# Performance, Vision and Strategy (PVS) *for*







Technical Capability



Human and Financial Capital

Interaction with the Private Secto

Safeguarding Public Health and Market Access

## National Food Safety Services

2<sup>nd</sup> Edition 2008





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the Private Sector



Safeguarding Public Health and Market <u>Access</u>

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## Introduction

The availability of a safe food supply is fundamental to ensure human health and productivity, national economic well-being and poverty reduction. Millions of people are affected each year by foodborne illnesses, some of which are fatal and may lead to severe sequelae. Each year, globally 1.8 million people die from food- and water-borne diarrheal illnesses. Foodborne illnesses result from the ingestion of contaminated foods and include a broad group of illnesses caused by pathogens, chemicals and parasites that contaminate food at various points along the food production, distribution and preparation continuum. Growing international trade, migration, and travel have the potential to increase the spread of dangerous pathogens and contaminants in food. In today's interconnected and interdependent world, local foodborne illness outbreaks may become a potential threat to the entire globe.

Foodborne illnesses cannot only spread faster, but they also appear to be emerging more rapidly than ever before, and might be able to circumvent conventional control measures. In many countries, as food trade has increased, so has the incidence of foodborne illnesses caused by hazardous microbial contaminants such as Salmonella spp., Campylobacter spp. and Escherichia coli 0157:H7. Similarly, chemical contaminants in the food chain continue to be significant sources of food-borne illnesses and health concerns. These chemical contaminants include toxins of biological origin such as mycotoxins, botulism and ciquatera, as well as environmental contaminants such as mercury and dioxin, and residues from the improper use of pesticides and veterinary medicines. In addition, emerging food safety challenges that have or may have an impact on public health such as highly pathogenic avian influenza and bovine spongiform encephalopathy (BSE) must be addressed. The seemingly growing incidence of foodborne illness outbreaks worldwide has negatively affected public confidence on the ability of official services to ensure the safety of foods and thus protect public health.

To respond to the challenges presented by current food safety issues and by the growing global demand for food, national food safety systems must adopt expanded roles and a broader vision, extending their traditional range of activities to include the entire food continuum, from inputs for production to the final product for consumption, that is, from farm or pond to table.

To strengthen national food safety systems, it is essential to promote and support their development based on science. Risk analysis and process- and risk-based inspection, for example, must be incorporated into the design, implementation, and management of national food safety assurance systems.

Initiatives aimed at ensuring the sustainability and reliability of national food safety systems should be based on a process of identification, analysis and prioritization of needs. This process requires an instrument that guides the characterization and discussion of institutional and operational capabilities of each food safety service within the national food safety system, measures advancement, and allows strategic actions for technical cooperation to be identified that will help modernize these services. (Note that in many countries there are two or more institutions entrusted with food safety control responsibilities, often within separate ministries or other governmental administrative units. Therefore, it is appropriate to refer to a "food safety system," as opposed to a "food safety service." Nevertheless, to ensure the safety of the entire food supply of a country, it is necessary to examine the individual capacities of each component or service comprising the system and ensure that all the services achieve an appropriate and harmonic level of competence.)

To assist in this effort, the Inter-American Institute for Cooperation on Agriculture (IICA) and the Pan American Health Organization (PAHO) joined forces to adapt the Performance, Vision and Strategy (PVS) instrument, originally developed by IICA for national veterinary services, for use by national food services comprising the national food safety system. The PVS instrument can assist national food safety services to determine their current level of performance, create a shared vision with the private sector on how the services should perform in the future, individually and in relation to other services within the national food safety system, establish priorities, and facilitate strategic planning to fulfill their enormous responsibility towards the consumer, and to take full advantage of the new opportunities and commitments brought about by globalization.

IICA's efforts are directed at assisting the countries of the Americas to strengthen their national food safety systems, with the goals of contributing

to the protection of consumer health, improving efficiency, and helping the countries to successfully compete in national and international markets. These goals are achieved by helping food safety systems modernize by improving their regulatory mechanisms, adopting science-based procedures, and increasing their technical capacities. Such improvements enhance a country's ability to increase the safety of its food supply throughout the entire food continuum and help identify, in advance, emerging issues that may impact public health and/or food trade.

The aim of the Pan American Health Organization (PAHO), in turn, is to address some major determinants of health and disease: in this case, unsafe foods, that is, foods in which chemical, microbiological, zoonotic and other hazards pose a risk to health and to household food security. The final goal is to reduce the health, social and economic burdens of foodborne disease and food contamination. The achievement of this goal will require advocating and assisting member countries in the development of risk-based, sustainable, integrated food safety systems; developing science-based measures along the entire food production continuum that would help prevent exposure to unacceptable levels of microbiological agents and chemicals in food; and assessing, communicating and managing foodborne risks, in cooperation with other partners. In addition, PAHO has the responsibility to support countries in complying with the International Health Regulations (IHR 2005).

IICA and PAHO share the common interest of helping the countries of the Americas comply with the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) of the World Trade Organization (WTO), and the standards, guidelines and recommendations of the Codex Alimentarius.

Countries with highly credible food safety systems have services with the following four fundamental components in common: 1) the *technical capability* to address current and new issues based on scientific principles; 2) the *human and financial capital* to attract resources and retain professionals with technical and leadership skills; 3) *interaction with the private sector* to stay on course, identify needs and conduct joint programs and services; and 4) the *ability to safeguard public health and access markets* by complying with existing standards and regulations and having the flexibility to adapt to new ones. These four components provide the basic structure of the PVS instrument.

### Applying the PVS Instrument

It must be kept in mind that every service comprising the food safety system must be examined separately and in relation to the rest of the system, if applicable. To best determine the current level of performance of each national food safety service, create a shared vision, set priorities and facilitate strategic planning, a series of six to eight critical competencies have been identified for each of the four fundamental components. Qualitative levels of advancement are described for each critical competency. To help visualize the potential or cumulative level of advancement within each critical competency, a pie chart is shown next to the explanatory text for each level.

In addition to the description of qualitative levels, a space has been provided after each critical competency to either expand upon or clarify responses, if so desired. The following hypothetical example illustrates the levels of advancement for *harmonization*, one of the twenty-seven critical competencies covered in the PVS instrument.

#### 3. Harmonization

The capability and authority of national food safety services to be active<sup>1</sup> in harmonization, to ensure that national regulations covered by their mandates are consistent with international norms, guidelines and recommendations.

#### Levels of advancement:

- The national food safety services have no process in place for being informed of international norms. National food safety regulations do not take account of international norms, guidelines and recommendations.
- The national food safety services are aware of relevant international norms, guidelines and recommendations but have no process in place for identifying gaps, inconsistencies, and non-conformities between national food safety regulations and international norms, guidelines and recommendations.
- The national food safety services periodically review national food safety regulations with the aim of *harmonizing* them with international norms, quidelines and recommendations.
- The national food safety services are also active in *reviewing and commenting* on proposed new or revised international food safety norms, quidelines and recommendations.
- The national food safety services actively and regularly participate at the international level in the formulation and revision of international food safety norms, quidelines and recommendations.

The national food safety service has reviewed and harmonized all regulatory norms in the dairy production chain, and is currently reviewing the regulatory norms relevant to the fresh vegetable production chain.

<sup>1</sup> A country can be active in international standard setting without actively pursuing national changes. The importance of this element lies in the promotion of change in the country.

## Using the results

The PVS instrument is easy to understand, flexible and easy to use. More than a diagnostic tool, it is a process geared to the future that can be used in a passive or active mode, depending on the level of interest and commitment to improve the national services over time.

In the passive mode, the PVS instrument raises awareness, improves understanding, and teaches the various participating sectors and stakeholders the basic components and critical competencies needed for national food safety services to function adequately. In this mode, the instrument can also be used to develop a shared vision, foster dialogue, and adopt a common language for discussion.

The active mode generates maximum potential and yields the best results, assuming both the official and private sectors are committed to the process. In this mode, performance is assessed, differences are explored, and priorities are established. Leadership from the official sector is critical for success. It is in the active mode that actions happen, investments are made, and commitments are fulfilled. Continuity of the PVS process is assured when a true partnership exists between the public and the private sectors.

For example, the director of a national food safety service might use the instrument to monitor advances in each of the four components. Furthermore, the different users can participate in the analysis and discussion of results to assist in defining common policies, identifying priorities, and proposing actions to be taken.

The results of the PVS instrument can help: 1) ascertain overall performance in each of the four components; 2) rate the relative performance of each of the competencies; 3) compare the performance of each national food safety service with that of others in the national system, the region or globally, for the purpose of exploring areas for cooperation or negotiation; 4) identify differences in the responses of different users with a view to arriving at a common point of view; 5) foster common understanding in order to achieve greater levels of advancement; 6) help determine the benefits and costs of investing in national food safety services and obtaining assistance from financial

and technical cooperation agencies; 7) provide a basis for establishing routine monitoring and follow-up mechanisms for assessing the overall level of performance of the national food safety system and services over time; and 8) help identify and specify objectives and needs when applying for financial support (grants).

## Fundamental Components

I. Technical Capability

II. Human and Financial Capital

III. Interaction with the Private Sector

IV. Safeguarding Public Health and Market Access

## I. TECHNICAL CAPABILITY



- 1. Diagnostic and food analysis capability
- 2. Early detection and emergency response capability
- 3. Inspection and registration services
- 4. Surveillance
- 5. Emerging issues
- 6. Risk analysis
- 7. Technical innovation

## 1. Diagnostic and food analysis capability

The capability and authority of national food safety services to identify, quantify, and record hazardous biological, chemical and physical contaminants in food that can adversely affect food safety and thus the health of consumers.

s of advancement (identification and quantification of hazardous contaminants):
The national food safety services cannot carry out the identification and quantification of common, hazardous physical, chemical and biological contaminants in foods.
For the <i>most prevalent</i> hazardous biological, chemical and physical food contaminants, the national food safety services can collect samples anywhere in the country and immediately ship them to a laboratory for identification and quantification.
For the <i>most prevalent</i> hazardous biological, chemical and physical food contaminants, the national food safety services can carry out the identification and quantification on samples from anywhere in the country through a nationwide laboratory network.
Same as previous level, plus the food laboratories actively participates in international laboratory networks such as the <i>Inter-American Network of Food Analysis Laboratories (INFAL)</i> , to harmonize its analytical protocols, test its proficiency, improve its quality assurance system, and strengthen scientific and technical cooperation.
The national food safety services promote the accreditation of or grant official approval to private laboratories and audit the quality of their diagnostic, collection of samples, and shipment procedures. The national network and private laboratories have quality assurance programs.

## 2. Early detection and emergency response capability

The capability and authority of national food safety services to respond rapidly to unexpected outbreaks of foodborne illnesses or situations that place public health at immediate risk.

Level	s of advancement:
	The national food safety services do not have a system for determining whether a food safety emergency exists; if they have such a system, they do not have the authority to declare an emergency and take action.
	The national food safety services have a system to determine whether or not a food safety emergency exists but lack the necessary legal authority and financial support <sup>1</sup> to take action in response to such emergencies.
	The national food safety services have a system that facilitates timely decision making on whether or not a food safety emergency exists. The national food safety services have the legal authority and financial support to take action in response to such emergencies.
	Same as previous level, plus the national food safety services have institutional guidelines and mechanisms in place that enable them to coordinate the response to food safety emergencies with other relevant State organizations or institutions <sup>2</sup> involved in the food chain, and the private sector.
	Same as previous level, plus the capability of notification and reporting to INFOSAN emergency and IHR.

<sup>1</sup> Legal authority and financial support: the national food safety services already have in place the legal framework and financial resources needed to take immediate action.

<sup>2</sup> Relevant organizations or institutions: any official institutions responsible for control or surveillance in any part of the food chain.

## 3. Inspection<sup>1</sup> and registration<sup>2</sup> services

The capability and authority of national food safety services to ensure compliance with food safety regulations along the food chain.

#### Levels of advancement:

- The national food safety services have a national registration requirement for food production, processing, and preparation establishments but registration is not linked to an inspection.
- The national food safety services have a national registration requirement for food production, processing, and preparation establishments but inspection services are reactive (i.e., based on problems presented or perceived).
- The national food safety services have registration requirements for food production, processing, and preparation establishments, as well as an inspection program capable of making periodic inspections, taking samples, and certifying food for local consumption, ensuring compliance with national standards and facilitating surveillance, but inspection is based on sanitary aspects and end product sampling and analysis.
- Same as previous level, but the national food safety services inspection is based on process and risk, carried out by properly trained inspectors, in coordination with the private sector, and provides verifiable results demonstrating that products and procedures meet existing national standards and food safety regulations. End-product sampling and analysis is done only for verification purposes.
- Same as previous level, plus the national food safety services inspection program promotes voluntary observance by food producers of procedures such as Good Agricultural Practices (GAP) and Good Animal Husbandry Practices (GAHP), and of application by food processors of modern food safety assurance systems such as Good Manufacturing Practices (GMP), and, where appropriate, Hazard Analysis and Critical Control Points (HACCP).

Inspection service: has as its principal objective to ensure that food products comply with established standards and food safety regulations throughout the food chain.

<sup>2</sup> Registration service: government-regulated authorization for individual products to be marketed and for establishments that process, pack, transport, commercialize, prepare or serve foods to operate.

### 4. Surveillance

Levels of advancement:

The capability and authority of national food safety services to maintain an ongoing and systematic process of collection, analysis, and interpretation of food safety data for use in risk assessment to enable the design and adoption of science-based food safety policies, regulations and standards.

The national food safety services do not conduct any regular monitoring of common biological and chemical food contaminants.
The national food safety services occasionally collect samples anywhere in the country for monitoring of common biological and chemical food contaminants.
The national food safety services regularly collect samples anywhere in the country and analyze them to determine, qualitatively and quantitatively, the presence of common biological and chemical contaminants.
Same as previous level, plus the national food safety services coordinate food hazard monitoring programs with epidemiological surveillance programs conducted by the national public health authorities and share with them the results of monitoring programs on common biological and chemical food contaminants.
Same as previous level, plus the national food safety services match the data from food hazard monitoring programs to epidemiological survey data on human food-borne diseases to identify potential sources (food products or groups of products) of such hazards and illnesses and enable the adoption of appropriate risk management options.

## 5. Emerging issues<sup>1</sup>

The capability and authority of national food safety services to *identify* in advance sanitary problems or sanitary situations covered by its mandate which may put at risk, harm or benefit public health or the trade in food products.

Level	s of advancement:					
	The national food safety services do not have mechanisms to identify in advance emerging issues that may put at risk, harm or benefit public health or the trade in food products.					
	The national food safety services gather and evaluate information on emerging issues at the national or international level that may put at risk, harm or benefit public health or the trade in food products.					
	The national food safety services assess the risks, costs or opportunities of the emerging issues previously identified.					
	Based on scientific risk analysis, the national food safety services implement, with other relevant State institutions and/or their users, prevention or risk control actions to address adverse emerging issues, or alternately, benefits associated with emerging issues.					
	Based on scientific risk analysis, the national food safety services coordinate and implement actions with other countries to anticipate emerging issues, including audits of food safety services in countries that export food products to their country, and participation in international emergency networks.					

<sup>1</sup> Emerging issues: the emergence of new situations associated with competitiveness, market access, protection of public health, agricultural health, and the environment. Depending on their nature, emerging issues may represent threats but may also provide opportunities. The appearance of an emerging pathogen and changes in standards are examples of emerging issues.

### 6. Risk analysis<sup>1</sup>

The capability of national food safety services to make decisions and take action based on scientific principles and evidence, including the assessment, management and communication of risk.

#### Levels of advancement:

- The national food safety services do not compile data or other types of information that can be used to identify potential sanitary hazards and to analyze risk<sup>2</sup>. Food safety-related decisions are not supported by scientific evidence.
- The national food safety services compile and maintain sources of information or can access the information necessary only for hazard *identification*. Food safety-related decisions may be based on scientific evidence.
- The national food safety services have systems for actively seeking and maintaining relevant data and information for *risk assessment*<sup>3</sup>. They also have personnel dedicated to this task. Scientific principles and evidence provide the basis for options considered by food safety decision makers for *managing risk*.
- Same as previous level, plus the national food safety services are consistent in conducting scientifically-based risk assessments and developing food safety measures (managing risk) on this basis.
- Same as previous level, plus the national food safety services are consistent in managing risk and communicating the decisions taken to the designated national SPS authority or focal point, or in the absence of the latter, directly to the Committee on Sanitary and Phytosanitary Measures of the World Trade Organization (WTO/SPS), trading partners, and users.

<sup>1</sup> Risk analysis: the assessment, management, and communication of risk.

<sup>2</sup> Risk: the likelihood of manifestation and probable magnitude of the consequences of an adverse health outcome produced by one or more hazards present in food products.

<sup>3</sup> Risk assessment: the integration of hazard identification, hazard characterization, exposure assessment, and risk characterization.

#### 7. Technical innovation

The capability of national food safety services to update their overall service in accordance with the latest scientific advances and based on the food safety norms and guidelines of the Codex Alimentarius.

Levels	s of advancement:
	The national food safety services have <i>only informal</i> access to technical innovations through personal contacts or external media sources <sup>1</sup> .
	The national food safety services maintain an information base on technical innovations and international norms through subscriptions to scientific journals and electronic media <sup>2</sup> .
	The national food safety services have specific programs that identify technical innovations that can improve their operations and procedures.
	The national food safety services incorporate technical innovations into selected functions and procedures with specific resources and the collaboration or contributions of its users.
	The national food safety services have a dedicated budget and the collaboration and contributions of their users to continually implement technical innovations throughout the national service. In addition, the food safety services can rely on their capacity to secure outside cooperation and technical assistance funds for innovation.

External media: sources of information to which the national food safety services may subscribe, such as scientific publications and magazines.

<sup>2</sup> This includes consulting publications and news in web pages of the international reference organizations (Codex, OIE, IPPC, and WTO) as well as regular participation in international forums, Codex committees, International Food Safety Authorities Network (INFOSAN), etc.

## II. HUMAN AND FINANCIAL CAPITAL



- 1. Human talent
- 2. Training
- 3. Funding sources
- 4. Stability of policies and programs
- 5. Contingency funds
- 6. Technical independence
- 7. Capability to invest and grow

#### 1. Human talent

The capability of national food safety services to efficiently carry out professional and technical functions. It assesses professional staff in two ways: on the basis of their academic degrees<sup>1</sup> and their qualifications and training<sup>2</sup>.

A. Lev	vels of advancement (academic degrees):
	Within the national food safety services, it is estimated that less than ten percent of the professional personnel hold a relevant university degree <sup>3</sup> recognized by the State.
	Within the national food safety services, it is estimated that more than ten percent but less than a quarter of the professional personnel hold a relevant university degree recognized by the State.
	Within the national food safety services, it is estimated that more than a quarter but less than half of the professional personnel hold a relevant university degree recognized by the State.
	Within the national food safety services, it is estimated that half but less than three quarters of the professional personnel hold a relevant university degree recognized by the State.
	Within the national food safety services, it is estimated that three quarters or more of the professional personnel hold a relevant university degree recognized by the State.

<sup>1</sup> Not all professional positions require a university degree. Nonetheless, the percentage of university degrees serves as an indicator of professional excellence within the national service.

<sup>2</sup> Not all national food safety services have sufficient professionals for the required functions; thus, the percentage of qualified and trained professionals is indeed an indicator of excellence in the service.

<sup>3</sup> Relevant university degree: one that is relevant to the position held.

D. LCV	cis di advancement (professional stati qualifications).
	Within the national food safety services, it is estimated that less than ten percent of the personnel are qualified and trained to carry out the functions of their position.
	Within the national food safety services, it is estimated that more than ten percent but less than a quarter of the personnel are qualified and trained to carry out the functions of their position.
	Within the national food safety services, it is estimated that a quarter but less than half of the personnel are qualified and trained to carry out the functions of their position.
	Within the national food safety services, it is estimated that half but less than three-quarters of the personnel are qualified and trained to carry out the functions of their position.
	Within the national food safety services, it is estimated that three- quarters or more of the personnel are qualified and trained to carry out the functions of their position.

## 2. Training

The capability of national food safety services to keep their personnel up-to-date in terms of relevant information and knowledge, measured in terms of the implementation of an annual, needs-based training plan for their staff and of access to scientific and technical information.

A. Le	vels of advancement (training):
	The national food safety services have no training plans for their personnel.
	The national food safety services have an annual training plan for their personnel but it is not updated or funded.
	The national food safety services have an annual training plan for their personnel that is updated and funded but only partially implemented <sup>1</sup> .
	The national food safety services have an updated and funded annual training plan for their personnel that is largely implemented.
	The national food safety services have an up-to-date annual training plan for their personnel that is fully implemented.

<sup>1</sup> Partially implemented: implemented for some personnel only or partially implemented for all personnel.

B. Le	veis of advancement (access to information):
	National food safety services personnel do not have access to current scientific and technical information.
	National food safety services personnel have access to current scientific and technical information only occasionally.
	National food safety services personnel have access to current scientific and technical information most of the time.
	National food safety services personnel have access to current scientific and technical information all the time.
	Same as previous level, plus the national food safety services encourage and often require selected personnel to read specified scientific and/or technical material.

## 3. Funding sources

The ability of national food safety services to access financial resources for their continued operation and sustainability, free of pressure from political sources or users.

Levels	s of advancement:
	Funding for the national food safety services is neither stable nor clearly defined. The national food safety services budget competes with those of other State institutions and depends entirely on resources from the general treasury.
	The national food safety services are funded from a specific line item prescribed within the national budget.
	The national food safety services are funded from a specific line item prescribed within the national budget and with fees collected from users for the provision of specific services (i.e., inspection, registration, and certification services).
	Same as previous level, plus the national food safety services also receive additional funds from users to conduct specific programs; management and administration of cooperation funds are adequate.

## 4. Stability of policies and programs

The capability of national food safety services to implement policies and programs that are sustainable, improve over time, and address new demands, independent of political changes. It is measured in two ways: national food safety services reorganization, and coordination capability among government institutions.

A. Levels of advancement (national food safety services reorganization):								
	The national all levels.	food	safety	services	are	reorganized	frequently	at
	The national some levels.	food	safety	services	are	reorganized	frequently	at
	The national f level wheneve		•			ganized <i>only</i>	at the politi	cal
	The national f	ood sa	fety ser	vices are	stabl	e <sup>1</sup> at the tecl	nnical level.	

Stable organization: one that has maintained its core structure and functions for 5 years or more.

Levels of advancement (coordination capability among governmen nstitutions):
National food safety legislation does not clearly define the obligation and competencies of all governmental institutions that comprise the food safety services.
Legislation exists that defines the obligations and competencies of governmental institutions that comprise the food safety services at the national and local levels.
Coordinated inter- and intra-institutional activities on food safety in the public sector take place at least at the national level.
Coordinated inter- and intra-institutional activities on food safety in the public sector take place at both the national and local levels.

## 5. Contingency funds

The capability of national food safety services to access extraordinary financial resources for responding to emergency situations or emerging issues. It is measured by the ease of the process through which contingency resources can be secured.

Levels of advancement:	
	No contingency fund exists and any extraordinary resources can only be obtained by the food safety services through legislation or by presidential decree.
	A contingency fund with <i>limited</i> resources has been established but additional resources for the food safety services must be approved via legislation or presidential decree.
	A contingency fund with <i>limited</i> resources has been established but additional resources for the food safety services must be approved by the competent Ministry.
	A contingency fund with <i>substantial</i> resources has been established but additional resources for the food safety services must be approved by the competent Ministry.
	A contingency fund with substantial resources has been established that is available to the food safety services as needed and includes additional resources from user fees.

## 6. Technical independence

The capability of national food safety services to carry out their duties with autonomy and free from political interference that may affect technical and scientific decisions. Two aspects are measured: political appointments<sup>1</sup> and technical support for decisions.

A. Levels of advancement (political appointments):		
	The directors and technical professionals of the national food safety services are political appointees.	
	The directors of national food safety services are the only political appointees.	
	There are no political appointees in the national food safety services. All positions are selected on the basis of merit.	

<sup>1</sup> Political appointments: appointments made by the political party in power, at the discretion of the president or minister, and subject to immediate removal.

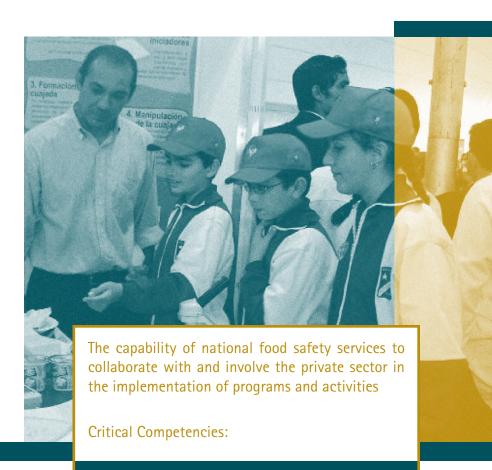
B. Levels of advancement (technical support for decisions):	
	The technical decisions made by the national food safety services are almost always based on political considerations.
	Technical decisions <i>incorporate</i> scientific principles but are frequently modified to conform to political considerations.
	Technical decisions are <i>based on</i> scientific principles but may be subject to review and possible modification based on political considerations.
	Technical decisions are <i>based only</i> on scientific principles and are not changed to meet political considerations.

## 7. Capability to invest and grow

The capability of national food safety services to secure additional resources over time for the sustained improvement of the entire service; the use of these resources is not subject to pressure from political sources and/or from users.

Levels	s of advancement:
	There are no sustained actions to invest in the overall structure of the national food safety services.
	The national food safety services elaborate and present proposals for structural improvements and secure investment funds from cooperation or donor agencies.
	The national food safety services secure over time significant resources for structural improvements through special allocations from the general treasury or special line items.
	Same as previous level, plus the national food safety services receive resources and capital investment from the private sector for improvements and jointly planned programs.

## III. INTERACTION WITH THE PRIVATE SECTOR



- 1. Information
- 2. Communication
- 3. Official representation
- 4. Accreditation (Authorization)
- 5. Capability to be responsive to user needs
- 6. Joint programs implementation

## 1. Information

The capability of national food safety services to inform their users, in an effective and timely manner, of activities, programs and food safety developments.

Leveis	or advancement:
	The national food safety services have no mechanisms in place to inform users about activities, programs and food safety developments.
	The national food safety services operate official communication outlets, which users can consult regarding standards, regulations and notifications.
	The national food safety services routinely <sup>1</sup> publish the results of their activities and programs, and information on food safety developments.
	The national food safety services make up-to-date information available, via Internet, on their programs, current activities, and food safety developments to the public, and also actively seek inputs from the private sector.
	Same as previous level, plus the national food safety services conduct educational and training programs for food producers and processors and their personnel, in cooperation with the private sector.
	Same as previous level plus the national food safety service have public outreach programs to inform and educate the public on food safety practices.

<sup>1</sup> In this case, every six months or less.

### 2. Communication

Levels of advancement:

The capability of national food safety services to maintain fluid communication with the public sector and with their users.

The national food safety services have no communication mechanisms in place to facilitate dialogue among the relevant State institutions and with the private sector.
The national food safety services maintain <i>informal</i> channels of communication with the relevant State institutions and the private sector.
The national food safety services establish and promote official dialogue with the various users on <i>proposed and current regulations</i> .
Same as previous level, plus the national food safety services hold forums and meetings with the various users to establish or improve programs and services.
Same as previous level, plus the national food safety services actively promote dialogue with and solicit feedback from the various users regarding national regulations, norms, and other relevant topics, and about the official representation at the WTO/SPS and the Codex Alimentarius.
Same as previous level, plus the national food safety services regularly inform the national SPS system or designated authority/focal point on SPS about changes in national food safety norms, standards or regulations, so that due notification is made to the WTO and trading partners as required by the SPS Agreement.

### 3. Official representation

The capability of national food safety services to regularly and actively participate, coordinate, and provide follow up to the meetings of international organizations such as the WTO/SPS and the Codex Alimentarius (through the national Codex Alimentarius Committee).

Levels	or advancement:
	The national food safety services do not participate in or follow-up or the meetings of the WTO/SPS and the Codex Alimentarius.
	The national food safety services participate sporadically or passively in the meetings of the WTO/SPS and the Codex Alimentarius.
	The national food safety services take into consideration the opinions of their users and participate regularly and actively <sup>2</sup> in the meetings of the WTO/SPS and the Codex Alimentarius.
	The national food safety services, in consultation with their users identify strategic topics, provide leadership, and coordinate topics with the delegates that represent the national agenda in the meetings of the WTO/SPS and the Codex Alimentarius.

<sup>1</sup> Passive participation: being represented at but contributing little during the meetings.

<sup>2</sup> Active participation: preparing in advance for and contributing during the meetings; includes exploring common solutions and generating proposals for possible adoption.

## 4. Accreditation (Official Authorization)

The capability and authority of national food safety services to accredit third parties (i.e. private individuals or firms, laboratories, etc.) or delegate the responsibility of carrying out specific services.

Levels of advancement:	
	The national food safety services have neither the authority nor the capability to accredit or authorize third parties to conduct specific activities or provide specific services.
	The national food safety services have the authority to accredit or authorize third parties to conduct a <i>specific activity</i> but not a <i>specific service</i> .
	The national food safety services have programs to accredit or authorize third parties to offer <i>specific services</i> .
	The national food safety services can develop and implement accreditation or authorization programs for <i>new</i> services.
	The national food safety services carry out external quality assurance audits of their official accreditation or approval programs to ensure their quality and maintain the confidence of users and trading partners.

#### 5. Capability to be responsive to users needs

The capability of national food safety services to collaborate with their users in developing new programs and services to respond to changing priorities and opportunities.

Levels	of advancement:
	The national food safety services do not involve their users in discussing changes in priorities and opportunities.
	The national food safety services have <i>informal dialogue</i> with their users regarding their current capacity, changes in priorities, and opportunities.
	The national food safety services hold meetings and forums with their users to identify changes in priorities and opportunities.
	The national food safety services and their users <i>collaboratively</i> identify resources, roles, and responsibilities of potential programs and services in response to changes in priorities and opportunities.
	The national food safety services, with the active participation and contribution of their users, periodically implement new programs and services.

#### 6. Joint programs implementation

The capability of national food safety services and the private sector to formulate and implement joint programs on an annual basis.

Levels	of advancement:
	The national food safety services have no joint programs.
	The national food safety services have established joint annual programs but they are not updated or funded.
	The national food safety services have joint annual programs that are updated and funded but only partially implemented. 1
	The national food safety services have joint programs that are updated annually, funded and fully implemented (i.e. food safety education programs).

1 Partially implemented: only some activities are implemented or all activities are only

partially implemented.

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# IV.SAFEGUARDING PUBLIC HEALTH AND MARKET ACCESS



- 1. Setting of food safety regulations
- 2. Compliance with food safety regulations
- 3. Harmonization
- 4. Certification
- 5. Equivalency and other sanitary agreements
- 6. Traceability
- 7. Transparency

#### 1. Setting of food safety regulations

The capability and authority of national food safety services to formulate and recommend for adoption national legislation, and set food safety regulations for processes and products covered by their mandates, and the coverage of such regulations.

A. Levels of advancement (participation in the national food safety legislative

and	d regulatory process):
	The national food safety services do not have the authority to propose national legislation and set food safety regulations.
	The national food safety services have the <i>technical capability</i> to develop national legislation and formulate food safety regulations.
	The national food safety services, based on national legislation, have the flexibility and <i>legal framework</i> necessary to develop legislation and set food safety regulations.
	The national food safety services, based on national legislation, develop and submit legislation for adoption, and set food safety regulations, applying procedures that take into consideration the opinions of their users and international norms, guidelines and recommendations.

evels of advancement (coverage of food safety regulations and mpliance monitoring):
Food safety legislation and/or regulations do not give the national food safety services authority to regulate and monitor compliance along the entire food chain.
Food safety legislation and/or regulations give the national food safety services authority to regulate and monitor compliance only by food producers and processors that export their products, or the food safety services only monitors compliance with regulations by exporters.
Same as the previous level, plus food safety legislation and/or regulations give the national food safety services authority to also regulate and monitor compliance by food producers and processors that sell their products locally under a registered brand name.
Same as the previous level, plus food safety legislation and/or regulations give the national food safety services authority to regulate and monitor compliance by all food producers and processors, regardless of size or market.
Same as the previous level, plus the food safety services have regulations covering street vendors, and monitor their compliance with such regulations.

#### 2. Compliance with food safety regulations<sup>1</sup>

The capability and authority of national food safety services to ensure that their users are in compliance with national food safety regulations.

A. Lev	A. Levels of advancement (compliance with regulations):	
	The national food safety services have no inspection or verification compliance programs to ensure user compliance with food safety regulations.	
	The national food safety services have implemented inspection or verification programs of compliance with food safety regulations for <i>selected</i> products and/or processes but <i>only report</i> instances of non-compliance.	
	The national food safety services have implemented compliance programs consisting of inspection and verification of compliance with food safety regulations for <i>selected</i> products and processes, if necessary <i>imposing penalties</i> for non-compliance.	
	The national food safety services have implemented compliance programs consisting of inspection and verification of compliance with food safety regulations for <i>all</i> products and processes covered by their mandates, if necessary <i>imposing penalties</i> for non-compliance.	
	The national food safety services conduct audits of their inspection and verification compliance programs.	

Food safety regulations: food safety measures that include all relevant laws, decrees, regulations, prescriptions, and procedures.

B. Lev	vels of advancement (nature and scope of inspection):
	The national food safety services have no regular inspection programs of primary food producing enterprises <sup>2</sup> and food processing establishments <sup>3</sup> .
	The national food services have regular inspection programs of primary food producing enterprises and food processing establishments, but inspection based on end product sampling and analysis.
	The national food safety services have regular inspection programs of primary food producing enterprises and food processing establishments, and the inspection is based on the adequacy of the process.
	The national food safety services have regular inspection programs of primary food producing enterprises and food processing establishments, and the inspection is not based only on the adequacy of the process but also on risk.

<sup>2</sup> Primary food producing enterprises: food packing establishments and other agribusinesses that perform only minor operations such as washing, sizing, cooling, or packing but do not transform agricultural products into processed products.

<sup>3</sup> Food processing establishment: industrial plant of any size where food is processed in ways that transform raw or semi-processed food into processed products.

#### 3. Harmonization

The capability and authority of national food safety services to be active<sup>1</sup> in harmonization, to ensure that national regulations covered by their mandates are consistent with international norms, guidelines and recommendations.

Levels	s of advancement:
	The national food safety services have no process in place for being informed of international norms. National food safety regulations do not take account of international norms, guidelines and recommendations.
	The national food safety services are aware of relevant international norms, guidelines and recommendations but have no process in place for identifying gaps, inconsistencies, and non-conformities between national food safety regulations and international norms, guidelines and recommendations.
	The national food safety services periodically review national food safety regulations with the aim of <i>harmonizing</i> them with international norms, guidelines and recommendations.
	The national food safety services are also active in <i>reviewing and commenting</i> on proposed new or revised international food safety norms, guidelines and recommendations.
	The national food safety services <i>actively and regularly participate at the international level</i> in the formulation and revision of international food safety norms, guidelines and recommendations.

A country can be active in international standard setting without actively pursuing national changes. The importance of this element lies in the promotion of change in the country.

#### 4. Certification

The capability and authority of national food safety services to certify products and processes covered by their mandates, in accordance with national food safety regulations and relevant international norms, guidelines and recommendations. <sup>1</sup>

Levels	s of advancement:
	The national food safety services have neither the capability nor the authority to certify products or processes.
	The national food safety services have the authority to certify <i>selected</i> products or processes.
	The national food safety services conduct certification programs for selected products or processes.
	The national food safety services can develop and conduct certification programs for <i>new</i> products or processes.
	The national food safety services have the certification programs necessary for all relevant products and conduct audits of their certification programs to ensure the quality of these programs and maintain confidence in the system.

In conducting certification programs, the national food safety services must always operate free of political interference or influence or pressure from the private sector. However some of these programs can be carried out by independent parties delegated by the national food safety services and/or audited by them.

# 5. Equivalency<sup>1</sup> and other food safety-related agreements

The capability and authority of national food safety services to negotiate, implement and maintain equivalency and other food safety-related agreements with other countries regarding regulations, norms and processes under their mandates.

Levels	Levels of advancement:		
	The national food safety services have neither the authority nor the capability to negotiate and approve equivalency and other food safety-related agreements with other countries.		
	The national food safety services have the authority to <i>negotiate and approve</i> equivalency and other food safety-related agreements with other countries.		
	Same as previous level, plus the national food safety services <i>evaluate</i> and propose equivalency agreements with other countries for selected products and processes.		
	Same as previous level, plus the national food safety services actively pursue the development of equivalency agreements with other countries on new products and processes.		
	Same as previous level, plus the national food safety services have programs that provide feedback from their users as well as information on advances in international standards, guidelines and recommendations, and pursue specific equivalency agreements with other countries.		

<sup>1</sup> Equivalency: alternative food safety measures proposed by an exporting country to an importing country which offer the same level of protection as those in use by the importing country.

#### 6. Traceability

The capability and authority of national food safety services to ensure, across the entire food chain, that they can track the history, location, and distribution of any food and related products covered by their mandates.

Leveis	s of advancement.
	The national food safety services have no tracking programs for food products.
	The national food safety services or authorized third parties can inspect and document the sanitary status of <i>selected</i> food and related products at <i>specific points</i> of the food chain.
	The national food safety services have established procedures in place and can track selected food and related products across that portion of the corresponding food chain covered by its mandate.
	The national food safety services, along with other relevant State institutions and the private sector, have coordinated procedures in place for tracking food and related products across the entire food chain for all foods.
	Same as previous level, plus the national food safety services, in cooperation with other relevant State institutions and the private sector, carry out audits of their traceability procedures.

#### 7. Transparency

The capability and authority of national food safety services to notify the national SPS authority or designated focal point, or in the absence of the latter, directly to the WTO/SPS and regional integration initiatives (when applicable) of their national regulations, and to notify the INFOSAN network of any food safety emergency having actual or potential international significance, in accordance with the procedures established by those organizations.

#### Levels of advancement:

The national food safety services do not notify the WTO/SPS, directly or
indirectly, about changes in their food safety regulations, nor do they
voluntarily inform INFOSAN or INFOSAN-Emergency of any food safety
emergency having actual or potential international significance.

- The national food safety services *partially* notify the WTO/SPS, directly or indirectly, of changes in their food safety regulations, and voluntarily inform INFOSAN or INFOSAN-Emergency of any food safety emergency having actual or potential international significance.
- The national food safety services notify the WTO/SPS, directly or indirectly, of changes in their food safety regulations, in full compliance with the notification criteria of those bodies, and voluntarily inform INFOSAN or INFOSAN-Emergency of any food safety emergency having actual or potential international significance.
- Same as previous level, plus the national food safety services inform their users of changes in national and international food safety regulations.
- Same as previous level, plus the national food safety services, along with other relevant State institutions, conduct external audits of their transparency procedures.

## Glossary of Selected Terms

**Audits:** A systematic and functionally independent examination, the objective of which is to determine if an activity or process and subsequent results meet prescribed objectives.

**Codex Alimentarius:** A joint program of the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) established to protect the health of consumers and ensure fair trade practices in food trade by developing internationally acceptable standards, guidelines.

**Food contaminant:** Biological, physical or chemical agents, foreign materials or other substances hazardous to health intentionally or unintentionally added to food.

**Food chain:** All activities involved in the production, processing, transportation, distribution, commercialization, preparation, and consumption of food products.

**International norms, guidelines and recommendations:** As regards food safety, those established by the Codex Alimentarius.

**Laboratory:** A properly equipped facility endowed with competent technical personnel to carry out analyses and clinical diagnostic methods and tests. The laboratory should be authorized by the respective national food safety service.

**National food safety services:** Governmental institutions involved in food safety control, surveillance and monitoring across the food chain; it includes officially accredited private entities.

**National food safety system:** The set of all governmental institutions involved in food safety control, surveillance and monitoring across the food chain; it includes officially accredited private entities.

**Users of national food safety services:** Include the private sector, academic institutions, public-private associations, and consumer associations.

WTO/SPS: The Committee on Sanitary and Phytosanitary Measures of the World Trade Organization that oversees compliance with and issues related to the Agreement on the Application of Sanitary and Phytosanitary Measures.

## **Check List**

I. Technical Capability
<ul> <li>□ Diagnostic and food analysis capability</li> <li>□ Early detection and emergency response capability</li> <li>□ Inspection and registration services</li> <li>□ Surveillance</li> <li>□ Emerging issues</li> <li>□ Risk analysis</li> <li>□ Technical innovation</li> </ul>
II. Human and Financial Capital
<ul> <li>☐ Human talent</li> <li>☐ Training</li> <li>☐ Funding sources</li> <li>☐ Stability of policies and programs</li> <li>☐ Contingency funds</li> <li>☐ Technical independence</li> <li>☐ Capability to invest and grow</li> </ul>
III. Interaction with Private Sector
<ul> <li>☐ Information</li> <li>☐ Communication</li> <li>☐ Official representation</li> <li>☐ Accreditation (Authorization)</li> <li>☐ Capability to be responsive to users needs</li> <li>☐ Joint programs implementation</li> </ul>
IV. Safeguarding Public Health and Market Access
<ul> <li>Setting of food safety regulations</li> <li>Compliance with food safety regulations</li> <li>Harmonization</li> <li>Certification</li> <li>Equivalency and other sanitary agreements</li> <li>Traceability</li> <li>Transparency</li> </ul>

## Additional notes

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## Additional notes

### **Check List**

I. Technical Capability
<ul><li>Diagnostic and food analysis capability</li></ul>
<ul> <li>Early detection and emergency response capability</li> </ul>
Inspection and registration services
Surveillance
Emerging issues
Risk analysis
Technical innovation
II. Human and Financial Capital
Human talent
Training
Funding sources
Stability of policies and programs
☐ Contingency funds
☐ Technical independence
Capability to invest and grow
III. Interaction with Private Sector
☐ Information
Communication
Official representation
Accreditation (Authorization)
Capability to be responsive to users needs
Joint programs implementation
IV. Safeguarding Public Health and Market Access
Setting of food safety regulations
Compliance with food safety regulations
Harmonization
Certification
Equivalency and other sanitary agreements
Traceability
Transparency



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