. General questions

- Who are the key stakeholders in the food safety environment in the country (from the public and private sectors, social and international community)?[24]
- How many public agencies are engaged in public food safety management? What are they? How many of them have control functions?
- Who is responsible for developing food policies?
- Who is responsible for drafting, updating, and managing regulations, acts, and measures in the food safety area?
- Who is responsible for collecting and analyzing data for food safety monitoring, surveillance, and risk analysis on a national basis?
- What is the hierarchy among the public agencies involved in food safety control?
- How many public agencies are responsible for food safety control along the food chain?
- Has the government established a national food safety emergency coordination body? If so, what is the role of this body and who are its members?
- What are the roles of public and private laboratories in the system?
- Which are the key public laboratories in the area? To which public authority are they responsible?
- Are the outputs of laboratory services in the country internationally accredited?[25] Are they accepted in target export markets?

Part II. If several public agencies perform official control over food safety:

- Specify the public agencies responsible for food safety control at each stage in the food chain.[26] How clear, understandable, and accessible is the required information? Is one agency considered the primary or leader agency?
- If several public agencies perform official control over food safety, is there duplication in the official controls exercised at any stage in the food chain?[27]
- Are there any stages in the food chain where official control is not performed?
- What is the level of collaboration among agencies? Is this collaboration formal?
- Who controls food exports and imports at the border? Is there any specific control on exports or imports of food of animal origin?

Part III. The private sector and the social and international communities

- How active is the private sector in the country? On which food safety issues is the private sector more active and effective?
- What is the role of the international community in food safety in the country?
- Are the private sector and social community involved in the formulation and development of government food safety policy?
- How strong are consumer organizations in the country? Do they influence government policy in the food safety area?
- How strong and active are industry associations? Which are the main ones?
- Who are the stakeholders involved in the development of food safety policies and the regulatory framework?
- What is the role of the international community in the development of food safety policies and the associated regulatory framework? Is the international community involved in any current initiatives in the area?
- What is the role of academia in the development of food safety policy and the regulatory framework?
- Who are the key supporters and opponents of changes in the national food safety system? What are the reasons for their points of view?

[24] If gender issues are within the scope of the assessment, it is recommended to examine any differences in the roles usually played by men and woman be added.

[25] If laboratory services are performed by an ISO 17025 accredited lab with the ability to perform analytical testing, the results of the testing should be accepted.

[26] The analysis might be different for plant-based food and food of animal origin. It is therefore recommended that both options be analyzed.

[27] To answer this question, the analysis must determine how control is organized at different levels, for example, the provincial, regional, and national level.

b. Institutional framework

There are three major types of institutional structure in national food control systems: the single-agency model, the multiple agency model, and the integrated agency model.

- The single-agency system: a system whereby all responsibilities for protecting public health and food safety are consolidated in one CA with a clearly defined mandate
- The multiple agency system: a system whereby food control responsibilities are shared between two or more CAs
- The integrated system: a system whereby food control occurs at several operational levels, and different CAs are responsible for the formulation of policy, the development of regulations, the coordination of food safety control, inspections, and capacity building[28]

Stakeholder mapping provides all information required to define the type of food safety control system in the country. Once the system is established and there is more than one CA involved in food safety control, the next step is to identify and make a list of the CAs responsible for official control along the food chain (from primary production to food distribution, including food import and export operations). The list is needed to support analysis of how the system operates.

For the assessment, official control means any form of control that the agency responsible for official control in food safety performs to verify compliance with the national requirements in food safety. This includes official audits, inspections, monitoring, surveillance, and other activities considered to be a form of official control under the national legislation of the country where the assessment is taking place. It might be useful to check detailed definitions of food control, food inspection, audit, and monitoring provided in guidelines by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO).[29]

Knowing all public agencies involved in food safety control allows the structure of the system to be visualized, including all the connections and roles within the structure. This also facilitates an analysis of how official control is organized along the food chain and the development of a schematic description of the structure. If there is only one CA responsible for food safety control, the development of the schematic description is still recommended because it will show how the CA relates with the key ministries that formulate food safety policy as well as the relationship between the CA, the central office, and regional units.

During work on the scheme, it may be useful to check the EU Food Safety Almanac, as well as websites of national food safety authorities presented in the almanac.[30] In clarifying the institutional structure of the national food safety control system, one might question the need for the schematic description. Experience shows that the scheme development process is one of the most efficient ways to determine if all required information has been collected and analyzed. The scheme shows gaps and areas in the control system where improvements are required. It is also a good advocacy tool during discussions with government decision-makers on the need for change. In addition, the development of a schematic illustration of the institutional structure of food safety control in most developing countries is usually challenging, and, if this is the case in the current assessment, this may be more evidence that the system needs an upgrade because the graphic scheme shows that the division of control functions across the public sector is not clear. Consequently, gaps, duplications, and discrepancies can be perceived in the food safety control system. As a result, it becomes clear that the country has a system that lacks efficiency and may be criticized by trading partners.

[28] For more on the models of national food safety control system institutions, see World Bank, 2014, "Food Safety Toolkit: Institutional Structure," March, Investment Climate Department, World Bank, Washington, DC, https://documents.worldbank.org/en/publication/documents-reports/documentdetail/829181471594886767/food-safety-toolkit-institutional-structure

[29] FAO (Food and Agriculture Organization of the United Nations) and WHO (World Health Organization), 2003, "Assuring Food Safety and Quality: Guidelines for Strengthening National Food Control Systems," Food and Nutrition Paper 76, FAO, Rome, http://www.fao.org/3/a-y8705e.pdf.

[30] BfR (Bundesinstitut für Risikobewertung, German Federal Institute for Risk Assessment), 2021, *EU Food Safety Almanac*, 5th ed., Berlin: BfR, https://www.bfr.bund.de/cm/364/eu-food-safety-almanac.pdf.

The identification of the public agencies involved in official food safety control and the development of the scheme requires scrutinizing national legislation, including analysis of the different types of legal acts. The following list of relevant legislation may be used as a guide in analyzing national legislation to dissect the regulatory framework:

- Food law that establishes the institutional structure and defines the responsibilities of the public authorities involved in controlling food safety at the regional and central levels. The law might refer to secondary legislation for details on the specific responsibilities of public authorities in relation to food safety control. In this case, there is a need to check if these legal acts are as described and if they have been implemented and analyze the mandates of the public agencies established in these acts.
- The law that stipulates the elements of the national control system, the delegation of authority, the principles of official control, the types of control, and the collaboration among agencies.
- The law that regulates issues linked to consumer protection in relation to food.
- Laws that regulate the production of different types of food (for example, laws on baby food, milk and dairy products, meat, or fish); these laws may contain provisions on the official control in relation to food products that are within the scope of the laws.
- Secondary legal acts with the mandates of CAs in relation to food safety control.

Apart from providing information on how control functions are distributed across agencies, scrutinizing the regulatory framework will also show if these functions are articulated clearly and if there are any gaps, overlaps, or duplications. This exercise will also allow a determination whether the regulatory framework for food control arrangements is outdated and if there is a need for the internal harmonization of national legal acts. Thus, it may be useful to take notes on the legal documents during the work, including information of the dates when the provisions were adopted and the most recent revision. Notes are also useful on specific provisions that explain the questions that are of interest in the analysis. This will help in developing a list of recommendations on ways to enhance the national system of control in food safety.

Once the CAs responsible for official control have been identified along the food chain, the next step is to specify the types of official control they perform. This will reveal whether the definition of official control corresponds with the one used in the Codex.

To clarify what is meant by official control in food safety in the country, the following are required:

- The definitions of all types of official control in national legislation.
- Analysis of the definitions of all types of official control in national legislation (audits, inspections, monitoring, sampling, surveillance, and others). This is *required to help reach an understanding of which functions performed by the CAs may be classified as official control functions.*
- An examination of all the forms of control that are performed by each control agency in relation to food safety. *If several CAs are involved in food safety control, the forms of control performed by the CAs should be compared. This will not only provide information on what the CAs are doing in relation to food safety control, but it will also reveal if the forms of control exercised by each CA are actually different.*
- An assessment of the performance of CAs:
  - *What were the most severe actions taken by CAs in the case of businesses found to be in violation?*
  - *Are the CAs authorized to undertake terminal sanctions, intermediate sanctions, and preventive and corrective actions?*
  - *Have CAs undertaken actions at all three levels? If not, why not?*
  - *Is there any process or procedural hindrance?*
- A determination whether private sector entities have been authorized to perform certain forms of official control. Provide details on such cases, including the following:
  - *Cases in which control could be performed by the private sector on behalf of CAs*
  - *Who may be authorized to perform official control on behalf of the CAs (natural person or delegated bodies)*
  - *Conditions for delegating certain official control tasks to natural persons or delegated bodies*

In analyzing the mandates of control of CAs in the multiple agency system, pay attention to the approach followed in distributing control functions among the agencies. This may be guided by the type of product if the control over food of animal origin across the food chain is under one CA, while all the rest is under another CA. Conversely, different CAs may cover primary production, food processing, distribution, retail, and food exports and imports. A combined approach or an approach different from any of the above may also have been implemented.

Check the legal definition of food to determine if it is well formulated and if there is a clear distinction between foods of animal and nonanimal origin. If the definition is ambiguous, this might result in confusion among CAs in their areas of responsibility in relation to control functions.

If the control of food safety is based on a value chain approach, check if the same CA is responsible for controlling primary production in both the export market and the domestic market. In some developing countries, CAs are more focused on food exports and related operations rather than on food production for domestic consumption. This might cause gaps in control over food safety relative to primary production for the domestic market.

Another problem may be masked in the mandates of CAs responsible for the control of primary production and the processing of food of animal origin. Thus, milk or meat processing might be controlled by the CA responsible for primary production (operations linked to raw inputs, for instance, raw milk, meat, fish, and eggs) and the CA responsible for food processing (all operations after the processing of raw materials). In such systems, the distribution of control functions may not be well defined, and the CAs may not understand precisely at which stage they should be engaged in inspecting food processing facilities. This should be checked by scrutinizing CA mandates.

The potential of food exports is often a key incentive for strengthening food safety in developing countries. Governments are focused on improving food export procedures. However, because this area is often the least understood, it is important to analyze export procedures to determine if there are any gaps or uncertainties in regulations that might create barriers in the trade with foreign markets. For instance, in the case of the multiple agency system, it is important to check which CA issues export certificates and how well this function is articulated in the CA's mandate. This information is critical to understanding the trade with developed markets in which trading countries require food to be accompanied by certificates issued by the national CAs of the exporting countries. Also, check if there are approved model certificates and how difficult it is to identify the CA that issues export certificates and how this is done.

Laboratory services are an essential element in food safety control. Thus, identifying the agencies that test the samples for official control and how they are engaged in the system is a must. This requires an analysis of the structure of the national system of laboratories involved in food safety.

Checklist 4 provides a list of questions that will help identify the CAs in food safety area. It also includes questions that help clarify the place of laboratories in the food safety control institutional framework.[31] This exercise will reveal issues that need to be addressed to ensure efficient food safety control at the national level.

Even if a country has only one CA responsible for food safety control, food analysis laboratories may be under the control of several public bodies, such as the ministry of health, the ministry of trade, and the ministry of agriculture. An independent public agency may provide the laboratory services for official control. There are likewise cases in which private laboratories are authorized to carry out testing services for official control. In these instances, the authorizing CA needs to be identified. All this information should be reflected in the description of the institutional framework.

[31] For more information on quality infrastructure and the place of national food safety laboratories within the infrastructure, see Kellermann, Martin, 2019, "The Importance of QI Reform and Demand Assessment." In *Ensuring Quality to Gain Access to Global Markets: A Reform Toolkit*, Martin Kellermann, 17–40. International Development in Practice Series, Berlin: Physikalisch-Technische Bundesanstalt; Washington, DC: World Bank, https://thedocs.worldbank.org/en/doc/249621553265195570-00900220l9/original/FullQIToolkitReport.pdf.

Checklist 4. Institutional Framework

Part I. General questions

- List legal acts that define the institutional framework for official control in food safety.
- Is there a separate law that establishes the institutional structure of the national system of food safety control and regulates control arrangements?

Part II. Food safety control agencies

- What is the type of the institutional structure?
  - Single-agency model
  - Multiple agency model
  - Integrated agency model
- What CAs are engaged in food safety control?
- How is official control distributed among CAs across the food chain? Identify the CAs engaged in food safety control at each stage of the food chain.
  - Is the division of control clear?
  - Is the division of control among CAs based on the type of food product? Does it depend on the stage in a food chain?
  - How clear are CA mandates?
  - In case several CAs are involved in food safety control, are there any gaps, duplications, or overlaps in the relevant mandates? If so, specify what they are.
  - In case several CAs are involved in food safety control, what is the level of collaboration and information exchange among them?
  - Who is responsible for control in import and export processes?
  - Which CA issues export certificates? Specify if different CAs issue export certificates depending on the type of food product (animal or plant).
  - Which CA controls food imports?
  - What is the chain of command among CAs: centralized or decentralized?
  - How is food safety control organized across the district, regional, provincial, and national levels?[32]

Part III. Food monitoring laboratories

- Which laboratories perform food analysis for official control (both domestic and trade)?
- Does the government have a list of existing laboratories, both public and private?
- Under which CA do food analysis laboratories operate?
- Under which jurisdiction do food analysis laboratories operate (local, regional, provincial, or state authorities)?
- Is the system of communication between laboratories and CAs established?
- Do the food laboratories exchange information with other public health laboratories to identify outbreaks or illness clusters more quickly and target testing to find the contaminated food?
- Are there cases when private laboratories are authorized to provide food testing for official control? If yes, who is the authorizing CA? Do these laboratories have national of international accreditation? Is the list of approved laboratories publicly available?
- If the government relies on private laboratories, how often does the government audit these laboratories to ensure that they meet national standards and enforce national laws? Do public and private laboratories have the analytical ability to detect and identify pesticides, pathogenic bacteria, foodborne viruses, parasites, radionuclides, additives, environmental chemicals, and biotoxins? To answer this question, it may be useful to review the scope of accreditation of the laboratories involved in food safety control.
- How many private laboratories that provide services in food safety operate in the country?
- Is there an official register of private laboratories?
- Is there any officially defined demand for testing services in the country?
- What types of tests are currently lacking in the country?
- Is there enough capacity in the country to perform all food testing required for food exports?
- Are there cases in which FBOs or CAs need to use testing services from abroad because of a lack of national capacity? If so, in which countries?
- How many food samples are run by the government a day? A month? A year?
- Who collects the samples for analysis, inspectors employed by the government or private plant employees?
- Is there a sample database in the country in which this information could be collected? If so, who is the owner and is it available to the public?
- What types of food products are the most frequently targeted for testing? What types of food products are the least frequently targeted for testing?
- Does the government sample imported food at the same rate as domestic foods or at a higher or lower rate?
- What are the benchmarking (accreditation, certification) requirements for the government laboratories and the approved private laboratories?

[32] To answer this question, review the country's administrative structure and how the CAs in food safety are organized. For Instance, there may be regional departments and a central entity.

III. Assessment of food safety control arrangements

An understanding of how the food safety control system operates requires an exploration of the food control arrangements. This will entail analysis of a national strategic food safety control plan and a national food safety emergency response plan, if such exist, as well as the national FBO registration regime and inspection procedures along the agrifood value chain and for food imports and exports.[33] Checklist 5 is recommended for this purpose.

Food safety should be secured along the entire food chain (plow to plate, farm to fork, stable to table), thereby covering all potential hazards emerging from primary production, processing, transportation, distribution, retail, catering, food service, and the home use of food. Each link in the food chain has no ability or little ability to exert control over other links in the chain. Good regulation and enforcement may help address this issue. The production of raw materials, all inputs and outputs in food production, and materials that come into contact with food should be covered by a regulatory framework. Regulations should be implemented and enforced in line with food law and codes of practice in enforcement.

The risk-based approach should be applied at all stages of regulatory design and delivery. This includes the design of legislation using a risk-based scientific approach.[34] This might cover, for instance, risk criteria, the risk categorization of food and food establishments, and relevant regulations developed through science-based analysis. Regulatory agencies might also be required to plan and prioritize activities in a risk-based manner and implement risk-based approaches in inspections of premises to ensure that inspectors focus on activities that pose the highest risk. The use of non–risk-based regulations leads to unnecessary burdens and costs for the food industry and, ultimately, consumers.[35]

In a food safety system, primary responsibility for the safety of food resides with FBOs, that is, primary producers, processors, retailers, importers, and food service operators. If primary responsibility for food safety does not lie with the food business, then this problem needs to be addressed to improve the system. In lower-middle-income countries, stakeholders sometimes seem to believe that primary responsibility for food safety sits with the government even if national legislation states otherwise. In such cases, it may be useful to determine if awareness campaigns have been conducted or are planned and if the low level of awareness on this issue has had negative outcomes among consumers and FBOs.

Here, inspection means examination by an agency empowered to perform regulatory or enforcement functions relative to food products or systems for the control of raw materials, processing, and distribution. This includes in-process and finished product testing to verify that products conform to regulatory requirements.

[33] For more on national food safety emergency response plans, see FAO (Food and Agriculture Organization of the United Nations) and WHO (World Health Organization). 2010. "FAO/WHO Framework for Developing National Food Safety Emergency Response Plans." FAO, Rome. https://apps.who.int/iris/handle/10665/338628.

[34] "A risk-based scientific approach is the international standard for food safety legislation. The EU, United States, and other developed countries have legislative frameworks that embed a risk-based approach to food safety controls," page 9, World Bank, 2014, "Food Safety Toolkit: Legislative Reform," March, Investment Climate Department, World Bank, Washington, DC, http://documents1.worldbank.org/curated/en/905911471588854058/pdf/107902-v3-WP-TAG-TOPIC-investment-climate-PUBLIC.pdf.

[35] See World Bank, 2014, "Food Safety Toolkit: Institutional Structure," March, Investment Climate Department, World Bank, Washington, DC, https://documents1.worldbank.org/curated/en/200341471590393837/pdf/107902-v4-WP-TAG-TOPIC-investment-climate-PUBLIC.pdf.

A country may have well-drafted food laws, but, if the laws are not enforced (inspection, recalls, and so on), it will be difficult for FBOs to enhance their food safety practices.

Checklist 5. Food safety control arrangements: general questions

Strategic planning

- Is an inspection policy and sampling strategy in place?
- Is there a national strategic food safety plan? Does the plan include food safety control measures?
- Does the plan provide a good explanation of the existing food safety and food control system in the country?
- What are the key challenges in the food safety control system and the solutions based on the plan?
- Is there a national food safety emergency plan in the country? Does it include a rapid response and recall system?

Basic principles of food safety control

- Is food safety secured along the entire food chain?
- Is official control based on the from farm to fork approach?[36]
- Is food safety control preventive and risk based?
- Is the risk categorization of food businesses in place?
- Does primary responsibility for food safety reside with FBOs?

FBO registration system

- Is the FBO registration system in place?
- If a large number of FBOs are not registered and operate in informal or traditional markets, are there any procedures that allow CAs to collect information about them and track their activities?
- Is there a division of FBOs into groups based on risk assessment or other criteria? If so, do registration procedures differ across risk categories?
- Are FBOs inspected by CAs after the registration process and prior to the launch of activities?
- Are there any groups of FBOs that are not under the control of CAs? Who ensures food safety in these cases?
- How many FBOs are there? Is this information publicly available?
- How many registered FBOs are there? Is this total different from the total number of FBOs?
- How long does take to register an FBO? How much does registration cost?
- Is digital FBO registration possible?
- Are there any challenges to FBO registration? If so, what are they?

It is critical for the efficiency of the national food safety control system to ensure that all FBOs are under official control and that CAs have current information on FBOs along the food chain. In some countries, home or family food production is not controlled because of a perception that households produce an insignificant number of foods that cannot do any harm to consumers. This is not correct, and such production needs to be addressed. However, before making any changes, it is essential to understand why such practices exist in the country.

[36] This approach is a basis of food safety policy in the European Union. See Food Safety in the EU (dashboard), Directorate-General for Communication, European Commission, Brussels, https://european-union.europa.eu/priorities-and-actions/actions-topic/food-safety_en.

The primary objective of inspections is to help prevent unsafe food from reaching consumers and to support FBOs and enable them to improve the safety of their products. Often in developing economies, the primary goal of inspections is to determine cases of noncompliance and place sanctions on FBOs. This results in a negative attitude and a lack of trust with respect to food safety inspectors among businesses. The real goal of inspections may be revealed by the type of sanctions in the case of noncompliance and by statistics on the incidence of noncompliance. If fines are the most frequent outcome of food safety inspections, then the concept of food safety control should be changed in the country. The improvement of food safety and better consumer protection should be the primary goal.

A checklist or a list of questions is often used as a tool during various kinds of inspections and audits to structure the procedures and ensure that all critical issues are covered. Checklists for inspections are based on national food safety requirements, and checklists for audits are based on the requirements of the private sector standards on which the audits are based (checklists 6 and 7). The checklists may be detailed or include only essential issues that need to be inspected or controlled. In analyzing checklists, specify how detailed they are, if references to specific norms and details of legal acts that govern the requirements are provided, and how clearly the requirements are formulated.

Checklist 6. Food safety control arrangements: national inspection frameworks

The nature of inspection systems

- How many inspectors are there under each CA?
- Are the inspectors paid employees of the government, or are they paid by the food industry? Is the system a combination of government and private sector inspections?
- Does the government rely on privately employed inspectors? If so, what are the criteria?
- If the government relies on privately employed inspectors, how often does the government audit these inspectors to ensure that they enforce national food safety laws? What are the licensing requirements?
- Is there official data on the sanctioning or firing of privately employed inspectors?
- How many FBOs are under the control of each inspector?
- How many times a year are FBOs inspected?
- Do inspection activities focus on many parts of the food supply process from farms to the retail sector, or do they focus on only one point in the food chain?

The regulation and monitoring of inspection procedures

- What is the primary objective of inspections?
- Are formal inspection procedures and tools, including checklists, in place? Are the procedures well formulated and updated?
- Have inspection checklists been developed for different types of FBOs? If so, is this done based on the type of food product, the type of food production operation, volume, size, and so on?
- Do FBOs have access to inspection procedure tools, for example, inspection checklists?
- Could inspection tools, such as checklists, be used by FBOs as guidance? Are they clear and easy to understand? Do they help avoid subjectivity in assessing food safety in facilities?
- Is there any schedule of planned inspections? Is the schedule risk based?
- Do inspectors have the authority to close FBOs? What other authority do inspectors have if they find noncompliance during inspections, for example, fines, seizing food?
- Are there initial inspections by CAs before FBOs are approved?
- Do CA inspectors consider the information received on FBOs from certification bodies?[37]
- How are data on inspections collected and analyzed?
- Is there any official database of the results of inspections? If so, who has access to this database?

[37] See vTPA Programmes (Voluntary Third-Party Assurance Programmes), Standards and Trade Development Facility, World Trade Organization, Geneva; United Nations Industrial Development Organization, Vienna, https://stdf-vtpa-survey.wto.org/.

Checklist 7. Food safety control arrangements: food imports and exports

Food imports

- Is there a public register of food importers?
- Which CA is authorized to control food imports?
- Is there a risk-based control program for imported food?
- Are food import control procedures in place? Do these include any kind of certification and laboratory testing?
- Is there a system of notification for food imports? Who manages it?
- How many border inspection posts (BIPs) for food imports exist in the country?
- Do all BIPs cover all types of imported foods, or is there a division of BIPS based on the origin of food, for instance, plant food or food of animal origin?
- Are BIPs well equipped and able to undertake all required tests?
- Do the CAs responsible for food import controls have their own inspectors at BIPs?
- What is the level of collaboration among the CAs authorized to control food imports, state customs services, and other agencies involved in food import control?
- Do FBOs have access to the food safety requirements of exporting countries?
- Do CAs in the country have the capacity to support FBOs in meeting exporting country requirements? How does the system operate in practice?
- Is domestic food considered by consumers in the country to be as safe as food shipped from other countries?

Food exports

- Is there a public register of food exporters?
- Are there any additional inspections of food exporters?
- How different are the food safety requirements for FBOs that operate on the domestic market and FBOs that operate in export markets?
- The inspectors of which CAs issue export certificates?
- How many CAs are involved in providing export certification services?
- Do the CAs responsible for food exports have enough capacity to check if the food produced meets export requirements?
- How much time does it take for an FBO to receive an export certificate?
- Is there a system of inspections of FBOs in importing countries? How does it operate?
- Is the exported food considered to be safer by national consumers?

National food recall and traceability systems are essential elements of the national food safety control system. It is therefore critical to analyze whether these elements are in place and how they operate. The following questions facilitate an analysis of recall and traceability systems and reveal issues that need to be addressed in the effort to enhance food safety control in the country.

Checklist 8. Food recall and traceability

- Do food laws allow measures to be taken in emergency situations and to recall food products?
- Are companies required to release information to the public on the distribution of food that has subsequently been recalled so consumers may obtain the information quickly and easily?
- Is there a national program or national plan on food recall and traceability?
- Which CAs manage national recall and traceability systems?
- Does the national program require companies to recall food products that are found to be unsafe? If so, what are the responsibilities of FBOs in relation to unsafe food? Does the national program require food companies to label their processed food products so consumers can identify the origin? What is the level of compliance with the labeling and recall requirements in the country?
- Does the national program require that processors label their products with lot numbers or other identification to facilitate traceback and recall?
- Are processed foods required to be packed in a manner that would make tampering quite evident, for example, the use of seals or closed packaging?

Checklist 9. Foodborne disease surveillance and investigation systems

- Is there an incident management system at the national level?
- Does the food industry have a mechanism to inform government officials of threats against their products or unusual consumer complaints? Is it a mandatory requirement or voluntary initiative?
- Is information about food safety emergencies disseminated quickly to consumers in a manner that allows them to avoid illness?
- Which agency or agencies are involved in the national outbreak alert and response system?
- How sensitive is the surveillance system? Does it only work in the event of large outbreaks of foodborne illness, or can it identify small clusters of incidents before they spread and become a crisis? If such differentiation exists, how large or small are the clusters defined in national legislation?
- Is the surveillance system active or passive? Does it give risk managers real-time information, or must they wait for years to identify trends in incidents of food poisoning?
- Is surveillance coordinated across the regions of a country? Is it coordinated with health agencies in neighboring countries and with international organizations?
- Does the country collaborate with food safety authorities in other countries under the International Food Safety Authorities Network?[38]

[38] For more details, see INFOSAN (FAO/WHO International Food Safety Authorities Network) (website), Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/food/food-safety-quality/empres-food-safety/early-warning/en/

IV. Assessment of the capacity-building framework

In a national food safety system, a capacity-building framework is a set of activities aimed at expanding the technical, scientific, and regulatory capacity of national food safety authorities and the food industry.

Inadequate capacities in developing countries continue to be a major obstacle in the prompt and efficient response to food safety challenges and ensuring appropriate consumer protection. Underdevelopment poses difficulties in the production of safe food for domestic consumption and export. Underdevelopment has technical and human dimensions. Capacity-building activities should therefore include (1) steps to improve technical aspects, such as the use of laboratory equipment or other modern technologies, and (2) initiatives focused on strengthening domestic expertise in food safety, including the creation of a pool of qualified consultants by strengthening the national educational program. The importance of the latter cannot be underestimated.

The revision of the capacity-building framework and the associated responses within a country require the prioritization of areas in which decisive actions are required the most in the short-, medium-, and long-term perspectives.

For the purpose of the assessment, the revision of a national capacity-building framework might be divided into two stages: (1) ensuring the appropriate correspondence with guiding principles and (2) reviewing the various components of the framework to confirm that they are suitable.

Guiding principles of a capacity-building framework in food safety

Ownership and leadership

- All CAs responsible for the development and implementation of national food safety strategies and programs must be clearly identified.
- The senior management of the CAs responsible for the development and implementation of national food safety strategies and programs must clearly show commitment, provide consistent leadership and management, and support ongoing processes aimed at improving food safety in the country.

Demand-driven technical support

- The hierarchy of needs in capacity building in relation to food safety is well defined by CAs.
- CA needs are clearly articulated to external partners.
- CAs work in close collaboration with external partners on the development of capacity-building programs.
- The level of coordination among external partners is sufficient to avoid overlap and discrepancies in capacity-building activities.

The proof of evidence: international expert working groups organized to coordinate technical support in food safety areas in the country.

Context-specific

- All capacity-building activities are based on approaches that take account of the concerns and the realities in the country from different perspectives, including economic development, environmental issues, and the cultural and historical context.

Participation

- Capacity-building activities involve all stakeholders in the food sector, including those (1) who might be influenced by new requirements, (2) who lack knowledge on how to implement modern approaches to food safety, and (3) who should cooperate and coordinate food safety–related activities, for instance, public sector food laboratories and regional food safety inspection authorities.

Learning and knowledge exchanges

- The existence of systematic, comprehensive, and effective programs of training and education in food safety to build national food safety expertise and skills among both public and private sector experts.

The proposed analysis of national educational syllabuses will determine (1) the level of understanding of the importance of strong national expertise in food safety, (2) the level of the capacity available to build strong national expertise in food safety, and (3) the extent to which the national system is based on modern approaches to food safety, for example, whether the national food safety control system is based on a reactive or a preventive approach or whether a substantial upgrade of the system is required. The following questions may be helpful in the analysis.

Checklist 10. Capacity-building framework in food safety

- When does the need for training and the strengthening of education in food safety usually arise? Is it only after an incident or is the country following a preventive approach? Is there an understanding that food safety incidents may occur because FBOs lack expertise or are not in a position to apply food safety knowledge given the deficiency in supporting policies or infrastructure?
- Do educational establishments and related disciplines exist that are focused on the food industry or are there separate departments in professional and higher educational establishments focused on the food industry and related disciplines, for instance, food technology, quality control, food safety management, food microbiology, and food chemistry?
- How well are technical institutions equipped? Are there opportunities to learn food safety management in practice through hands-on experience or do educational programs follow a theoretical approach?
- When were the food safety syllabuses developed? What is the basis of these syllabuses?
- Are there refresher courses and advanced training for CA staff on food safety issues?
- Do CAs address the specific training needs of food inspectors and laboratory analysts throughout the country or is training available only for limited numbers of staff in central offices?
- How well are extension service staff trained in food safety? Are they qualified at a level that enables them to provide advice to food businesses across the food chain from farm to fork?
- How high is the level of awareness of food safety and food quality issues in the public and private sectors?
- Are there training programs implemented by CAs or other stakeholders for FBOs with a focus on increasing knowledge about better practices, including improved personal and environment hygiene and the use of tools to monitor the safety of foods or the use of the cold chain? If so, do CAs track effectiveness and efficiency?

The proof of evidence: awareness campaigns in social media that are supported by CAs; active consumer protection organizations; informative CA websites for various food safety sector stakeholders

Checklist 11. Components of the capacity-building framework in food safety

- Infrastructure to perform all types of official control on food safety

The analysis of CA infrastructure includes the assessment of (1) the technical level of food control laboratories and (2) the availability of rapid food safety testing that may be performed by inspectors during on-site visits, as well as other equipment and transport facilities that might be required, such as mobile laboratories, means of transportation, and publishing staff.

- Budget allocations on capacity-building activities allow the technical infrastructure of CAs to be supported at a level that is sufficient to permit CAs to undertake official controls on food safety and implement relevant learning and awareness programs.
- CA capacity to (1) cooperate with international organizations on the harmonization of international standards and national food safety policies and regulations; (2) the use of modern tools that have been shown to be efficient in strengthening food safety, developing the food industry, and ensuring better consumer protection across the world; and (3) the capacity to carry out risk assessment
- Participation in international standard-setting organizations
- Disease surveillance systems
- Scientific and technical expertise
- Existing extension and advisory services in the food sector
- Food legislation and the regulatory framework
- Collaboration and cooperation across food control agencies
- The implementation of food quality and safety assurance systems

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Section III[39]

Food Fortification

[39] This updated version of the IFC Scan Guide Section III (Food Fortification) reflects practical experience from recent assessments and aims to improve the Guide's clarity, relevance, and usability. The team gratefully acknowledges the valuable contributions of WHO colleagues Juliawati Untoro and Manasi Shukla Trivedi to its development.

1. Introduction[40]

Since the 1992 International Conference on Nutrition (FAO and WHO 1992), food-based approaches have been considered the most sustainable in addressing micronutrient deficiencies. Food fortification is one of these food-based approaches.

"Fortification," according to the World Health Organization (WHO), "is the practice of deliberately increasing the content of an essential micronutrient, i.e., vitamins and minerals (including trace elements) in a food so as to improve the nutritional quality of the food supply and provide a public health benefit with minimal risk to health."[41]

Governments across the globe often rely on national food fortification policies and programs as tools to address issues linked to the nutritional status of populations. Among the elements affecting the efficiency of national food fortification policies and programs is food fortification legislation, along with the monitoring system of competent authorities (CAs) at food processing facilities and border control points, the enforcement of relevant laws and regulations, capacity building, and awareness activities. To understand how a national food fortification framework should operate, these and other elements should be analyzed and assessed through a stepwise procedure.

[40] This document is focused on industrial food fortification. It does not cover biofortification or home food fortification.

[41] Fortification of Rice (dashboard), eLENA (e-Library of Evidence for Nutrition Actions), World Health Organization, Geneva, https://www.who.int/elena/titles/rice_fortification/en/.

2. Key definitions

The following terms are among those covered by key food fortification definitions: essential nutrient, micronutrient, food, food vehicle, fortification, malnutrition, mandatory and voluntary nutrient addition. Proper definitions are critical because definitions affect the interpretation and implementation of laws and the efficiency of national food fortification programs. To check if the definitions used in national legislation correspond to international practice, the definitions in Codex standards and guidelines should be examined, including (a) the revised Guidelines on Nutrition Labelling (FAO and WHO 2021) and (b) the revised General Principles for the Addition of Essential Nutrients to Foods (FAO and WHO 2015).

"**Essential nutrient** means any substance normally consumed as a constituent of food which is needed for growth and development and/or the maintenance of life and which cannot be synthesized in adequate amounts by the body" (FAO and WHO 2015).

"Food means any substance, whether processed, semi-processed, or raw, which is intended for human consumption, and includes drinks, chewing gum, and any substance which has been used in the manufacture, preparation, or treatment of "food", but does not include cosmetics, or tobacco, or substances used only as drugs" (FAO and WHO 2024).

"**Food vehicle** is a food product, such as wheat flour, that is fortified through the addition of fortificants. The term "vehicle" is derived from the fact that these food products are the means by which additional vitamins and minerals are provided to those who consume them" (WHO 2021).

"Fortification or, synonymously, **enrichment** is the addition of one or more essential nutrients to a food, whether or not it is normally contained in the food, for the purpose of preventing or correcting a demonstrated deficiency of one or more nutrients in the population or specific population groups" (FAO 1996, annex 4).

"Malnutrition refers to deficiencies, excesses, or imbalances in a person's intake of energy and/or nutrients. The term malnutrition covers two broad groups of conditions. One is undernutrition, which includes stunting (low height for age), wasting (low weight for height), underweight (low weight for age), and micronutrient deficiencies or insufficiencies (a lack of important vitamins and minerals). The other is overweight, obesity, and diet-related noncommunicable diseases (such as heart disease, stroke, diabetes, and cancer)" (WHO 2024).

"**Mandatory nutrient addition** is when competent national and/or regional authorities require food manufacturers to add specified essential nutrients to particular foods or food categories" (FAO and WHO 2015).

"**Micronutrients** is a collective term for specific vitamins and minerals that the human body requires daily in small quantities. Although calcium is not strictly a micronutrient, it is often included in this definition." (WHO 2021).

"**Nutrient** means any substance normally consumed as a constituent of food: (a) which provides energy; or (b) which is needed for growth, development, and maintenance of life; or (c) a deficit of which will cause characteristic biochemical or physiological changes to occur" (FAO and WHO 2021).

"**Voluntary nutrient addition** is when food manufacturers choose to add specified essential nutrients to particular foods or food categories" (FAO and WHO 2015).

3. General background

It is recommended that the assessment start with answers to the following five questions:

- Is there a national food fortification program?
- Is there a national food fortification policy or strategy and action plan?
- Is fortification embedded (or included) within an existing national nutrition or micronutrient policy or strategy and action plan?

Appropriate, positive changes in food fortification policies and programs will show if food fortification is a government priority and if the government is undertaking the initiatives necessary to realize the priority.

- What food vehicles are currently fortified in the country (mandatory and/or voluntary)?
- Is fortified food mainly produced domestically or imported?
- How is fortification/nutrition integrated into the food act and related primary legislation?
- Are there specific laws, regulations, or standards on food fortification? Are they mandatory or voluntary?
- Which competent authority (CA) is responsible for:
  - a. technical oversight of food fortification/nutrition?
  - b. compliance monitoring and enforcement?
- What challenges exist in fortifying specific foods (e.g., cost, technical feasibility, supply chain)?

The answers to these questions should facilitate the development of the outlines of a food fortification system.

For the analysis of a national regulatory framework in food fortification, check the Global Fortification Data Exchange, which aggregates data on five commonly fortified foods incl. maize flour, oil, rice, salt, and wheat flour and publishes indicators on 196 countries on the scope of food fortification legislation, fortification standards, the proportion of industrially processed foods, the availability of regulatory monitoring protocols, the quality of fortification, and population coverage.[42]

[42] See GFDx (Global Fortification Data Exchange) (dashboard), https://fortificationdata.org/.

4. Key food fortification actors

The next step is to determine the key players in the area, that is, undertake *fortification stakeholder mapping and the identification of food fortification champions*. To achieve this, it may be useful to follow approaches and use tables listed in Section II (Food Safety) of the IFC Scan Guide. Food fortification stakeholder mapping will allow the following questions to be answered:

- Who are the main actors influencing and formulating food fortification policies (e.g. CAs and regulatory bodies; private sector including food business associations; civil society and non-governmental organizations (NGOs); academia and research institutions; international organizations; development partners and donors)?
- Are there private sector initiatives in food fortification (voluntary programs, public-private partnerships, product innovation, advocacy)?
- What multisectoral coordination or partnership mechanisms exist (e.g., national bodies, alliances, task forces)?
- What is the level of stakeholder involvement in developing policies and legislation?
- Is there a national registry/database of enterprises involved in fortification (producers, importers, exporters, wholesalers, retailers, premix manufacturers and importers)? How often is it updated?
- Which laboratories (public and private) are engaged in food fortification testing?
- What are the key challenges for:

  a. Food industry

  b. Government

  c. Consumers

To understand the level of stakeholder involvement in the development of food fortification policies and legislation, the way the relevant policy and legal documents are usually drafted should be examined. For instance, there may be a practice of organizing group stakeholder meetings by CAs, and the groups initiate the drafting process. Or the drafts may be developed by the CAs and then shared with stakeholders, who are invited to review the material and suggest changes.

5. National policy, legislation, and the regulatory framework

An analysis of the national policy and regulatory framework would enable the following:

- An understanding of the principles that guide national food fortification policy
- A determination of whether these principles are in line with the Codex Alimentarius
- An understanding of whether relevant national legislation is sufficiently flexible to meet population needs and evolve with advances in science and food technology
- The identification of any standards focused on food fortification
- A determination of the requirements of food fortification
- An understanding of how food fortification controls are organized in both the public and private sectors.

Answers to the following questions would facilitate an *assessment* of food fortification *legislation*:

- What is the scope of the food fortification legislation (specific foods only, or broader coverage)?
- How were the requirements on food fortification adopted (a) in law or (b) through regulations and standards?
- Is there a specific national law on food fortification or are food fortification provisions embodied in the basic food act or in numerous food-related laws?
- If the specific national law on food fortification exists, when was it adopted, and has it been revised in the last 5 years?
- Are there discrepancies between national legal requirements, standards, and technical regulations (lack of internal harmonization)? If so, how are they resolved?
- Are there standards on the composition, nutritive properties, safety, and hygiene of fortified foods?
- Are there regulations on the methods of manufacturing, packaging, storing, transporting, and distributing fortified foods?
- Are there specific labeling and advertising requirements for fortified foods (including logos, claims, and quality marks)?
- How are vitamin and mineral premixes regulated (incl. definitions, licensing, registration)?
- Do national food fortification laws and regulations refer to international instruments (e.g., Codex, WHO/FAO)?

The answers to these questions will demonstrate the extent to which food fortification arrangements are up to date and internally harmonized, and how rapidly national food fortification requirements can be revised when necessary.

6. The scope of food fortification in the country

- Do fortification requirements apply equally to domestically produced and imported foods?
- Is food fortification mandatory or voluntary? If food fortification is mandatory, are the foods that should be fortified specified and have all appropriate specifications been established?
- On what basis are food vehicles and nutrients selected (e.g., consumption data, deficiency data, etc.)?
- How often is the list of mandatory food vehicles reviewed, and is there a formal review mechanism?
- If fortification is mandatory, are the specific foods and specifications clearly defined?

Mandatory food fortification is initiated and overseen by the government, while, in voluntary food fortification, food business operators (FBOs) may decide (or not) to add nutrients to foods they produce. In both cases, food fortification should be governed by regulatory limits. This is critical and should be checked during the analysis of the food fortification framework in a country.

- Are there exceptions to fortification requirements for foods/nutrients?
- Are fortified foods targeted at the general population or specific groups (e.g., children, pregnant women)?
- Are Recommended Dietary Allowance (RDA) levels considered in legislation/regulations? If so, are they based on Codex, national studies, or risk assessments?
- Are RDAs applied as population averages or differentiated by demographic/vulnerable groups?
- Have Recommended Daily Intakes (RDIs) or Nutrient Reference Values (NRVs) been established at the national level, and if so, through which mechanisms?
- Which authority is responsible for establishing and updating RDI/NRV values, and how often are they reviewed?
- Are national RDI/NRV values aligned with Codex Alimentarius NRVs[43], or are they based on national dietary intake data or other assessments?

Recommended RDAs and RDIs, or NRVs, serve distinct functions within national nutrition frameworks. RDAs are primarily used to inform public health policy, dietary adequacy assessments, and food fortification design, while RDIs/NRVs are mainly applied for nutrition labeling and consumer information.

Understanding whether RDAs and RDIs/NRVs are formally established at the national level, and the basis on which they are determined, is essential to assess whether these reference values are appropriate for the country context. This includes whether they are informed by country-specific evidence (such as dietary intake data, nutritional status or risk assessments), or whether they rely solely on direct adoption of international reference values without national adaptation, which may not fully reflect national dietary patterns, geography, or population needs.

- Are any categories of foods, domestic or imported, exempt from fortification requirements, and if so, on what grounds?

Exemptions may be adopted to meet the needs of people with certain medical conditions. If this is the case, the exemption procedures must be clear, including how the exempted food is handled.

[43] Lewis, J. 2019. Codex nutrient reference values. Rome. FAO and WHO.

7. Alignment with international guidelines

- Are key food fortification terms in line with the Codex Alimentarius and the guidelines of the Food and Agriculture Organization of the United Nations (FAO) and WHO (see above)?
- If food fortification with vitamins and minerals is voluntary, to what extent are the conditions under which it is permitted clearly defined (food categories, nutrient levels, labeling requirements etc.)?
- To what extent does the food fortification standards development process take international and regional guidelines into account?
- Are mechanisms in place to adapt international/regional standards to national context?
- Are national fortification standards aligned with WHO global recommendations on micronutrient levels (min/max)?

8. Compliance and quality control measures

The answers to the following questions help in assessing compliance and quality control arrangements:

- Which CAs are responsible for the official supervision of any issues in food fortification?
- Are the respective mandates, roles, and functions of these authorities clearly defined in legislation/regulations and/or implementing instruments (SOPs[44], inter-agency coordination mechanisms)?
- Are there any overlaps, gaps, or discrepancies between the functions of CAs (e.g. between standards-setting, inspection, laboratory testing, and enforcement)? If yes, what are the practical consequences for compliance (duplication of inspections, unclear requirements, inconsistent decisions)?
- How are overlaps, gaps, or discrepancies in the mandates of CAs addressed in practice, including through mechanisms such as lead agency designation, joint inspections, referral pathways, formal coordination committees, and dispute-resolution procedures?
- Which CAs perform the official supervision of imported fortified foods?

Responsibilities for the control of fortified foods are often distributed across multiple authorities, including food safety control bodies and conformity assessment bodies. Clear and well-defined delineation of roles and responsibilities is therefore essential to prevent overlaps, address potential gaps, and ensure effective and coherent regulatory oversight.

- Where are the regulatory procedures for official inspection, investigation, sampling, and testing of fortified foods formally published, and to what extent are they current?
- Are there any inspection protocols for fortified foods?
- Does national legislation provide for the enforcement of national food fortification requirements, and if so, what mechanisms does this involve?
- What mechanisms are in place to ensure compliance of imported fortified products with national requirements, such as border testing, market surveillance, or both?
- What is the current level of laboratory readiness to conduct compliance and quality control testing for fortified foods and premixes, including the availability of qualified staff, appropriate equipment, reagents and reference materials, accreditation status, validated analytical methods, analytical capacity, and rapid test methods?
- Are fortified products routinely tested for compliance across all food categories?
- How often are samples collected from production sites and retail (legally required vs. actual practice)?
- To what extent are laboratory results provided to businesses within appropriate timeframes?
- Are there accredited/approved laboratories for testing fortified foods and premixes? Are test methods validated?

[44] Standard Operating Procedures

- Are private laboratories authorized or permitted to participate in food fortification testing, including for regulatory control and compliance purposes?
- To what extent are legally defined minimum and maximum fortification tolerance levels established for fortified foods and premixes, and how consistently are these levels applied across all laboratories involved in food fortification testing?

An effective mandatory food fortification system requires both an adequate laboratory network to support testing by food business operators and competent authorities' official controls, as well as clearly defined tolerance levels for minimum and maximum fortification values. Together, these elements ensure that laboratory results can be generated, interpreted, and enforced in a consistent and predictable manner; in their absence, compliance with fortification requirements cannot be reliably assessed in practice.

- Are there published, up-to-date inspection protocols for fortified foods (domestic and imported)?
- Does the inspection checklist include fortification requirements, and are inspectors trained in sampling, handling, and transport protocols?
- To what extent does legislation establish enforcement mechanisms for fortification requirements, including sanctions or corrective measures such as reconditioning, relabeling, or destruction?
- Are inspection criteria and compliance assessment methods for fortified foods transparently communicated to FBOs (what exactly will be checked, acceptable tolerance ranges, sampling plans, inspection frequency, laboratory methods, decision rules, and appeal mechanisms)?
- Are monitoring systems effective in ensuring safety and achieving nutrition outcomes?
- Which CA(s) are responsible for the official supervision of production, import, storage, marketing, and retail of fortified foods?
- Are the requirements in food fortification clear to all stakeholders, including provisions that define prohibitions in relation to food fortification?
- Is the monitoring of food fortification programs and other initiatives efficient? Does it enable steps to ensure that fortified foods are safe and that fortification achieves the expected outcomes?

In relation to safety, quality controls should enable a determination that food fortification is performed within the required limits to avoid the underuse or overuse of certain micronutrients. For instance, tools should be established to detect excessive levels of iodine in salt to avoid cases of thyrotoxicosis. This requires checks of the protocols used in laboratory testing.

- Are there special provisions on the handling of fortified foods? Do incentives exist to promote food fortification, for example, favorable tax or tariff treatment or priority in the display of the foods on shelves in retail outlets?
- Are there inspection procedures and protocols for the official supervision of the production, transportation, storage, labeling, marketing, retail, import, and export of fortified foods?
- Is there a requirement for mandatory quality control procedures that should be developed and routinely followed by FBOs that are applied throughout the manufacturing process to ensure that finished products comply with food fortification regulations?
- What are the sanctions for failure to comply with regulatory requirements on food fortification?
- What are the consequences if it is discovered that foods do not meet food fortification requirements? For instance, there may be requirements to recondition foods so that they meet food fortification requirements, to relabel foods so they are not consumed, or to destroy foods.

To protect consumers, it is critical for any national food safety system to establish mechanisms for the detection of unsafe foods or foods that do not meet regulatory requirements and to ensure that such foods will not reach consumers unless they are reconditioned. The same approach is relevant in food fortification. Thus, the consumption of foods in which nutrients have been overused may adversely affect health, especially the health of vulnerable population groups.

9. The assessment of the national capacity to undertake food fortification

Food fortification policies and regulations are tools that shape a system. To ensure that the system works and is efficient, the public and private sectors should possess adequate capacity. The answers to the following questions will help in assessing this capacity:

- What share of the budget is allocated to food fortification activities (including inspections, laboratories, and training), and is this allocation adequate to meet the country's needs?
- Are there tax/tariff incentives for premix imports?
- Is there a reliable, sustainable national premix procurement/distribution system?
- Are there subsidies or financial mechanisms to support SMEs in acquiring fortification equipment?
- Is there an adequate number of trained official inspectors and private sector experts?
- Do official websites provide up-to-date, consolidated information and downloadable tools for FBOs (laws and regulations, standards, guidance notes, templates, checklists, reporting forms)? If not, how are FBOs currently informed, and what are the main information gaps?
- What is the level of preparedness of the food industry to undertake food fortification, including access to and functionality of equipment required to combine premixes with food products?
- Are there national learning and awareness programs on food fortification?
- Are there functional monitoring and evaluation systems to track implementation and impact?
- Are there regular capacity-building opportunities (training, workshops, guidance) for regulators, laboratories, and industry?
- Are there academic or professional training programs that include fortification modules?
- To what extent is technical assistance available at the national or subnational level to support industries or laboratories facing technical or operational challenges in food fortification?
- Are there systems for reporting, investigating, and addressing non-compliance (complaints, market surveillance etc.)?
- Are there national/subnational coordination platforms (alliances, working groups) to review gaps in, and propose actions for, the food fortification framework?

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Section IV

Food Loss and Waste

1. Introduction[45]

The food loss and waste (FLW) challenge has captured world attention because of its multiple negative impacts on the environment, the economy, and the livelihoods of people worldwide.

Because FLW problems, to a greater or lesser extent, are common to most countries, different initiatives have been developed and applied worldwide. The establishment of national policies and a regulatory framework is one such initiative.

Prior to learning what and how to assess and understand the relevant national policies and regulatory framework and how they operate, it is necessary to focus on what is meant by food loss and waste; why these two terms are often used together; and the cases in which there is a need to use them separately.

The term food loss and waste is used widely In many sources. At the same time, in a number of cases, either food loss or food waste is used. What is the difference? Why is it sometimes necessary to use two approaches in working on FLW? The answer is that the use of the terms depends on the purpose. The application of food loss and food waste together is common in cases in which there is a need to describe issues linked to total food losses and waste through the food value chain, from primary production to food consumption and to focus on common solutions. The use of food loss or food waste separately arises because of the need to focus on challenges and solutions that are associated with specific stages in the food value chain. Food loss is associated with upstream operations, including food production and processing, and food waste is relevant to downstream stages, such as distribution, retail, catering, and consumption.

- There is no single definition of FLW. Definitions vary depending on the FWL issue that is in focus, for example, as follows (Sirisupluxana and Bunyasiri 2021):
  - Context: food security, the environment, the social or economic context
  - Scope: about human consumption or not, or both situations
  - The stage of the food value chain
  - Assessment criteria: utilization, edibility, nutrition
  - By type: qualitatively or quantitively.
- For instance, the Food and Agriculture Organization of the United Nations (FAO) defines food waste as "the decrease in the quantity or quality of food resulting from decisions and actions by retailers, food service providers, and consumers."[46] Food means "any substance, whether processed, semiprocessed, or raw, which is intended for human consumption, and includes drinks, chewing gum, and any substance which has been used in the manufacture, preparation, or treatment of 'food' but does not include cosmetics or tobacco or substances used only as drugs."[47]
- Meanwhile, food waste is "any food, and inedible parts of food, removed from the food supply chain to be recovered or disposed (including composted, crops ploughed in/not harvested, anaerobic digestion, bio-energy production, co-generation, incineration, disposal to sewer, landfill or discarded to sea)" (EU 2018, 2).

[45] While the problem of food loss and waste has many dimensions, this paper is focused on an assessment of policies and regulations, as well as official control arrangements and capacity-building activities linked to food production and related activities. It does not cover national environmental, infrastructure, fiscal, or other policies that might guide certain aspects of FLW problems.

[46] Food Loss and Food Waste (dashboard), Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/platform-food-loss-waste/en/

[47] See "General Standard for the Labelling of Prepackaged Foods," Standards (database), Codex Alimentarius, International Food Standards, Codex Alimentarius Commission Secretariat, Food and Agriculture Organization of the United Nations, Rome, http://www.fao.org/fao-who-codexalimentarius/codex-texts/list-standards/en/.

- "Food that completes the food supply chain up to a final product, of good quality and fit for consumption, but still doesn't get consumed because it is discarded, whether or not after it is left to spoil or expire," is the definition of food waste according to the United Nations Environment Programme. "Food waste typically (but not exclusively) takes place at retail and consumption stages in the food supply chain," it continues. It also splits FLW into two parts and defines food loss as "food that gets spilled, spoilt, or otherwise lost, or incurs reduction of quality and value during its process in the food supply chain before it reaches its final product stage. Food loss typically takes place at production, post-harvest, processing, and distribution stages in the food supply chain."[48]

The definitions of the corresponding terms used in national legislation may vary. Thus, the quality of the assessment of national policies and the regulatory framework on FWL depends on the definitions that are used.

In reviewing national policies and legislation that govern the public management of FLW, pay attention to how FLW together and food loss and food waste separately are used, the scope of the definitions, the food value chain stages that are covered, and the context.

While FLW is a common problem through the world, the reasons, the size of the problem, and the elements of the problem vary from country to country. According to FAO (2015, 2), "food loss and waste are heavily dependent on the specific conditions and local situation in a given country or culture." This should be considered in any analysis of how FLW management is built at the national level. Based on FAO estimates, more than 40 percent of FLW in developing countries is associated with food losses because of poor infrastructure, lack of knowledge about the application of good practice, and technical limitations at downstream food production stages. In developed economies, the biggest share of FLW by volume is represented by food waste at the retail stage and after foods reach consumers because of consumer behavior or because of private food standards and lack of specific regulations that address issues related to food waste. This is worth consideration in assessing a national FLW framework.

[48] "Definition of Food Loss and Waste," United Nations Environment Programme, Nairobi, Kenya, https://www.unep.org/thinkeatsave/about/definition-food-loss-and-waste.

2. General background

It is recommended that any assessment start by checking the FAO Food Loss and Waste Database, which provides information on FLW by countries across the food value chain based on resources that are open to the public.[49] The database shows "the level and variety of losses by showing the range of losses by stage of the value chain."[50] This will be helpful in identifying the stage of the value chain at which interventions aimed at reducing FLW are most required.

The next step is to check if the country has a system to measure FLW. If it does, several questions should be addressed, as follows (UNEP 2021):

- What is the country's food loss index?
- What is the country's food waste index?
- Does the country follow the FAO methodology for identifying the FLW index?

Browsing through information linked to national food loss and food waste indexes will also provide useful information for the identification of the stages of the food value chain stages at which the FLW problems are most acute and where policy and regulatory interventions as well as capacity-building activities are most needed.

To understand the general background, the following issues should be addressed:

- Is there a national FLW strategy? If so, check the following:
  - How FLW is defined in the strategy?
  - What is the scope of FLW in the strategy?
  - What is the basis of the strategy (for example, FAO documents, regional or international treaties, and so on)?
- Are there national policies on FLW?

> **!** The topic of FLW is relatively new on the agendas of policy makers. There are few examples across the globe of comprehensive national FLW strategies published by national governments. There is thus a high probability that there will be no national FLW strategy or policies in the country where the assessment is being performed. Elements of an FLW policy and regulatory framework may be scattered across many different laws.

- Is there a national food waste prevention program?

> **!** Food waste prevention programs are a well-known instrument in European countries. They are focused either on the reduction of household waste, as in the LIFE-FOODWASTEPREV Project in Hungary, or on covering the entire food value chain, as in the Estrategia Nacional, Más alimento, menos desperdicio, in Spain, Denmark without Waste II, and the Food Waste Prevention Plan of the Croatia (Caldeira, De Laurentiis, and Sala 2019).

- Are there sector guidelines on FLW? If so, analyze which of them target food safety policy areas and how.
- Is there specific national FLW legislation and regulations?
- Which CA is responsible for officially checking compliance with FLW requirements during food production stages and at retail?

[49] Food Loss and Waste Database (dashboard), Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/platform-food-loss-waste/flw-data/en/

[50] See "How to Use the FLW Database," Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/platform-food-loss-waste/flw-data/user-guide/en/

3. Key FLW actors

The next step is to determine the key players in the area, that is, undertake FLW stakeholder mapping and the identification of FLW champions. To accomplish this, it may be useful to follow approaches and use tables listed in Section II of the IFC Scan Guide.

FLW stakeholder mapping will allow the following questions to be answered:

- Who influences and formulates national policies?
- Are there any private sector initiatives in FLW?
- What are the appropriate levels of multisectoral coordination and public-private partnership in FLW?
- Are one or more government departments or agencies responsible for FLW?
- Is there coordination among various authorities to obtain a holistic view of FLW, for example, departments of the environment, agriculture, food, food safety, ecology, sustainability, and social welfare?
- Are there any international representatives, for instance, trade associations, that are working on FLW initiatives locally and that introduce novel approaches?
- Are academic institutions working on FLW that can provide data and insights?
- What nongovernmental and civil society organizations are active in FLW?
- What role does global trade play in preventing or exacerbating FLW? For example, the export of packed seafood may lead to waste if products do not meet buyer food cosmetics, quality, or safety standards. Buyers may have rules preventing the redistribution of lost food.
- Which organizations are innovators in FLW prevention?

Voluntary agreements with food businesses to implement good practices that allow a reduction in FLW is a frequent approach in developed economies. It may be useful to check if such initiatives exist in the country. If so, analyze the following:

- The scope of voluntary FLW initiatives
- The context of such initiatives
- If voluntary FLW initiatives influence national policies
- How efficient and popular voluntary FLW initiatives are
- FBOs that have implemented voluntary FLW initiatives
- The level of implementation of voluntary FLW initiatives
- The role of any public agencies that are involved

Discussions with industry associations will help determine if FLW voluntary agreements exist in the country. They may also share information about small-scale initiatives that cover only certain regions of the country or certain type of food products. They may be focused on raising awareness about approaches that help reduce food waste. For instance, professional organizations in the hospitality industry in France run a program aimed at encouraging members to separate, collect, and recycle organic waste (Caldeira, De Laurentiis, and Sala 2019). A similar approach might be followed by big retailers or catering chains.

- What are the key challenges linked to FLW that are faced by FBOs across food value chains because of national policies, legislation, and other initiatives?
- What is the level of stakeholder involvement in the development of FLW polices and legislation?
- Is there a national database of fortified food producers, importers and exporters, wholesalers, and retailers?

To understand the level of stakeholder involvement in the development of FLW policies and legislation, the way the relevant policy and legal documents are usually drafted should be examined. For instance, there may be a practice of organizing group stakeholder meetings by CAs, and the groups initiate the drafting process. Or the drafts may be developed by the CAs and then shared with stakeholders, who are invited to review the material and suggest changes.

4. National policy, legislation, and the regulatory framework

An analysis of national policy and the regulatory framework would enable the following:

- An understanding of the principles that guide any national FLW policy in the country. If there is no policy, an understanding of the principles that guide national legislation or legislative initiatives in relation to FLW
- An understanding of whether relevant national legislation facilitates a reduction in FLW in practice and evolves with advances in science and food technology
- The identification of food standards (public or private) that remove food that is still safe from the market, for example, on the basis of color or shape

An example of how food quality standards may result in an increase in food waste is provided by a case involving carrot quality standards at a supermarket chain (FAO 2011). Because of the supermarket's requirements about the brightness and shape of carrots, large quantities of carrots were rejected and used as animal feed.

- A determination of the legal requirements linked to FLW that might allow a reduction in FLW or make such a reduction difficult
- An understanding of how FLW controls are organized in the public and private sectors

In addition, it is recommended that the following issues be analyzed in relation to policies:

- How are FLW policies determined? Does the process incorporate information from the grassroots level, such as local food or agriculture organizations?
- Are there agroecological programs to support farmers in managing inputs that work to prevent pest attacks and the resulting waste?
- Does legislation or other initiatives encourage a circular economy, for example, feeding vegetable waste to animals?
- Conversely, does legislation or policy discourage a circular economy, for instance, not feeding bone meal to animals and not using it as fertilizer either?
- Is food waste prevention through, for example, food donations accepted as a safety net? In the United Kingdom, for instance, the number of food banks has grown significantly during the pandemic. This represents community action to support hungry people because they have lost jobs or cannot afford to buy food. It does not address the larger issue of the lack of an adequate government welfare safety net.
- Are there complementary policy interventions that could lead to a reduction in FLW, for example, agricultural policy, fisheries policy, food quality, food safety and marketing standards? Thus, European Union (EU) legislation on cosmetic marketing standards for fruits and vegetables have led to a misinterpretation of standards and waste.
- Do subsidies inadvertently contribute to FLW by encouraging overproduction?
- Do consumer health and safety policies inadvertently contribute to food waste, such as through inappropriate shelf-life requirements?
- Do waste and taxation policies discourage FLW?
- Have principles of circularity and zero waste been adopted?
- What is the infrastructure (roads, storage, sorting and packing centers, cooperatives, transport) to support access to markets for perishable produce, such as fish, fruits, and vegetables?

Answers to the following questions may facilitate an assessment of FLW legislation:

- Is there a specific national law on FLW or are FLW provisions embodied in the basic food act or in numerous food-related laws?
- When was the legislation on FLW adopted and amended?
- Is there any mention in the relevant legislation that FLW legislation is based on international standards?
- How were the requirements on FLW adopted: (a) in the law or (b) through regulations and standards?

The answers to these questions will show whether FLW arrangements are flexible and can be updated or changed quickly according to need. If most requirements have been adopted through regulations, then the system is flexible because it enables the government to be immediately responsive in case of need. Such an approach is more flexible than, for example, the use of laws to govern FLW, which would mean that change can only occur through an entire legislative process.

- What is the scope of FLW legislation? Does it address only food loss or food waste, or both?
- Are there mandatory requirements linked to the reduction of FLW across the food value chain? If so, what do they involve?

In a number of EU countries, the FLW regulatory framework includes provisions that guide food donations (Croatia), forbid food waste by supermarkets (France), regulate the donation of unsold food to local food banks (the Czech Republic), and explain measures to prevent food waste through the food supply chain (Romania).

Compliance with regulations and standards could be a cause of problems related to FLW in the country. Thus, in assessing legislation and the regulatory framework, it is critical to check not only if good practices are incorporated in national legislation, but also to analyze if there are norms that impede the country in reducing FLW.

- Are there national sanitary requirements at all stages of the food value chain? For Instance, the absence of sanitary requirements among wholesale markets may lead to food trade in unsanitary conditions that will result in rapid food spoilage.[51]
- Are national food safety requirements updated, and do they follow approaches aimed at reducing FLW? The requirements may be outdated, too unspecific, or exceed essential requirements of food safety, thereby limiting the ability of FBOs to reduce FLW.[52]
- How difficult are national procedures on the application of new technologies in the food industry?[53]
- Are there requirements on food recall and withdrawal? If so, do the procedures adopted allow recalls and withdrawals for food safety concerns in a well-defined manner?
- Are there mandatory requirements on the implementation of food traceability by FBOs? This is important because food product traceability is the foundation for differentiated, accurate recalls and withdrawals. Well-refined traceability systems result in less food waste during a recall or withdrawal.
- Are there mandatory requirements on the cold chain, for instance, the temperature regime during storage, transportation, retail, and so on?

[51] To answer this question, check for the existence of sanitary requirements in food handling across all stages of the value chain and their accessibility to the public.

[52] To answer this question, it is critical to discuss the issues with FBOs. The perspective of such practitioners is required.

[53] This question is aimed at understanding whether FBOs could readily adopt new technologies, tools, and approaches to optimize their operational processes, including those focused on FLW reduction.

- Are there binding requirements about using only plastic-free, biodegradable, and reusable food packaging?
- How clear are the requirements on food labeling in relation to food product shelf life? What is the approach? Is there a differentiation in shelf life labeling for highly perishable foods? There are many cases of food labels that confuse consumers about the safety of food products, leading consumers to throw away safe and edible food.

The EU approach to labeling practices about food shelf life is instructive. One reason for its development was to reduce FLW caused by lack of clarity about whether nonperishable foods could be consumed. In the EU, highly perishable food is labeled with a use-by date. After this date, the food is to be considered unsafe for human consumption. For other foods, best before labels or maximum safe storage dates are used indicating the date at which the food may no longer maintain its specific properties if properly handled. Such food may be consumed after the best before date, or it may be sold or donated (EU 2011).

- Are there requirements on food donations or requirements that ban the disposal of edible food that was unsold? Are there food banks in the country? Are there any regulations that guide food donations or food sharing?
- Are there mandatory requirements to separate food waste by categories? If so, are there implementation tools in place?

5. Alignment with international guidelines

- What is the country's commitment to the Paris agreement (United Nations 2016)?
- Is FLW legislation aligned with Sustainable Development Goal 12: "By 2030, halve per capita global food waste at the retail and consumer levels and reduce food losses along production and supply chains, including post-harvest losses."[54]
- Are there plans in the country to implement the FAO Voluntary Code of Conduct on FLW (FAO 2021)?
- Which state agency is the FAO contact point and leads activities in the implementation of the FAO Voluntary Code of Conduct on FLW?

The development of the FAO Voluntary Code of Conduct on FLW was initiated by the FAO Committee on Agriculture in 2018 during its 26th Session with the objective of developing the following:

- "Internationally recognized, nationally adaptable guiding principles and standards for responsible practices for food loss and waste (FLW) reduction
- "Framework for strategies, policies, institutions, legislation, and programs on FLW reduction
- "Guidance against which different stakeholders can gauge the actions they take to reduce FLW
- "Facilitate joint action, harmonization of approaches, and assessment of progress" (Njie 2021).
- Because the FAO Voluntary Code of Conduct was approved only in June 2021, active implementation is still in the future. If the country in which the assessment is taking place has not started the implementation process, check with the national FAO contact point if there are plans to do this and when.

[54] "Sustainable Development Goals," Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/sustainable-development-goals/indicators/1231/en/.

6. Compliance and control measures

- What are the main causes of FLW in the country?
- Where in the food chain are the losses occurring?
- Are national or industry targets set to reduce and prevent FLW?
- Where are the regulatory procedures for official inspection in relation to FLW?
- Are there any inspection protocols for FLW?
- Does national legislation provide for the enforcement of national requirements related to FLW management? What does this involve?
- Do incentives exist to promote the implementation of practices and approaches aimed at reducing FLW?

To launch business activities, FBOs may be required to register or obtain relevant licenses. In this case, national legislation should contain provisions defining the cases in which FBO registrations, licenses, or operational permits may be restricted, suspended, or revoked if an FBO does not meet the requirements embodied in the national legislation. This represents a powerful enforcement tool. It is recommended to check whether such enforcement measures are applied to FBOs in relation to FLW management.

7. The assessment of the national capacity to undertake approaches aimed at reducing FLW

Use the following questions to assess national capacity:

- Are there state budget allocations for activities aimed at reducing FLW?
- Does the CA of the government facilitate knowledge-sharing activities aimed at reducing FLW across the food value chain in the country?
- Is there an adequate body of trained official inspectors and private sector experts who could consult and support small and medium FBOs in the implementation of efforts to reduce FLW?
- What is the level of readiness of the public and private sectors? This includes infrastructure, cold storage facilities for crop producers, technical equipment that can maintain temperature regimes during transportation and distribution, and the availability of expertise on the issue?
- Is there FLW-related guidance recommended by the government for the food industry and consumers?
- Are there national learning and awareness programs on FLW reduction for the food industry and the staff of CAs?
- Is valorization encouraged?
- Are there valorization initiatives? An example is the potential to transform agricultural produce into added value products, such as surplus vegetables made into sauce or food waste into compost.
- Are there systems to manage industrial food waste and wastewater and recycle it safely back into biomass?
- Are there local or national education programs on FLW?
- Are there education programs to help consumers understand how to prevent food waste, for example, cooking with unfamiliar parts of vegetables or maximizing a full animal carcass in recipes?

8. Cultural attitudes to FLW

- What is the attitude to community FLW initiatives, such as food banks?
- Are there any cultural practices or barriers to managing FLW, for example, taboos in taking home unfinished food from banquets?
- Do women have a role in community engagement and education?

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Section V

Animal Welfare and Antimicrobial Use

Introduction[55]

In the past decade, the importance of animal welfare has been increasingly recognized in commercial livestock operations. Governments, academic institutions, and animal welfare professionals are addressing animal welfare across the agricultural supply chain, while consumers are demanding higher standards of food safety and animal welfare (IFC 2014). Observing good animal welfare practices has a positive impact on animal health and shows a strong link to enhanced productivity.

According to the World Organization for Animal Health (OIE 2021b, 333):

Animal welfare means the physical and mental state of an animal in relation to the conditions in which it lives and dies.

An animal experiences good welfare if the animal is healthy, comfortable, well nourished, safe, is not suffering from unpleasant states such as pain, fear, and distress, and is able to express behaviors that are important for its physical and mental state.

Good animal welfare requires disease prevention and appropriate veterinary care, shelter, management, and nutrition, a stimulating and safe environment, humane handling, and humane slaughter or killing. While animal welfare refers to the state of the animal, the treatment that an animal receives is covered by other terms such as animal care, animal husbandry, and humane treatment.

There are important relationships among animal welfare, livestock enterprise productivity, animal health, food safety and quality, and the demand arising from consumers and civil society.

- Businesses that address or enhance animal welfare are likely to win or retain a competitive advantage in the global marketplace by reducing the costs associated with enhanced human-animal relationships and other welfare benefits, which can lead to increased productivity.
- Preventing and controlling disease contribute greatly to animal welfare and make a difference in the survival of a business. Disease causes avoidable pain and distress among animals, and the humane destruction of affected animals entails significant costs to businesses.
- The product quality of productive animals is directly linked to animal welfare. Animals that are healthy and well rested prior to slaughter are more likely to produce good-quality meat.
- Affluence in many parts of the world has increased consumer choices and heightened expectations in food production standards. Surveys in Europe and North America find that the majority of consumers care about animal welfare and report a willingness to pay more for animal products they perceive to have come from farm animals raised humanely (IFC 2014).

Although animal welfare problems are extremely diverse, certain generic problem areas occur globally. These include problems linked to:

- *transportation, especially over long distances*
- *slaughter and preslaughter management*
- *on farm maintenance and housing, which also involve adequate feed and water*
- *the handling of animals by humans*
- *the culling of animals that are unhealthy or of low commercial value; and keeping animals under conditions for which they are not genetically suited*

A global movement is under way to improve animal welfare standards. Countries in Africa, Asia, Latin America, and the Middle East that previously offered little or no statutory protection for farm animals are developing generic anticruelty and animal welfare legislation and specific regulations. Australia, Canada, members of the European Union (EU), New Zealand, the United Kingdom, the United States, and other countries are refining regulatory frameworks by extending the standards that apply to particular farming systems or species (IFC 2014).

[55] For this assessment, animal welfare and the use of antimicrobials are considered in relation to livestock production.

There is a close link between animal welfare and the prudent use of antimicrobial agents. Following animal welfare requirements and observing basic principles of hygiene during the keeping of animals significantly decrease the necessity to use antimicrobial agents.[56]

The use of antimicrobial agents among healthy animals to prevent disease has now become common in husbandry systems in which large numbers of animals are housed under poor to moderate hygienic and animal welfare conditions without appropriate biosafety measures. Similarly, if a few members of a flock have a disease, all animals are sometimes treated to prevent the spread of the disease. Besides such treatment (therapeutic) and prevention (prophylactic) uses, antimicrobials have been added in low dosages to animal feed to promote more rapid growth. Although more countries are prohibiting the use of antimicrobials as growth promoters, their use in this way remains common in many parts of the world.[57]

Excessive or inappropriate use of antimicrobial agents can lead to the emergence of resistant bacteria that do not respond to antibiotic treatment. This phenomenon, antimicrobial resistance (AMR), which has been seen more widely in recent decades and which poses a threat to disease control throughout the world, is a primary concern for human and animal health (OIE 2015).

AMR increases illness and mortality in humans, animals, and plants. In agriculture, it causes production losses, damages livelihoods, and jeopardizes food security. AMR can spread among hosts and the environment, and antimicrobial resistant microorganisms can contaminate the food chain.

The rise of AMR is a shared responsibility across human, animal, and plant sectors and therefore requires a coordinated, multisectoral, and global response. The tripartite partnership among OIE, the Food and Agriculture Organization of the United Nations (FAO), and the World Health Organization (WHO) mirrors the One Health Approach to AMR that has been tested as a means of addressing the animal and public health risks associated with zoonoses and animal diseases (WHO, FAO, and OIE 2019, 2021).[58]

National policies and programs on animal welfare and antimicrobial use are key components in addressing the following:

- *The humane treatment of animals*
- *The quality and safety of food*
- *The prevention of the spread of animal diseases*
- *The abuse, overuse, misuse, and release of antimicrobials*
- *Antimicrobial use to minimize the risks of AMR*

The efficiency of national animal welfare and antimicrobial policies and programs is built on two main pillars: legislation and effective enforcement of the legislation. To understand how a such a framework on animal welfare and antimicrobial use should operate, these and other elements—capacity building, stakeholder involvement, awareness activities, compliance with obligations, establishment of international agreements, and so on—should be analyzed and assessed through a stepwise procedure, as proposed below in part A (animal welfare) and part B (antimicrobial use).

[56] An antimicrobial agent is "a naturally occurring, semisynthetic or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of microorganisms) at concentrations attainable in vivo. Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition." (OIE 2021b, xiii).

[57] Antimicrobial Resistance (dashboard), Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/antimicrobial-resistance/key-sectors/animal-health/en/.

[58] "One Health Approach: a collaborative, multisectoral, and transdisciplinary approach working with the goal of achieving optimal health outcomes recognizing the interconnection between humans, animals, plants/crops, and their shared environment" (FAO and WHO 2021, 4).

Part A. Animal welfare

1. Key definitions

Key animal welfare definitions include animal handler, animal welfare, biosecurity, slaughter, stocking density, and stunning. Proper definitions are crucial because definitions affect the interpretation and implementation of laws and the efficiency of national programs on animal welfare. To check if the definitions used in national legislation correspond to international practice, the definitions in the OIE Terrestrial Animal Health Code (OIE 2021b, xiii–xxii) should be examined.

"**Animal handler** means a person with a knowledge of the behavior and needs of animals who, with appropriate experience and a professional and positive response to an animal's needs, can achieve effective management and good welfare. Competence should be gained through formal training or practical experience."

"**Animal welfare** means the physical and mental state of an animal in relation to the conditions in which it lives and dies."

"**Biosecurity** means a set of management and physical measures designed to reduce the risk of introduction, establishment, and spread of animal diseases, infections, or infestations to, from, and within an animal population."

"**Death** means the irreversible loss of brain activity demonstrable by the loss of brain stem reflexes."

"**Killing** means any procedure that causes the death of an animal."

"**Resting point** means a place where the journey is interrupted to rest, feed, or water the animals; the animals may remain in the vehicle, vessel, or container or be unloaded for these purposes."

"**Slaughter** means any procedure that causes the death of an animal by bleeding."

"**Slaughterhouse/abattoir** means premises, including facilities for moving or lairaging animals, used for the slaughter of animals to produce animal products and approved by the veterinary services or other competent authority."

"**Stocking density** means the number or body weight of animals per unit area on a vehicle, vessel, or container."

"**Stunning** means any mechanical, electrical, chemical, or other procedure that causes immediate loss of consciousness; when used before slaughter, the loss of consciousness lasts until death from the slaughter process; in the absence of slaughter, the procedure would allow the animal to recover consciousness."

2. General background

It is recommended that the assessment start with answers to the following questions:

- Is there a national program, strategy, or policy on animal welfare? If so, check the following:
  - The scope
  - Correspondence with regional and international agreements. Specify the agreement or any other document that is mentioned as a basis for the program.
  - Does the program cover issues related to antimicrobial use?

The existence of an animal welfare program, strategy, or policy indicates if animal welfare is a government priority and if the government is ready to undertake or is already undertaking the initiatives necessary to realize the priority.

3. Alignment with regional and international animal welfare standards[59]

- Does the country have obligations in the implementation and use of regional and international animal welfare standards? What is the basis of the obligations (for instance, international agreements or membership in regional or international organizations)?

The OIE, at the request of its member countries, is the international organization responsible for setting standards on animal welfare.[60] All OIE member countries are encouraged to use and to implement the OIE terrestrial and aquatic animal health codes through national legislation (OIE 2021a, 2021b).

There is a tendency today to include the issue of compliance with animal welfare standards in trade agreements. For instance, for the last 20 years, the European Commission has been striving to include animal welfare in trade agreements and in cooperation efforts with non-EU countries.[61]

- Is there a national strategy for the implementation of regional and international standards on animal welfare through national legislation? If so, check the following:
  - What is the basis of the national strategy (for example, international agreements)?
  - What is the scope of the national strategy in animal welfare?
  - Does the national strategy provide a step-by-step action plan with appropriate deadlines for implementation of regional and international standards on animal welfare through national legislation?
- Does the existing national legislation on animal welfare comply with regional and international animal welfare standards?

[59] For example, standards of the Commonwealth Veterinary Association, FAO, the International Society for Applied Ethology, OIE, the World Veterinary Association, international nongovernmental animal welfare organizations, and international primary industry organizations.

[60] Animal Welfare (dashboard), World Organization for Animal Health, Paris, https://www.oie.int/en/what-we-do/animal-health-and-welfare/animal-welfare/.

[61] See Animal Welfare (dashboard), European Commission, Brussels, https://ec.europa.eu/food/animals/animal-welfare_en.

Conclusions on the level of compliance of national legislation with regional and international animal welfare standards should be based on comparative analysis, tables of correspondence, and so on.

- Does the national lawmaking system require a compulsory check of draft legal acts before their adoption to verify compliance with regional and international standards?

4. Stakeholders

The next step is to determine the key players, that is, undertake animal welfare *stakeholder mapping and the identification of animal welfare champions*. To achieve this, it may be useful to follow approaches and use tables presented in Section II of the IFC Scan Guide. Thus, animal welfare stakeholder mapping will allow the following questions to be answered:

- Who would formulate and adopt national policy on animal welfare?
- Which competent authority (CA) is responsible for official supervision over animal welfare?

If there are several public agencies involved in the official monitoring of animal welfare, check their mandates to identify areas of responsibility for each. Analyze whether CA functions overlap.

- Who influences and formulates national animal welfare policies beyond public authorities?

To understand the level of stakeholder involvement in the development of animal welfare policies and legislation, the way the relevant policy and legal documents are usually drafted should be examined. For instance, there may be a practice of organizing group stakeholder meetings by CAs, and the groups initiate the drafting process. Or the drafts may be developed by the CAs and then shared with stakeholders, who are invited to review the material and suggest changes.

- What is the level of stakeholder involvement in the development of animal welfare policies and legislation?
- What is the extent of public-private partnerships in animal welfare?
- Are there any private sector initiatives in animal welfare? If so, analyze the following:
  - Scope
  - Context
  - Correspondence with OIE codes and any other standards (specify)
  - Are the following factors taken into consideration during the development of initiatives: sound science, research, practical experience, cultural differences?
  - Do private sector initiatives influence national policies? If so, explain how and provide examples
  - How effective and popular are these initiatives?
  - How many business operators have implemented private sector initiatives? Is there any sort of register or database on this issue?
  - What is the level of implementation of private sector initiatives throughout the country?

Transnational and national commercial companies have adopted animal welfare policies and higher standards to regulate their own livestock activities or those of their suppliers of livestock-derived products. In some countries, such standards may be higher and can be applied more quickly than those required by government regulations (IFC 2014).

- The role of public agencies if they are involved
- What are the key challenges linked to animal welfare that are faced by the following because of national policies, legislation, and other initiatives?
  - Business operators
  - The government
- Is there a database of farms and live animal exporters?
- Are there quality assurance programs on animal welfare?[62] Is there independent verification or certification systems?[63] If so, specify their role.

5. National policy and regulatory framework

An analysis of the national policy and regulatory framework would enable the following:

- Whether the factors examined during the development of the national policy and regulatory framework included sound science, research, practical experience, cultural differences

To check if sound science, research, practical experience, cultural differences, or other relevant factors are considered in national policies and legislation, analyze whether provisions in national legislation reflect any of these factors or confirm that these factors were considered when the specific legal act was developed. It may be useful to consult with the authorities involved in the development of national policies and legislation about whether these factors have been implemented in national legislation in practice.

- An understanding of the principles that guide national animal welfare policy in the country; if not, an understanding of the principles that guide national animal welfare legislation or animal welfare initiatives and the determination of whether these principles are in line with international guiding principles on animal welfare

International guiding principles on animal welfare are based on the universally recognized Five Freedoms, first published in 1965, which include freedom from hunger or thirst, freedom from fear and distress, freedom from physical and thermal discomfort, freedom from pain, injury, disease, and freedom to express normal patterns of behavior.[64]

[62] "Quality assurance programs . . . provide training for the owner, operator, and all staff and require written protocols for production practices, including those directed at animal well-being. Assurance programs should dictate continual review of existing systems and practices, especially as new science and technology become available and economically viable. Many quality assurance programs apply auditing or assessment procedures, the features of which will depend on the livestock operation, program, and region." (IFC 2014, 15).

[63] "A credible certification system would be one which is independent, cost-effective, based on objective and measurable performance standards, and developed through consultation with relevant stakeholders, such as local people and communities, indigenous peoples, and civil society organizations representing consumer, producer, and conservation interests. Such a system has fair, transparent, and independent decision-making procedures that avoid conflict of interest." (IFC 2014, 21).

[64] See article 7.1.2 of the *Terrestrial Animal Health Code* (OIE 2021b, 333). General principles on the welfare of animals in livestock production systems are established in article 7.1.5 (OIE 2021b, 334–35).

- An understanding of whether relevant national legislation on animal welfare is flexible and addresses the changing needs of business operators, consumers, and government
- An understanding of how animal welfare controls are organized

Answers to the following questions would facilitate an assessment of animal welfare legislation:

- How were the requirements on animal welfare adopted? In the law? Through bylaws (regulations)? Through standards?

The answers to this question will show whether animal welfare arrangements are flexible and can be updated or changed quickly. If most requirements have been adopted through bylaws (regulations), then the system is flexible because the government can be immediately responsive in case of need. Such an approach is more flexible than, for example, the use of laws to govern animal welfare, which would mean that change can only occur through an entire legislative process.

- Is there a specific national law on animal welfare? Are animal welfare provisions embodied in the basic law on animal health (veterinary law), the protection of animals from brutal treatment, and so on, or in numerous related laws?
- What bylaws, regulations, or standards establish animal welfare requirements? When were they adopted and amended?
- Does the country's legal system foresee a mechanism for the direct use of regional or international animal welfare standards?
- Is there any mention in relevant legislation that it is based on regional or international standards?
- Are there ongoing or planned activities to improve animal welfare legislation, such as a list of draft laws and bylaws, regulations, or standards or issues to be addressed in future legislation?
- Are there national standards on animal welfare? Are these standards mandatory or voluntary?

6. The scope of animal welfare regulations

It is recommended that the OIE Terrestrial Animal Health Code be followed by OIE member countries. In relation to scope, the code covers such issues as the transport of animals by sea, air, and land; animal slaughter for human consumption; animal killing for disease control purposes; and broiler chicken, pig, and beef and dairy cattle production systems (OIE 2021b).

The scope of animal welfare requirements has expanded in recent years partly because of the new or increased use of animal health and welfare assessment criteria. In addition to scrutinizing inputs related to husbandry practices, resources, and facility design, practitioners are now also focusing on health and welfare outcomes among animals. This is based on the growing realization that the same welfare benefits can be achieved among animals by relying on a range of practical approaches that are well suited to country- or region-specific conditions.

- Does legislation establish animal welfare requirements at all stages of animal production or only at certain stages, for instance, during transportation and keeping, but not during slaughter?
- What types of animals are covered or not covered by animal welfare legislation in the country?
- Does animal welfare legislation regulate issues related to the use of antibiotics?

- For whom is animal welfare legislation compulsory: business operators, animal keepers, animal owners, official inspectors, and so on?
- Who is exempted from an obligation to fulfill the requirements of animal welfare legislation?
- Do animal welfare requirements apply also to animals that are imported, or are there specific, separate import requirements?

Table 4.1. Assessment of National Animal Welfare Legislation in Livestock Production Systems

Terrestrial Animal Health Code	National legislation on animal welfare		
	Addressed[a]	Partially addressed[b]	Not addressed
Broiler chicken production systems (OIE 2021b, 443–49)			
Biosecurity and animal health			
Thermal environment			
Lighting			
Air quality			
Noise			
Nutrition			
Flooring, bedding, resting surfaces and litter quality			
Prevention of feather pecking and cannibalism			
Stocking density			
Outdoor areas			
Protection from predators			
Choice of broiler strain			
Painful interventions			
Handling and inspection			
Personnel training			
Emergency plans (developed and put in place in the facility)			
Location, construction and equipment of farms			
On farm harvesting			
Pig production systems (OIE 2021b, 472–84)			
Training of personnel			
Handling and inspection			
Painful procedures			
Provision of feed and water			
Environmental enrichment			
Prevention of abnormal behavior			
Housing (including outdoor production systems)			
Space allowance			
Flooring, bedding, resting surfaces			
Air quality			
Thermal environment			

Terrestrial Animal Health Code	National legislation on animal welfare		
	Addressed[a]	Partially addressed[b]	Not addressed
Noise			
Lighting			
Farrowing and lactation			
Weaning			
Mixing			
Genetic selection			
Protection from predators and pests			
Biosecurity and animal health (biosecurity and disease prevention)			
Contingency plans			
Disaster management			
Humane killing			
Dairy and beef cattle production systems (OIE 2021b, 433–42, 450–62)			
Biosecurity and animal health			
Thermal environment			
Lighting			
Air quality			
Noise			
Nutrition			
Flooring, bedding, resting surfaces and outdoor areas			
Social environment			
Stocking density			
Protection from predators			
Genetic selection			
Reproductive management			
Colostrum			
Weaning			
Transfer of beef cattle to dry feed			
Painful procedures			
Handling and inspection			
Personnel training			
Emergency plans to be developed and introduced by facilities			
Location, construction and equipment			

Terrestrial Animal Health Code		National legislation on animal welfare		
		Addressed[a]	Partially addressed[b]	Not addressed
For dairy cattle	Artificial insemination, pregnancy diagnosis and embryo transfer			
	Dam and sire selection and calving management			
	Newborn calves			
	Cow-calf separation and weaning			
	Rearing of replacement stock			
	Milking management			
Humane killing				

Source: Developed based on OIE 2021b.

Note: Livestock production systems include coverage of broiler chickens, pigs, dairy, and beef cattle.

a. Indicate the national legal act that addresses the issue (the name of the legal act, the date of adoption, and the number). Indicate the particular article or provision of the legal act.

b. Indicate the national legal act that partially addresses the issue (the name of the legal act, the date of adoption, and the number). Indicate the issue addressed. Indicate the particular article or provision of the legal act.

7. Compliance and control measures

- Does the country have a specific law on official (state) control over compliance with legislation on animal welfare, or the control measures are embodied in different related laws?
- Does the legislation on official control fully cover all stages of animal production (onfarm, during transport, and during slaughter) or are there legal gaps?
- Which CA is responsible for official control over compliance with animal welfare legislation?

The purpose of official controls in animal welfare is to enforce, monitor, and verify the fulfillment of relevant animal welfare requirements by business operators at all stages of relevant activities.

- Do the official controls take place on the basis of documented procedures so as to ensure that they are carried out uniformly? Are the procedures up to date?
- Are the official controls applied with the same care on products for export, products processed domestically, and products that have been imported?
- What official control methods and techniques are used in animal welfare, for example, in monitoring, surveillance, verification, audit, inspection, sampling, analysis, and so on?
- Do standard procedures offer step-by-step instructions on how to perform official controls?
- What actions are taken by CAs in case of noncompliance with animal welfare requirements?
- What are the sanctions for failure to comply with regulatory requirements on animal welfare, for instance, administrative sanctions on offenders, warnings, notifications, remedy orders, fines, temporary bans on business activities, and so on? Are the sanctions effective, proportionate, and dissuasive? How is the consistent application of sanctions ensured?

8. Assessment of national capacity building to improve animal welfare

The proper implementation of national animal welfare policies crucially depends on adequate capacity. The answers to the following questions help in assessing this capacity.

- Are state budget allocations for the implementation of animal welfare programs adequate?
- Are animal welfare issues covered in the national educational system?

> "Education is needed to create awareness of animal welfare and a greater understanding of the significance of animal welfare for successful animal production. In the case of animal producers and handlers, such education may ultimately lead to the implementation of new procedures that improve animal welfare outcomes. Education directed to the general population may lead eventually to people supporting forms of animal production that involve good animal welfare." (Fraser et al. 2009, 19)

- Does the veterinary profession cover animal welfare issues?
- Do national animal welfare training programs exist for inspectors, business operators, and so on?

> "Training refers to the process of teaching a particular skill or type of behavior through practice and instruction over a period of time. Although training exists for certain professionals, such as veterinarians and agronomists, there is a great need for training related to animal welfare for people engaged in handling, transport, slaughter, and euthanasia." (Fraser et al. 2009, 21)

- Does the country participate in regional or international training programs on animal welfare?

> Many organizations today assist countries in capacity building in good animal welfare practices. For instance, the OIE strengthens the capacity of national veterinary services among its member countries through tools and programs, such as the Performance of Veterinary Services Pathway and training sessions, and by emphasizing the importance of including animal welfare in the curricula of veterinary students, veterinary paraprofessionals, and students in agricultural training colleges.[65]

- What is the level of readiness of CAs in the proper performance of official control? Are there sufficient numbers of trained inspectors? Are standard operating procedures and other documented procedures available? Is the proper technical equipment accessible?
- What is the state of readiness of the private sector in complying with national animal welfare requirements? This includes technical issues, such as equipping animal breeding facilities, which takes time and may be costly. It also includes operational issues, such as altering animal handling practices and stock handler selection and educating staff to improve attitudes and procedures.
- Are there established producers of vaccines and animal health supplies?
- Are there national awareness programs on animal welfare? If so, what is their scope?
- Are there research programs on animal welfare?

[65] See Capacity Building and Education (dashboard), World Organisation for Animal Health, Paris, https://www.oie.int/en/what-we-do/animal-health-and-welfare/animal-welfare/capacity-building-and-education/; PVS Pathway (Performance of Veterinary Services Pathway) (dashboard), World Organisation for Animal Health, Paris, https://www.oie.int/en/what-we-offer/improving-veterinary-services/pvs-pathway/.

Part B. Antimicrobial use

1. Key definitions

Key definitions in antimicrobial use (AMU) include antimicrobial agent, antimicrobial resistance (AMR), feed, food-producing animals, growth promotion, maximum residue limit, medically important antimicrobials, veterinary important antimicrobial agents, veterinary medicinal product.

Proper definitions are critical because definitions affect the interpretation and implementation of laws and the efficiency of national AMU programs. To check if the definitions used in national legislation correspond to international practice, the definitions in the Terrestrial Animal Health Code (OIE 2021b, xiii–xxii) and the revised Code of Practice to Minimize and Contain Foodborne Antimicrobial Resistance (FAO and WHO 2021) should be examined.

"**Antimicrobial agent** means a naturally occurring, semisynthetic, or synthetic substance that exhibits antimicrobial activity (kill or inhibit the growth of microorganisms) at concentrations attainable in vivo. Anthelmintics and substances classed as disinfectants or antiseptics are excluded from this definition" (OIE 2021b, xiii).

"**Antimicrobial resistance** (AMR): the ability of a microorganism to multiply or persist in the presence of an increased level of an antimicrobial agent relative to the susceptible counterpart of the same species" (FAO and WHO 2021, 3).

"**Feed** means any material (single or multiple), whether processed, semiprocessed, or raw, which is intended to be fed directly to terrestrial animals (except bees)" (OIE 2021b, xv).

"**Food-producing animals**: animals raised for the purpose of providing food to humans" (FAO and WHO 2021, 4).

"**Growth promotion**: administration of antimicrobial agents to only increase the rate of weight gain and/or the efficiency of feed utilization in animals. The term does not apply to the use of antimicrobials for the specific purpose of treating, controlling, or preventing infectious diseases." (FAO and WHO 2021, 4).

"The **maximum residue limit** (MRL) is the maximum concentration of residue legally tolerated in a food product obtained from an animal that has received a veterinary medicine."[66]

"**Medically important antimicrobials**: antimicrobial agents important for therapeutic use in humans, taking into account the WHO List of Critically Important Antimicrobials for Human Medicine, including the classes described in the Annex of the 'List of Medically Important Antimicrobials, categorized as Critically Important, Highly Important, and Important,' or equivalent criteria established in a national list, where available. It does not include ionophores or other agents determined not to be a foodborne AMR risk consistent with the Guidelines for Risk Analysis of Foodborne Antimicrobial Resistance." (FAO and WHO 2021, 4).

Veterinary important antimicrobial agents are "all antimicrobial agents used in food-producing animals, divided into critically important, highly important, and important antimicrobial agents" (OIE 2021c, 3).

"**Veterinary medicinal product** means any product with approved claims to having a prophylactic, therapeutic, or diagnostic effect or to alter physiological functions when administered or applied to an animal" (OIE 2021b, xxi).

[66] "Veterinary Drug Residues," Codex Veterinary Drug Residue in Food Online Database, Joint Food and Agriculture Organization of the United Nations–World Health Organization Food Standards Programme, Rome, https://www.fao.org/fao-who-codexalimentarius/codex-texts/maximum-residue-limits/en/.

2. General background

It is recommended to start the assessment with the answers to the following questions:

- Is there a national program for AMU? If so, check the following:
  - What is the scope of the program?
  - What is the basis of the program (for instance, regional or international agreements)?
- Is there a national AMU policy?
- Is there a national action plan to combat AMR? If so, check the scope of the plan.
- Is there a national AMR control program in veterinary medicine?
- Does specific legislation regulate AMU-related issues (laws, bylaws, regulations, and so on)?
- Are there standards on AMU? Are these standards mandatory or voluntary?
- Which CA is responsible for officially checking compliance with AMU requirements?

The answers to these questions should facilitate the development of the outlines of a national AMU system.

3. Alignment with regional and international standards

- Does the country have obligations in the implementation and use of AMU in regional and international standards? What is the basis of the obligations (for example, international agreements or membership in regional of international organizations)?

The OIE supports "individual member countries in their efforts to implement OIE international standards for prudent use of antimicrobials and to combat AMR in animals taking into account their respective social, economic, and cultural circumstances" (OIE 2016, 10).

- Is there a national strategy for the implementation in national legislation of regional or international AMU standards? If so, check the following:
  - What is the basis of the national strategy (for instance, international agreements, and so on)?
  - What is the scope of the national AMU strategy?
  - Does the national strategy include a step-by-step action plan with appropriate deadlines for implementation in national legislation of regional or international AMU standards?
- Does existing national AMU legislation comply with regional and international standards (table 4.2)?

Conclusions on the level of compliance of national legislation with regional and international standards should be based on comparative analyses, tables of correspondence, and so on).

- Does the national lawmaking system require the compulsory check of draft legal acts (before their adoption) to determine their compliance with regional and international standards?

Table 4.2. Assessment of National Policies on Antimicrobial Agents and OIE Recommendations

Terrestrial Animal Health Code		National policies on antimicrobial agents		
		Addressed[a]	Partially addressed[b]	Not addressed
Harmonization of national antimicrobial resistance surveillance and monitoring programs (OIE 2021b, 292–97)				
Main components of surveillance and monitoring	Statistics-based surveys			
	Sampling and testing[c]			
	Organized sentinel program[d]			
	Analysis of veterinary practice and diagnostic laboratory records			
Types of bacteria subjected to surveillance and monitoring[e]				
Periods of storage of bacterial strains				
Lists of clinically important antimicrobial agents or classes used in human and veterinary medicine[f]				
Antimicrobial susceptibility testing				
Recording, storage, and interpretation of data				
Designation of national reference laboratory (center) and its reporting				
Monitoring of the quantities and usage patterns of antimicrobial agents used in food-producing animals (OIE 2021b, 298–300)				
Sources of antimicrobial data	Basic sources			
	Direct sources			
	End-use sources (veterinarians and food animal producers)[g]			
	Other sources			
Types and reporting formats of antimicrobial usage data				
The interpretation and communication of antimicrobial data				
Responsibilities of the competent authority (OIE 2021b, 302–05)				
Marketing authorization for veterinary medicinal products (VMP)				
Quality control of antimicrobial agents and VMP containing antimicrobial agents				
Assessment of therapeutic efficacy				
Assessment of the potential of antimicrobial agents to select for resistance				
Establishment of acceptable daily intake, maximum residue limit, and withdrawal periods in food-producing animals				
An assessment of the impact of the proposed antimicrobial use on the environment				
Establishment of a summary of product characteristics for each VMP containing antimicrobial agents				
Postmarketing antimicrobial surveillance				

Terrestrial Animal Health Code	National policies on antimicrobial agents		
	Addressed[a]	Partially addressed[b]	Not addressed
Supply and administration of the VMP containing antimicrobial agents			
Control of advertising on antimicrobial agents			
Training on the usage of antimicrobial agents			
Publicly and industry-funded research			
Responsibilities of veterinary pharmaceutical industry with regard to VMP containing antimicrobial agents (OIE 2021b, 305–06)			
Marketing authorization for VMP			
Marketing and export			
Advertising			
Training			
Research			
Responsibilities of wholesale and retail distributors (OIE 2021b, 306)			
Distribution of VMP containing antimicrobial agents only on the prescription of a veterinarian or other suitably trained person authorized to prescribe VMP containing antimicrobial agents in accordance with national legislation and under the supervision of a veterinarian			
Appropriate labeling of VMP containing antimicrobial agents			
Recordkeeping			
Participation in training programs on the responsible and prudent use of VMP containing antimicrobial agents			
Responsibilities of veterinarians (OIE 2021b, 306–07)			
Use of antimicrobial agents			
Choosing antimicrobial agents			
Appropriate use of the chosen VMP containing antimicrobial agents			
Recording of data			
Labeling			
Training and continued professional development			
Responsibilities of food animal producers (OIE 2021b, 308)			
Implementation of animal health and animal welfare programs on farms to promote animal health and food safety			
Drawing up a health plan with the attending veterinarian that outlines preventive measures			
Use of VMP containing antimicrobial agents only on the prescription of a veterinarian or other suitably trained person authorized to prescribe VMP containing antimicrobial agents in accordance with the national legislation and under the supervision of a veterinarian			
Use of VMP containing antimicrobial agents in accordance with product label instructions, including storage conditions, or the instructions of the attending veterinarian			

Terrestrial Animal Health Code	National policies on antimicrobial agents		
	Addressed[a]	Partially addressed[b]	Not addressed
Isolation of sick animals, if appropriate, to avoid the transfer of pathogenic agents; dispose of dead or dying animals promptly under conditions approved by the relevant authorities			
Addressing onfarm biosecurity measures and taking basic hygiene precautions as appropriate			
Compliance with and record of the recommended withdrawal periods to ensure that residue levels in animal-derived food do not present a risk for the consumer			
Use of VMP containing antimicrobial agents within the expiry date and disposal of unused and expired surplus VMP containing antimicrobial agents under conditions safe for the environment			
Maintaining all the laboratory records of bacteriological and susceptibility tests			
Keeping adequate records on all VMP containing antimicrobial agents used			
Training			
Responsibilities of animal feed manufacturers (OIE 2021b, 308–09)			
The supply of medicated feed containing antimicrobial agents to farmers keeping food-producing animals by animal feed manufacturers only on the prescription of a veterinarian or by other authorized and suitably trained persons			
Preparation of medication in accordance with national legislation			
Appropriate labeling of medicated feed and medicated premixes (product identification, direction for use and withdrawal time, and so on)			
Recordkeeping			
Use only of approved sources of medications			
Implementation of appropriate production practices to prevent contamination of other feed			
Application of risk analysis for AMR (OIE 2021b, 310–15)			
Analysis of risks to human health			
Analysis of risks to animal health			

Source: Developed based on OIE 2021b.

a. Indicate the national legal act that addresses the issue (the name of the legal act, the date of adoption, and the number). Describe the topic precisely. Indicate the particular article or provision of the legal act.

b. Indicate the national legal act that partially addresses the issue (the name of the legal act, the date of adoption, and the number). Describe the topic precisely. Indicate the particular article or provision of the legal act.

c. Sampling and testing of (i) food-producing animals on the farm, at live animal markets, or at slaughter; (ii) products of animal origin intended for human consumption; (iii) feed ingredients or feed; and (iv) the environment.

d. For example, targeted sampling of food-producing animals, herds, flocks, and vectors, such as birds or rodents.

e. For instance, animal bacterial pathogens relevant to the country's priorities, zoonotic bacteria, commensal bacteria.

f. If addressed or partially addressed, specify the CA that is in charge of setting, maintaining, and controlling the use of the lists of antimicrobials (OIE 2021c; WHO 2019).

g. If addressed or partially addressed, specify whether the collection, storage, and processing of data are carefully designed and well managed and have the capability to produce accurate and targeted information.

4. Stakeholders

- Who influences and formulates national AMU policies?
- Are there any private sector initiatives in AMU? If so, analyze the following:
  - Scope
  - Context
  - Whether the private sector initiatives influence national policies
  - How efficient and popular private sector initiatives are
  - How many business operators have implemented private sector initiatives
  - The level of the implementation of private sector initiatives throughout the country
  - The role of any public agencies that are involved
- What are the key challenges linked to AMU that are faced by the following because of national policies, legislation, and other initiatives?
  - Business operators
  - The government
- What is the level of stakeholder involvement in the development of AMU polices and legislation?

To understand the level of stakeholder involvement in the development of AMU policies and legislation, the way the relevant policy and legal documents are usually drafted should be examined. For instance, there may be a practice of organizing group stakeholder meetings by CAs, and the groups initiate the drafting process. Or the drafts may be developed by the CAs and then shared with stakeholders, who are invited to review the material and suggest changes.

5. National policy, legislation, and the regulatory framework

An analysis of the national policy and regulatory framework would enable the following:

- An understanding of the principles and objectives that guide any national AMU policy in the country; if there is no policy, an understanding of the principles and objectives that guide national AMU legislation or AMU initiatives
- A determination of whether these principles and objectives are in line with international guidelines and principles

OIE member countries are committed to combating AMR and promoting prudent AMU in animals. The OIE strategy on AMR and the use of antimicrobials is built on the following four main objectives:

- "Improve awareness and understanding
- "Strengthen knowledge through surveillance and research
- "Support good governance and capacity building
- "Encourage implementation of international standards" (OIE 2016, 6)

A global AMR action plan would have five objectives:

- "To improve awareness and understanding of antimicrobial resistance through effective communication, education, and training
- "To strengthen the knowledge and evidence base through surveillance and research
- "To reduce the incidence of infection through effective sanitation, hygiene, and infection prevention measures
- "To optimize the use of antimicrobial medicines in human and animal health
- "To develop the economic case for sustainable investment that takes account of the needs of all countries and to increase investment in new medicines, diagnostic tools, vaccines, and other interventions" (WHO 2015, vii)

- An understanding of whether relevant national AMU legislation is flexible and addresses the changing needs of business operators, consumers, and the government

The answers to these questions will show whether AMU arrangements are flexible and can be updated or changed quickly according to need. If most requirements have been adopted through bylaws or regulations, then the system is flexible because it enables the government to be immediately responsive in case of need. Such an approach is more flexible than, for example, the use of laws to govern AMU, which would mean that change can only occur through a legislative process.

- An understanding of how AMU controls are organized

Answers to the following questions would facilitate an assessment of AMU legislation.

- How were AMU requirements adopted (a) in the law, (b) through bylaws or regulations, or (c) through standards?
- What basic laws establish the AMU requirements (for examples, laws on veterinary medicine, feed safety, food safety, and so on)? When were they adopted and amended?
- What bylaws, regulations, or standards establish AMU requirements? When were they adopted and amended?
- Does the legal system foresee a mechanism for the direct use of regional or international standards?
- Is any AMU legislation based on regional or international standards?
- Are activities ongoing or planned to improve AMU legislation (for instance, a list of draft laws and bylaws or regulations to be prepared and issues to be addressed)?

6. The scope of AMU

- Does AMU legislation establish requirements for the following:
  - Authorization, production, importation, labeling, prescription, sale, and use of veterinary medicines to prevent the uncontrolled sale or use of antimicrobials, as well as the sale of counterfeited or low-quality veterinary medicines?
  - Authorization, production, importation, labeling, sale, and use of feed, including feed additives and medicated feed?

National legislation on feed and feed additives could have a potential impact on AMR, especially in encouraging the development of alternatives to antimicrobials.

  - Establishment, monitoring, and control by the government of the maximum residue limits of veterinary medicines in food?

"Effective monitoring and surveillance systems that track the use of antimicrobials and the spread of AMR through human food chains are necessary. One part of such an effort are existing veterinary drug residue monitoring programs; these are currently in place in some countries but not in others, and often need to be strengthened."[67]

  - Approval of antimicrobials in crop production?

The release of antimicrobials that were approved for crop production could be passed on to animals or the human food chain or have an impact on the environment.

- Does AMU legislation cover the consistency between established requirements and measurement methods?
- Are there national lists of antibiotics (for example, critically important antimicrobials, medically important antimicrobials, antimicrobial agents of veterinary importance)? If so, do these lists take into consideration the corresponding lists established by regional and international organizations?

The OIE list of antimicrobial agents of veterinary importance is divided into three categories: veterinary critically important antimicrobial agents, veterinary highly important antimicrobials, and veterinary important antimicrobials (OIE 2021c). The list is designed in part to guide countries in the responsible and prudent use of antimicrobials in livestock and aquaculture production.

The WHO Advisory Group on Integrated Surveillance of Antimicrobial Resistance reviews and updates the WHO list of critically important antimicrobials for human medicine every two years (WHO 2019).

[67] Antimicrobial Resistance (dashboard), Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/antimicrobial-resistance/key-sectors/animal-health/en/.

7. Compliance and control measures

- Does the country have a specific law on official state control over compliance with legislation on veterinary medicine or are control measures embodied in different related laws?

The verification of compliance with legal requirements through controls is fundamentally important in ensuring that the objectives of AMU policy are achieved. Therefore, the CA should have the power to perform official controls at all stages of the production, distribution, and use of veterinary medicinal products, feed, food products, pesticides, fungicides, fertilizers, and so on.

- Which CA is responsible for conducting official controls?
- Do the official controls take place based on documented procedures to ensure that the controls are carried out uniformly? Are the procedures up to date?
- Are official controls applied with the same care to exports, to domestic markets, and to imports?
- What official control methods and techniques are used (for instance, monitoring, surveillance, verification, audit, inspection, sampling, analysis, and so on)? Specify the scope, aim, and data sources of monitoring and surveillance.
- Do standard operating procedures provide for step-by-step instructions on how to perform an official control?
- What actions are taken by CAs in the case of noncompliance?

Such actions may include the following measures: suspension or revocation of wholesale distribution authorization of veterinary medicinal products, removal of importers, manufacturers, and distributors from the manufacturing and wholesale distribution database, monitoring and, if necessary, ordering the recall, withdrawal, or destruction of feed or food, and so on.

- What are the sanctions for failure to comply with regulatory requirements (whether financial or other types of penalties)? Are the sanctions effective, proportionate, and dissuasive? How is the consistent application of sanctions ensured?

8. The assessment of national capacity building

Capacity building is a key element that ensures the proper functioning of national AMU policies and programs. The answers to the following questions will help in assessing this capacity.

- Are state budget allocations for the implementation of AMU and AMR programs and policies adequate?
- Is there a coordination mechanism between government health care authorities and veterinary medicine institutions?
- What is the state of laboratory readiness for generating high-quality data and metadata on AMR and antimicrobial residues?

Numerous tools can help in evaluating national laboratory capacity in AMR. For instance, FAO has developed the Assessment Tool for Laboratories and AMR Surveillance Systems, which is used by numerous countries and laboratories (FAO 2021). This tool may be useful in conducting a detailed laboratory diagnostic for AMR detection. Another recommended source is a World Bank toolkit, Ensuring Quality to Gain Access to Global Markets, which was designed to help development partners and governments assess and analyze a country's quality infrastructure ecosystem (Kellermann 2019).

- Is there a designated national reference center that performs the following?
  - Coordination of activities related to AMR surveillance and monitoring programs
  - Coordination and collection of information from participating laboratories within the country
  - Publication of an annual report on the AMR situation in the country
- If such a center exists, does it have access to the following:
  - Raw data
  - Complete results of quality assurance and interlaboratory calibration activities
  - Interlaboratory proficiency testing results
  - Information on the structure of the surveillance or monitoring system
  - Information on the laboratory methods selected
- Are there national AMU and AMR training programs for official inspectors, business operators, and so on?
- Does the country use international mechanisms to improve AMU capacity?

"The OIE is committed to supporting veterinary services of member countries to build their capacity as well as to develop and implement national action plans for AMR, to regulate and promote prudent use of antimicrobial agents, and to implement monitoring and surveillance" (OIE 2016, 9).

"FAO is supporting countries in building and consolidating AMR surveillance and laboratory capacities. This support is helping countries to generate, collect, and analyze high-quality epidemiological data within national AMR surveillance systems in food and agriculture sectors and interpret findings across sectors."[68]

- What is the state of readiness of CAs in the proper performance of official control, particularly monitoring and surveillance? Is there a sufficient number of trained inspectors? Are procedures documented, including standard operating procedures? Is proper technical equipment available?
- Are national AMU policies and legislation recognized by trading partners? If so, provide examples and sources of information.
- What is the state of readiness of business operators to comply with national requirements (technical readiness, the competence of personnel, and so on)?
- Are there national AMU and AMR awareness programs? If so, what is their scope (AMR awareness, hygiene, sanitation, optimal use of antibiotics and vaccination, and so on)?

[68] "Surveillance and Monitoring," Antimicrobial Resistance (dashboard), Food and Agriculture Organization of the United Nations, Rome, https://www.fao.org/antimicrobial-resistance/key-sectors/surveillance-and-monitoring/en/.

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