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Objectives

Significant interest has been recently devoted to the modernization of food safety regulatory functions. The creation of new food regulatory agencies entrusted with food safety oversight and/or the modernization of existing organizations to support their ability to cope with emerging issues has led to the necessity to develop tools to help map food regulatory functions and ascertain their performance in support of continuous improvement and investments to enhance such functions based on evidence-driven evaluations.

Guidance from Codex texts **CXG 82-2013** (Principles and Guidelines for National Food Control Systems) and **CXG 91-2017** (Principles and Guidelines for Monitoring the Performance of National Food Control Systems) was used by FAO/WHO and resulted in the development of a “Food Control System Assessment Tool¹” which encompasses 162 criteria across 4 dimensions:

- ❖ Dimension A – Input and Resources – including the policy, and legal framework, the institutional framework, the financial resources, the infrastructure and equipment and the qualification of the personnel,
- ❖ Dimension B – Control Functions – including domestic controls, import controls, export controls, Monitoring Program performance across the food chain, foodborne disease surveillance, management of food safety emergencies,
- ❖ Dimension C – Interactions with Stakeholders – including relationships established between competent authorities and the private sector, communication, and engagement with consumers, and with competent authorities in other jurisdictions
- ❖ Dimension D – Science / Knowledge Base and Continuous Improvement – including access to scientific data and the capacity to analyse it based on the risk analysis principles, as well as the ability to continuously invest in enhancing the performance of these food regulatory functions.

The implementation of this approach by food regulatory jurisdictions presents some challenges related to the high level of investment required to complete the evaluation, including when such evaluation is considered a self-assessment. It also requires targeted training of evaluators and mobilization of significant resources from the various competent authorities involved.

There is therefore interest in developing a “lighter” approach that would still enable an initial high-level evaluation of food regulatory functions, to support prioritization of investments in strengthening such functions.

This document offers a proposal for such an alternative approach, based on the identification and mapping of key food regulatory functions, as described in Codex guidance (Figure 1).

This approach would result in **data collection**, enabling **gap analysis** with respect to these key **food safety regulatory functions** that need to be fulfilled with regards to **food regulatory oversight**, either for the entire food production system or in relation to a given value chain. This alternate approach can also be tailored to address the performance of segments of these regulatory functions, with relevance to select competent authorities where it could be utilized as a rapid self-assessment tool.

The proposed simplified **mapping** will focus on the identification and fulfillment of key food (safety) regulatory functions, in conjunction with the management of the food control system as a whole or with respect to a specific value chain.

The proposed mapping should:

- Identify each competent authority involved in managing food safety and quality requirements.
- Map their food (safety) regulatory functions and identify gaps in coverage of such functions, and where relevant their performance.

¹ <https://www.fao.org/documents/card/en/c/CA5334EN>

Mapping Food Regulatory Functions and their Operationalization

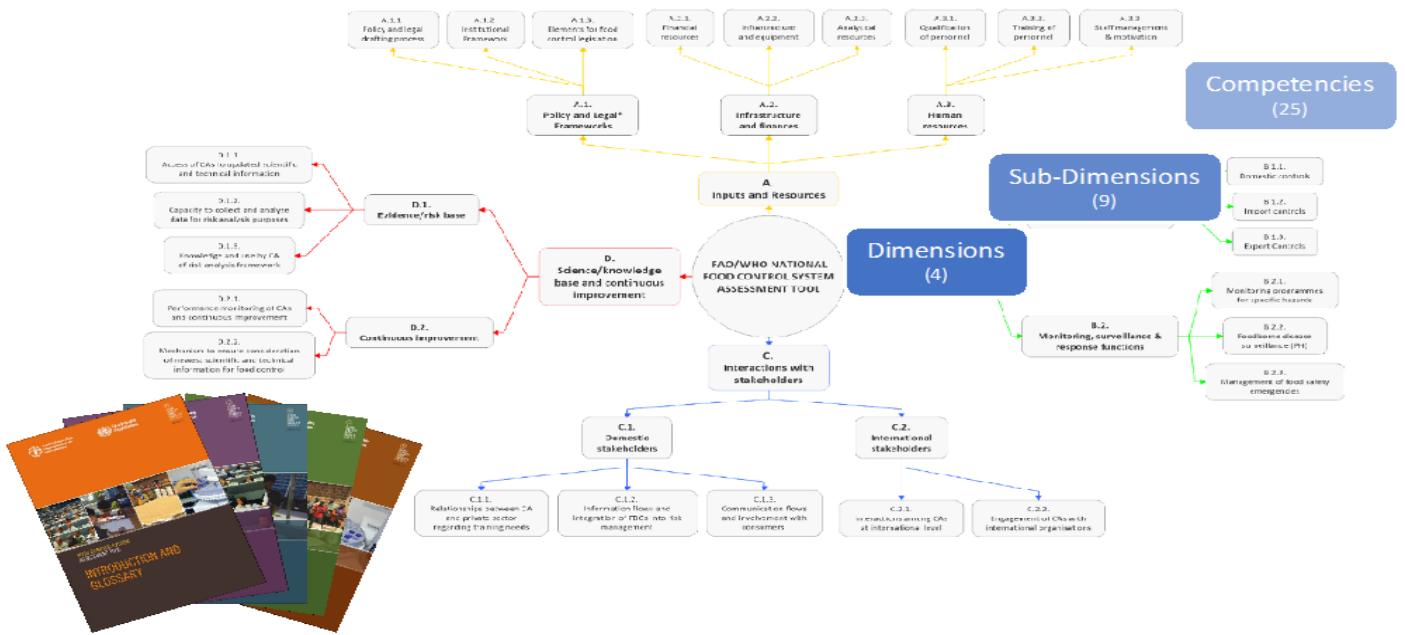


Figure 1: Proposed structure of FAO/WHO food control system assessment tool

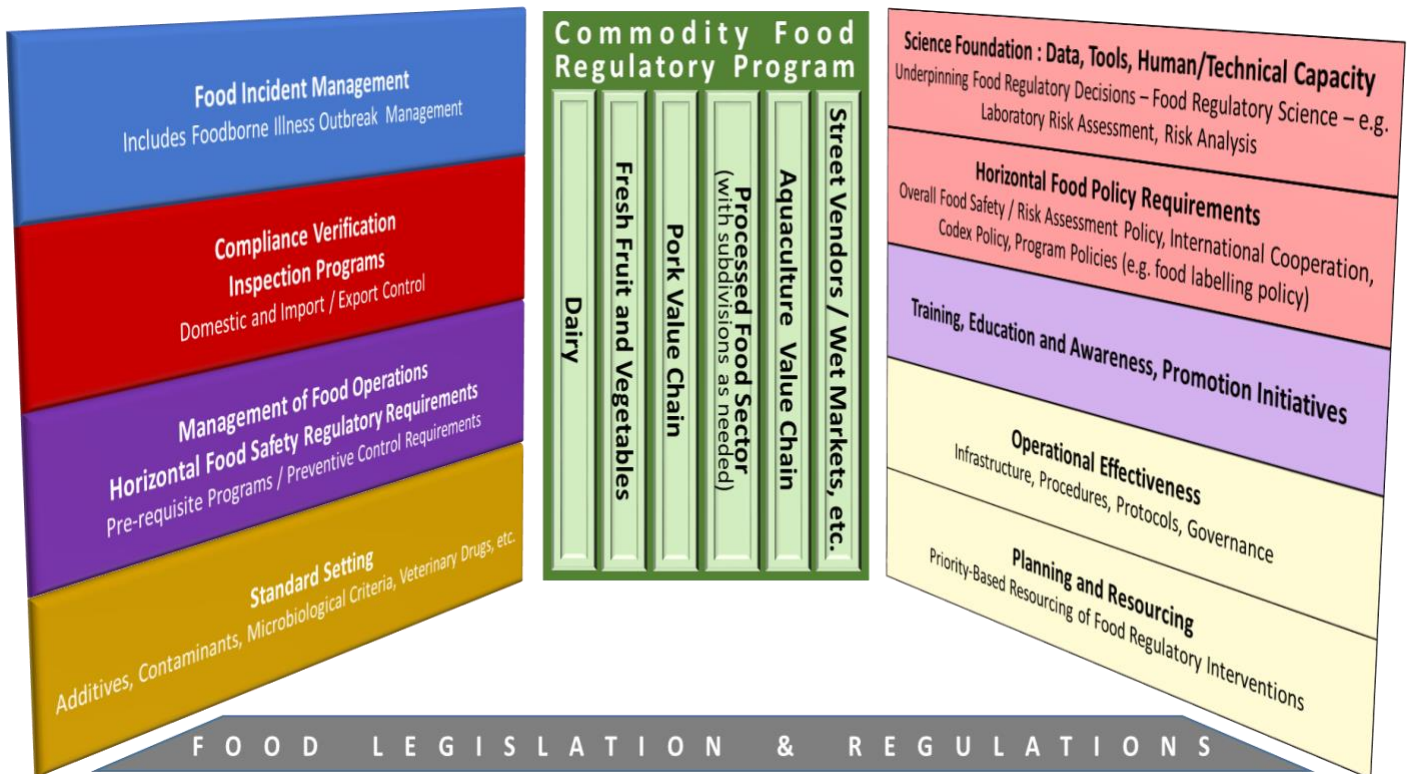


Figure 2: Food Regulatory Functions that need to be mapped

Figure 2 offers a schematic approach to illustrate the proposed mapping which will focus on the parameters developed in the sections to follow.

1. Food Safety Legal and Institutional Structure

This parameter focuses on **identifying the key competent authorities** involved, directly and indirectly, in overseeing food production and/or sale, including the definition of their mandate and functions as it **relates to food safety and quality oversight**.

It is important to **document the legal support for such mandate**: laws and regulations giving these authorities their prerogatives to enable their assessment.

It is also necessary to record any recent institutional outputs related to food safety and quality regulatory functions.

MAPPING OF PERFORMANCE INDICATORS

1. Competent Authority(ies) and Legal Framework(s)

Indicator	Demonstration of Achievement (Examples of aspects to be identified and/or documented)
Roles and Responsibilities and mandates of competent authorities responsible for food production and/or sale	Texts: laws, regulations, decrees describing the mandate of the organisations / competent authorities.
Legal framework providing empowerment and enabling interventions of competent authorities	<p>Demonstration of “recent” nature of legal framework (laws and regulations). Legal framework encompasses the powers / authorities needed for intervention by competent authorities and is based on international guidance and best practices:</p> <ul style="list-style-type: none"> ➤ Defines relationship between regulators and regulated parties ➤ Defines penalties and sanctions ➤ Supports Preventive approach in risk management ➤ Supports anchoring decisions in risk analysis ➤ Supports harmonization with international standards (references international standards) ➤ Offers enforceability of decisions made by competent authorities <p>Demonstration of existence of Regulation-making Authorities that allows to exercise the mandate of each competent authority</p>
Coverage of the Supply Chain with food regulatory competencies from primary production to final products	<p>Mandates / Competencies provided by the legal texts (laws / regulations and decrees) empowering competent authorities attest to the coverage of the oversight on productions:</p> <ul style="list-style-type: none"> ➤ From the primary production sector (and its inputs), up to final (processed) products ➤ From primary producers to retailers, importers and exporters <p>Identification of coverage gaps or overlap where relevant</p>
Indicator of implementation of mandate if shared between various competent authorities: Required coordination and collaboration	<p>Legal requirements defining relationships between competent authorities</p> <p>Practical considerations of collaboration and coordination: Committee structure, agendas of meetings and minutes</p> <p>Identification of gaps in collaboration between regulators / competent authorities with overlap or adjacent oversight on the production supply chain</p>

2. Documenting Horizontal Food Safety Regulatory Functions

It is important to map the following functions as they relate to food production and/or sale:

2.1 Development of Food Standards

Horizontal **standards** related to substances used in conjunction with food production (management of approval of food additives, veterinary drugs and requirements associated with the management of Maximum Residue Levels (MRLs), and of substances occurring in food (chemical and microbial contaminants), as well as labeling provisions applicable to food (both health-driven and provisions associated with the need to offer accurate information to consumers on food composition and conditions of production – e.g., halal, organic, etc.)

MAPPING OF PERFORMANCE INDICATORS

2.1 Standard Setting

Indicator	Demonstration of Achievement
<p>Standards of Food Safety and Quality Accessible to All Stakeholders and Partners, with emphasis on standards related to:</p> <p>A. Use of food additives</p> <p>B. Use of other substances relied upon in conjunction with food production</p> <ul style="list-style-type: none"> ➤ Incidental additives ➤ Processing aids ➤ Food contact material /packaging applications <p>C. Use of Veterinary Substances, feed additives in conjunction with production</p> <p>D. Use of pesticides in conjunction with food production (e.g., pesticides authorized for use in conjunction with food / agri-food production practices)</p> <p>E. Microbiological criteria related to food</p> <p>F. Chemical Contaminant requirements</p> <p>G. Quality standards related to methods of production such as “Halal”, “organic”, “local” etc.</p>	<p>Web-enabled Documents provided upon request describing the relevant food safety and quality standards.</p> <p>Or Documents available and accessible in an easy manner to demonstrate the achievement of these functions.</p>
<p>Standards of Food Safety and Quality Benchmarked Against Codex Standards and Where Differences Exist, Such Differences are Justified by a Risk Rationale or a Clear Rationale</p>	<p>Documents / publications referring to food safety and quality standards identifying references to Codex.</p>
<p>Risk Assessments Supporting Standards / Technical Requirements Developed and Accessible such as risk assessment validating the adoption of a MRL for a Veterinary Drug Residue, or of a Maximum Level for a contaminant in food</p>	<p>Risk Assessments published or made available for food safety and nutrition standards, in particular for those differing from Codex.</p>
<p>Processes and Protocols to Develop Food Safety and Quality Standards are Clear / Accessible to All Stakeholders including Decision-making Process / Governance for Food Standards Discussion and Adoption Available to All Stakeholders (aspect that will be assessed in other areas of performance)</p>	<p>Documents / Notes / Minutes corroborating the existence of food standards decision-making processes / procedures – for example: minutes of Committee meetings.</p> <p>WTO notifications for standards</p>

2.2 Management of (Food Business) Operators

This includes requirements destined to food business operators and production establishments – from farm to retail – supported by **registration and licensing regimes**. It is important that such requirements (underpinning licensing) feature preventive approaches, such as the development and implementation of preventive controls, as part of an integrated food safety and quality management scheme, adapted to the size of the operation and encompassing Pre-Requisite Programs (PRPs), Preventive Controls (PCs) and Traceability. In addition, and of equal importance, is the documentation of which authority is responsible for a particular area of registration or licensing, and identifying possible overlaps and/or gaps.

MAPPING OF PERFORMANCE INDICATORS

2.2 Management of (Food Business) Operators

Indicator	Demonstration of Achievement
<p>Technical Regulations / Technical Requirements Imposed on FBOs to Adopt Preventive Measures such as Requirements to Adopt Prerequisite Programs, Preventive Controls/HACCP and Traceability Measures, Including Through Recognition of Third-Party Food Safety and Quality Management Schemes</p> <p>➤ Example: For the production of food of animal origin, it is important to focus on the identification of requirements related to:</p> <ul style="list-style-type: none"> ▪ Good Animal Husbandry Practices (GAHP) ▪ Good Hygienic practices (GHP) ▪ Traceability 	<p>Regulations / Technical guidance documents provided to FBOs on preventive controls, prerequisite programs and traceability, across the supply chain.</p>

2.3 Compliance Verification and Inspection

This includes mapping compliance promotion, compliance verification – such as inspection activities – with the possible identification of sub-categories of targeted production establishments. It is important to map these functions addressing both products destined to the domestic market, as well as those destined to export. Additionally, documenting and mapping such functions and their deployment for imported products is essential.

MAPPING OF PERFORMANCE INDICATORS

2.3 Compliance Verification and Inspection

Indicator	Demonstration of Achievement
<p>Workforce Dedicated to Compliance and Enforcement, Including to Inspection of Domestic Establishments, Imported Food, Food Products Destined to Export</p>	<p>Documented human resource capacity.</p>
<p>Inspection – Domestic / Import and Export – Protocols and Procedures, Including Procedures to Recognize / Accredite Third Party Inspection Organizations or Certification (of Compliance) Bodies</p>	<p>Documents specific to protocols, procedures specific to inspection of domestic establishments, import and exports.</p> <p>Inspection reports.</p> <p>Notification / publication of inspection outcomes.</p>
<p>Culture of Compliance Promotion enabling gradual uptake of (enhanced) food safety and quality requirements, adapted to the performance of the production sector</p>	<p>Documents attesting to support provided to the sector to stimulate compliance e.g. trainings, guidance documents and other tools</p>

2.4 Incident Management and Enforcement Functions

This includes mapping the management of non-compliant functions related instances, enforcement measures associated with **food safety incidents** – such as **food recalls** – and the management of **foodborne illness outbreaks**. It is important that the mapping identifies the authorities involved, the function of the units and departments included in these functions, and the identification of any documents, procedures and protocols that support the documentation of the implementation of such functions

MAPPING OF PERFORMANCE INDICATORS

2.4 Incident Management and Enforcement Functions

Indicator	Demonstration of Achievement
Capacity of Food Safety Investigation: including capacity to document non-compliance incidents	Procedures and protocols covering food safety incidents covering: <ul style="list-style-type: none"> ➤ Incident documentation ➤ Incident assessment, including rapid risk assessment where required ➤ Decision-making process related to non-compliance incidents
Evidence-based management of non-compliance incidents including food (safety) incidents	Documented protocols offering orientation on situations of non-compliance to be assessed through a rapid risk assessment prior to decision-making Documented protocols, procedures showcasing the independence of the decision-making process in instances of non-compliance, including the reliance on scientific assessments and/or on established policies to direct enforcement action / interventions
Procedures and Protocols for Food Recalls (Including Follow-up on Effectiveness) and Food Incident Management (Including Foodborne Illness Outbreaks) supported by Risk Analysis	Documented recall protocols, supported by risk analysis Reports / publications / web postings associated with food recalls, food incidents and / or outbreak management.
Capacity to address food safety emergencies, including food borne illness outbreaks	Documented food safety emergency protocols or equivalent measures Foodborne illness outbreak protocol(s) or equivalent measures Documented Signal detection mechanisms for food safety emergencies, including contribution to international networks such as INFOSAN

3. Documenting Food Safety Regulatory Enablers

The implementation of the regulatory functions described above, in a manner that is consistent with Codex guidance and international best practices, requires the presence of **specific function enablers**. Namely:

3.1 Existing food (safety) scientific capacity supporting food regulatory functions, including:

- **Food testing capacity related to food:** this includes infrastructure and availability of equipment and consumables
- Existing contaminants and residues monitoring programs

- Existing **capacities and competencies** in risk assessment and risk analysis of the competent authorities involved in food oversight
- Existing data related to food safety oversight and the manner such data is managed.
- Existing risk assessment capacity to support food decision-making (trained personnel, data supporting risk assessment, technological tools to support risk assessment)

MAPPING OF PERFORMANCE INDICATORS

3.1 Food (Safety) Scientific Capacity Supporting Food Regulatory Functions

Indicator	Demonstration of Achievement
Reliance on Food Laboratory Data from Trusted Food Laboratory Sources	<p>Results of food testing in support of food regulatory decisions.</p> <p>Demonstration of reliance on a network of laboratories either self-managed or with established relationships</p>
Coverage of Food Safety, Quality and Nutrition Parameters with Laboratory Analysis	<p>Documented food testing capacity with:</p> <ul style="list-style-type: none"> ➤ List of official methods. ➤ List / reported food laboratory methods. <p>List of accredited laboratories.</p>
Timely Mobilization of Food Laboratory Infrastructure (Whether Internal or Contracted) to Address Food Regulatory Requirements / Decisions	<p>Plans / reports of food monitoring activities in support of food regulatory functions – risk assessments, standard setting, compliance verification and enforcement.</p> <p>Food Monitoring activities including residue (of veterinary drugs and/ or relevant pesticides) monitoring in food</p>
Risk Assessment Capacity in Support of Food Decision-making: <ul style="list-style-type: none"> ➤ Competencies ➤ Data ➤ Tools (IT support, etc.) 	<p>Documented capacity of risk assessment as demonstrated by reports developed internally or published, supporting food regulatory decisions</p> <p>Documented support of food regulatory decisions with scientific / risk assessment – e.g. risk-based classification of establishments, product shelf life or cooking/hold temperatures</p> <p>Demonstrated infrastructure to manage data in support of risk assessment and risk analysis, including IT capacity</p> <p>Demonstrated reliance on a specialized workforce supporting risk assessment and risk analysis</p>

3.2 Horizontal food (safety) policy capacity

To support food regulatory operations aiming for consistent risk management approaches – e.g., enforcement policy, food recall policy, or conditions to rescind an establishment license – or of a longer-term nature – e.g., **food safety policy consisting of a vision for the future and a direction for food safety investments targets**. Such policy capacity should also be expressed in the contribution of the relevant competent authorities in international food standard setting processes and harmonization efforts of food safety decisions at the regional or sub-regional efforts.

MAPPING OF PERFORMANCE INDICATORS

3.2 Food Safety Policy Capacity

Indicator	Demonstration of Achievement
Consistent Food safety decisions anchored in developed and implemented policies with a demonstrated involvement of partners and stakeholders	<p>Documented policies / decision documents serving as a reference for operational food regulatory functions e.g., food recalls, decisions related to food production operations; as well as a guidance for the development of standards / requirements e.g., food labelling policy. It is important also to identify indicators of application of such policies and guidance</p> <p>Documented processes that showcase involvement of partners (e.g., other competent authorities, relevant government organizations) and stakeholders (i.e., all those that may be impacted by food regulatory decisions)</p>
Longer term vision for food safety programs, supported by a food safety policy, a strategic plan or and equivalent forward-looking guidance	<p>Food safety policy including strategic plans developed and adopted by competent authorities.</p> <p>Where several of such policies and directional documents exist (for various competent authorities sharing the food regulatory oversight), the assessment and indicators of achievement should also address their level of alignment and complementarity</p> <p>Demonstration of reliance on a foresight approach that helps anticipate emerging issues and their identification with the relevant level of collaboration with partners and stakeholders</p>
Participation in Prioritized Codex Committees / Work	<p>Codex committee preparatory documents / reports / records of intervention.</p> <p>Documents of national Codex governance (national Codex committee): TOR, reports.</p>
Reliance on Codex to Develop Own Food Decisions	Document showing use of Codex standard as a source for food decisions.

3.3 Training, Awareness Development and a Culture of learning

This parameter should address the mapping of training and education efforts dedicated to the food competent authorities' workforce in specialized areas of food safety and quality science. In particular, to address the development of a robust scientific capacity, as well as efforts to address learning needs and education of regulated parties, in particular, upon the development and adoption of new / updated food safety requirements.

MAPPING OF PERFORMANCE INDICATORS

3.3 Culture of Learning, Training and Awareness Development

Indicator	Demonstration of Achievement
Availability of Training Programs and Learning Curricula within competent Authorities	Documented learning programs and associated documents: training material plans / reports of delivery.
Competency-based Assignment of Responsibility Focusing on Scientific Disciplines	HR plan with indication of identified competencies associated with key positions.
Availability of a Continuous Education Program, Planned and Executed for the Benefit of Key Personnel	Examples of job descriptions with identification of key (technical) competencies for food regulatory positions, in particular for food inspection staff. Example of learning plans and competency enhancement programs developed and implemented
Result-based Organizational Learning Framework	Evaluation of learning plans and their impact on organizational performance.
Culture of Learning and Continued Improvement Promoted, including Compliance Promotion with (enhanced) food safety and quality requirements, adapted to the performance of the production sector	Documents attesting to awareness raising initiatives and other support provided to the production sector to enhance food safety performance e.g., trainings, guidance documents and other tools

4. Governance and Stakeholder Engagement

The Gap analysis process should also map:

- A. **Existing mechanisms of food safety decision making** through documented **governance** – committees or relevant groups – entrusted to support the development and vetting and approval of food safety decisions.
- B. Existing capacity to engage and exchange information, data, consultations and develop collaborations with the stakeholder community, including:
 - Food Business operators and their representatives
 - Consumer organizations and their representatives
 - International food regulators at the regional and global levels

MAPPING OF PERFORMANCE INDICATORS

4. Effective Governance and Decision-Making Processes

Indicator	Demonstration of Achievement
Clear Roles and Responsibilities Within and / or Between Food Competent Authorities	Documented committee structures in support of food (regulatory) decision-making: terms of reference, minutes, reports, procedures / protocols, internal guidelines, etc. Documented delegation of authority documents or equivalent – document codifying who decides what and under which circumstance (i.e., aided by which advisory capacity) Documented notification / engagement with domestic stakeholders and trading partners for food regulatory decisions.

5. Operational effectiveness, Planning and Resourcing

The Gap analysis process should also map:

- A. **Existing mechanisms to deliver food regulatory functions** through a documented **procedures and protocols for key functions exercised by the various regulators**: supporting consistency, independence, and predictability, along with effectiveness in delivery and efficiency in resource mobilization and utilization
- B. Existing approaches to resource food regulatory functions, and to allocate such resources in alignment with the overall policies / strategies and where the need is most identified (i.e., using a risk-based lens)

MAPPING OF PERFORMANCE INDICATORS

5. Effective Operations, Planning and Resourcing of food regulatory functions

Indicator	Demonstration of Achievement
Food Regulatory Program Delivery Supported by Consistent and Transparent Procedures and Protocols	<p>Documented procedures to deliver key food regulatory functions such as:</p> <ul style="list-style-type: none"> ➤ Food standard setting (pre-market approvals, post-market decisions) ➤ Licensing and registration ➤ Enforcement decisions <p>Supported by the level of stakeholder engagement and accessibility of the information (transparency)</p>
Planning and Resources allocation to food regulatory functions aligned with strategic direction	<p>Effective planning processes: documented planning activities to identify intervention priorities and support resource allocation</p> <p>Effective performance evaluation of food regulatory functions, with documented impact on future directions</p> <p>Alignment of food regulatory program implementation with overall strategic direction as expressed by a food safety policy or strategic plan or equivalent forward-looking document</p> <p>Resources associated to food regulatory functions are documented and consistent (and align with plans)</p> <p>Documented resource allocation based on a risk-based approach – i.e., more resources are dedicated to areas deemed of higher risk</p>

6. Conclusion

The documentation of performance of food regulatory functions using the parameters of performance indicated above, even on a qualitative basis will help identify areas of investments to enhance the performance of such food regulatory functions, based on evidence collected and in line with the need to enhance the operationalization of food safety regulatory functions.

Operationalizing these food safety regulatory functions is not a simple task and requires not only to follow international guidance but to adapt such guidance to the national and local jurisdictional environment, with the aim to offer localised solutions and to ensure investments are dedicated to crucial areas of interventions, while addressing certain needs using regional and collaborative sources.