FOOD CONTROL SYSTEM ASSESSMENT TOOL

INTRODUCTION AND GLOSSARY
FOOD CONTROL SYSTEM
ASSESSMENT TOOL

INTRODUCTION AND GLOSSARY
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<td>ALOP</td>
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<td>AOAC</td>
<td>AOAC International - Association of Official Analytical Chemists</td>
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<td>BIP</td>
<td>Border Inspection Point</td>
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<td>CPD</td>
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<td>DALY</td>
<td>Disability-Adjusted Life Year</td>
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<td>EBS</td>
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<td>FBD</td>
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<td>FBO</td>
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<td>GAP</td>
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<td>GEMS/Food</td>
<td>Global Environment Monitoring System - Food Contamination Monitoring and Assessment Programme</td>
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<td>HACCP</td>
<td>Hazard Analysis and Control of Critical Points</td>
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<td>HCW</td>
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<td>IBS</td>
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<td>IICA</td>
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<td>ILAC</td>
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<td>IMS</td>
<td>Information Management System</td>
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<td>INFOSAN</td>
<td>International Network of Food Safety Authorities</td>
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IO International Organization
IPPC International Plant Protection Convention
ISO International Organization for Standardization
JECFA Joint FAO/WHO Expert Committee on Food Additives
JEMNU Joint FAO/WHO Expert Meetings on Nutrition
JEMRA Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
JMPR Joint FAO/WHO Meeting on Pesticide Residues
MoU Memorandum of Understanding
NNA National Notification Authority
OIE World Organisation for Animal Health
ORT Outbreak Response Team
PA Producers’ Association
PHEIC Public Health Emergency of International Concern
RASFF Rapid Alert System for Food and Feed
SMART Specific, Measurable, Attainable, Relevant and Time-Bound
SOP Standard Operational Procedures
SPS Sanitary and Phytosanitary
TBT Technical Barriers to Trade
ToRs Terms of Reference
WHO World Health Organization
WTO World Trade Organization
INTRODUCTION

BACKGROUND

National food control systems play a pivotal role in protecting the health of consumers and ensuring fair practices in the food trade. Within the framework of Codex Alimentarius Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013), countries have flexibility to determine how best to design their food control systems and implement specific control measures. National situations (e.g. appropriate levels of public health protection; legal and institutional frameworks; availability of support services, such as analytical resources) will influence the design of these systems; therefore, no two systems are alike. However, whatever the architecture of the national food control system, measuring its effectiveness is universally important to verify that resources are being well-used and consumers’ health and economic interests are protected. Being able to demonstrate performance can also be very important to inform plans for further strengthening of the system and to open new markets, improve trading relationships and build stakeholder confidence domestically.

To this end, FAO and WHO have worked on designing this assessment tool, to assist Member countries in assessing the effectiveness of their food control system, whatever the level of its maturity.

In developing this tool, FAO and WHO sought to learn from and build upon existing tools. FAO performed an initial review of all publicly available tools relating to the food chain or assessing SPS functions – including the Performance-Vision-Strategy tool of the Inter-American Institute for Cooperation on Agriculture (IICA), the World Organisation for Animal Health (OIE) tool for the evaluation of the Performance of Veterinary Services, and the International Plant Protection Convention (IPPC) Phytosanitary Capacity Evaluation tool – to identify possible approaches and build on existing knowledge and experience. A consultative approach was used through the establishment of a Review Committee involving other international, regional and national agencies and academia to regularly review progress. A sequence of pilots (9) in different regions (Africa, Asia, Europe and Near East), were organized to test the tool at various stages of development; findings emerging from the process and feedback by the different stakeholders involved in the assessment were integrated into the document to refine its approach and ensure adaptation to very different contexts.
SCOPE AND OBJECTIVES

The tool is based on Codex Principles and Guidelines for National Food Control Systems (CAC/GL 82-2013) as well as other relevant Codex guidelines for food control systems, which are referenced throughout the document. Its scope is given by the dual objectives quoted in Codex guidance for these systems: protect health of consumers and ensure fair practices in the food trade. The tool’s primary focus is analysis of the performance of competent authorities involved in food control. It covers: (i) controls performed by competent authorities to assure the safety of food as well as mandated quality attributes as defined in the food law; and (ii) non-regulatory approaches (such as capacity development, communication, etc.) that are contributing to improve these attributes of the food production. Aspects of voluntary quality certification are excluded from the immediate field of investigation of the tool.

For the purpose of the tool, the food chain is intended to cover the continuum from primary production up to the consumer. Food-borne disease surveillance systems and related considerations are also considered as a component of the national food control system.¹

The FAO/WHO tool is intended to be used by countries as a supporting basis for self-assessment to identify priority areas of improvement and plan sequential and coordinated activities to reach expected outcomes. By repeating the assessment on a regular basis, countries can use a tool to monitor their progress.

Some countries may find a benefit in receiving technical assistance for the implementation of assessments; because food control is multi-sectoral and involves a range of competent authorities, an external neutral partner such as FAO or WHO may facilitate the process while ensuring the tool is used to its full potential.

Countries may choose to share the results of the assessment with trading partners or other stakeholders to demonstrate openness, transparency and commitment to continuous improvement.

The main objective of the tool is to propose a harmonized, objective and consensual basis to analyse the performance of a national food control system, and more specifically:

> to offer an opportunity for developing a common understanding and vision among competent authorities and other associated stakeholders (private sector, consumers, academia) (1) of the current status of the national food control system, and (2) of the priorities for progress;

> to enable, guide and measure the improvement process that would be developed and implemented by the various stakeholders, supported by a clear baseline;

> to potentially support a dialogue with external stakeholders.

¹ References to “food control staff” or “competent authorities” would also include staff or authorities in charge of FBD surveillance when relevant to the context or organizational model of the country where the assessment is performed.
An initial assessment of a country’s food control system can inform the formulation and monitoring of food control capacity development projects, and can be used as the baseline against which the impact of the project activities can later be measured.

The tool has been developed taking into account the relevant Codex guidelines, while being able to explore in more detail different attributes of national food control systems, given the nature of FAO and WHO’s guidance, and their flexibility, versus Codex Alimentarius normative function. The tool is to be considered as an instrument that places Codex guidance in a practical context, and thus can help countries to implement Codex texts, taking into account their national situations. The tool should be seen as an opportunity to promote Codex objectives. When appropriate, the tool also refers to specific provision of the International Health Regulations (IHR)-2005. References to FAO and WHO publications that can offer a deeper understanding of the operations of effective food control systems are indicated in footnotes.

STRUCTURE OF THE ASSESSMENT TOOL

The primary focus of the assessment is the Competent Authorities (CAs) – how they work and what outcomes they are able to reach – as well as the enabling framework in which they work (for example, the policy and legal context). The information collected from the CAs is aggregated and analysed at system level to provide a global and integrated picture of the food control system.

The tool aims to provide an approach to analyse a national food control system not only for its “traditional” system dynamics (inputs, processes and outputs), but also for the interactions occurring within its processes and for its capacity to evolve and improve (see Figure 1 below). The tool is therefore structured as follows:

![Figure 1: Structural Logic of Food Control Systems](image)
The tool is structured around four central dimensions addressing the above questions. These are further divided into nine sub-dimensions, which in turn consist of a total of 25 specific system competencies, as presented in Figure 2.

**Figure 2: Structure of the Food Control System Assessment Tool**

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DIMENSION A
INPUTS AND RESOURCES

This dimension aims at mapping the fundamental elements necessary for the system to operate. These range from legal and policy instruments, including how the system is actually designed (institutional framework) and how it communicates with and coordinates the different authorities contributing to its operations, to financial assets, equipment and infrastructure (including access to laboratories) and human resources. It is always very difficult to provide direct answers about adequacy (qualitative and quantitative) of resources (human, financial or material); therefore we have approached this through checking the soundness of the logical relationship between strategic planning to reach policy objectives and implement legal requirements and available resources. This relationship, which can result in a feedback loop (adjusting strategy, and considering policy choices, to reflect resource constraints that cannot be lifted in the short term) is the underlying thread of this dimension.

DIMENSION B
CONTROL FUNCTIONS

This dimension covers the main control functions to be exercised by CAs to ensure food safety and quality along the food chain and to appropriately manage food safety hazards, fraud issues, emerging risks and emergencies. This section covers both controls in the “classical” sense of the term – i.e. inspection and other oversight over Food Business Operators (FBOs) producing or importing for domestic consumption or for export – and also other approaches for information collection processes that contribute to a better understanding of the food chain; this includes data collection programmes on food products (referred in this context as monitoring programmes) and on food-borne diseases (FBDs) (referred to in this context as surveillance programmes). This also includes programmes aiming at managing food safety emergencies, which should make use of all of the previously mentioned oversight mechanisms and information gathered. One challenge in the dimension was to distinguish different categories of activities with a complementary focus that may be carried out by the same unit (for example, inspection of a certain category of FBOs and monitoring programmes of the food hazards typically associated with the products produced by these FBOs).

DIMENSION C
INTERACTIONS WITH STAKEHOLDERS

While the regulatory arm (policy and legal basis supported by official control functions) is usually what comes first to mind when reflecting about a national food control system, the “non-regulatory” components of that system also need to be taken into consideration. Processes for constructive interactions – between CAs and FBOs, with consumers and with the international community (in a bilateral or multilateral environment) are very important to allow the system to continuously
adjust to the evolving needs of both national and international stakeholders, to inspire confidence and to keep them well informed about their responsibilities. Owing to their nature, these processes are less “codified” into good practices than some official control activities and would depend very much on the social context and needs. Therefore the assessment criteria proposed in the dimension aim to be outcome-oriented as much as possible to allow all possible flexibility for taking these circumstances into account.

DIMENSION D
SCIENCE/KNOWLEDGE BASE AND CONTINUOUS IMPROVEMENT

This dimension reviews the necessary features for the system to build scientific soundness, incorporate risk analysis principles and keep abreast of new scientific developments and innovations to continuously improve. The processes reviewed in this dimension make use of information generated by official controls, support the interactions with stakeholders, contribute to policy and legislation drafting or improvements and improve targeting of food control activities. We recognize that good practices are still under development on these matters, and a variety of international confirmed experience may still be lacking – for example, on issues regarding performance monitoring or foresight; therefore these are certainly areas that will be further developed in the next iterations of this tool.

APPROACH TO ASSESSMENTS

Underpinning the dimensions described above are the system competencies. While we acknowledge that their nature may vary, these can be broadly described as characteristics that the system must have to enable performance. The analysis of how each of these competencies is performing is therefore the backbone of the assessment process. In fact, the executive section of the report revolves around analysis and ratings of performance provided for each competency. A conscious choice has been made not to aggregate results at dimension or system level, for example.

The analysis of each competency is based on a sequence of assessment criteria (AC). There are currently 162 AC over the entire tool. To support a common understanding of the AC and support consistent measurement, detailed technical notes have been prepared.

In these technical notes each criterion is:

> supported by guidance and key elements supporting the rating of achievement of the criterion;

> complemented by an outcome statement which should provide the relevant perspective for the appreciation of the criterion;
illustrated by examples of indicators or sources of evidence which support the identification of the evidence that would support and document the judgment that is being made.

While there is logic to the order in which the AC are listed, it is also recognized that in many cases, depending on the situation, this logical order can be altered. This has no influence on the rating. Across competencies, some apparent overlaps or apparent repetitions of AC can be observed. These are intentional, as there are complementarities among competencies, and this ensures that specific key aspects are analyzed from different perspectives.

To the extent possible, AC are one-dimensional, often sequential (but not necessarily, as explained above) and, taken as a group, enable the proper achievement of a competency. In some cases, the analysis of some aspects of specific competencies is split over two assessment criteria: one is “basic level” and the next is a more “advanced level.” This is meant to enhance the measurement of improvement for some key aspects that might be challenging to improve all at once. These are marked with a note because, at first sight, they might appear repetitive to the assessment team.

While FAO and WHO consider that the current list of AC should remain relatively standard to respect the integrity of the assessment approach, it should be noted that in a few cases, some AC might not apply to all situations (e.g. AC relating the performance of the system in the context of the World Trade Organization (WTO) agreement in cases where the country is not a member of WTO). It is also possible that some countries would like to see a criterion added for their specific purposes, driven by the national or regional context, for example.

During the assessment process – for each assessment criterion that is applicable to its mandate – each CA provides detailed information about its processes, resources, outputs, activities and outcomes, as appropriate. The assessment team should aggregate this primary information coming from the different CAs for each assessment criterion. Specific tables (available in MS Word format upon request to FAO) can be used to ensure that each CA follows the same approach to provide information, which should facilitate this integration step. For each assessment criterion, the team shall decide if the status is globally (i.e. at system level, not at CAs level):

- Not achieved
- Partially achieved
- Achieved

For example under the competency “domestic inspection”, the concept of registration of FBOs is split over two AC, to measure improvement in coverage of the food chain (i.e. only a few key FBOs are registered; or all FBOs, including in primary production, are registered).
It is recognized that the value “partially achieved” will cover different situations, such as that one CA is performing well with regard to an assessment criterion, while others that should play a role in that regard are not; or that all CAs are performing well individually, but there is no consistency and complementarity where there should be.

The qualitative judgements on status are coded so that they translate into degree of achievement (i.e. “scores”) for each competency at system level (i.e. not at CA level). Encoded tables (available in Excel format upon request to FAO) make it possible to derive a global score of achievement for each competency by aggregating the results for each assessment criterion. “Not achieved” yields a “0”; “Partially achieved” yields “1” and “Fully achieved” yields “4”. These results at assessment criterion level are summed and expressed as a percentage of achievement of the total score achievable for the competency. The difference of score yielded between “partially achieved” (1) and “fully achieved” (4) is based on the recognition that reaching a truly harmonized status among CAs is an important challenge; this gives value to investing towards a system approach as opposed to a juxtaposition of single endeavours. In the same manner, when criteria consider a national plan (or strategy, or any other result), this is also to be interpreted as placing the emphasis on national integration of approaches form each relevant CA.

It should be noted that scores are established to facilitate:

> a quick review of major areas of weaknesses and strength; and
> tracking changes and/or monitoring progress over time.

While ratings or scores are useful as a snapshot to support communication with non-technical stakeholders, a key part of the assessment process is the descriptive analysis supporting the allocation of status and scores, which is also useful to understand what measures could be put in place to support progress.

As part of the guidance a glossary is also included.

When performing the overall review of the different contributions provided by CAs over the different competencies, it is important that:

> Validity of the information on which the assessment is based has been ascertained. The tool provides information about what information is sought and the outcome to be measured. The list of indicators and sources of evidence, while being indicative and open, should further support analysis of the validity of information provided. The assessment team should not underestimate this step, although it is recognized that this is a significant effort requested from the CAs providing the primary data. It is important to note that the quality of the assessment is totally dependent on the accuracy and quality of primary information provided by each CA. Therefore, the full engagement of all CAs, as well as their trust in the process, is key to the success of the assessment. Effort should be made to ensure that primary evidence submitted by CAs is relevant, sufficient, current and authentic.
Reliability is ensured; there should be consistency in the interpretation of the data. This is related to the technical competence and independence of the assessment team. While the tool provides guidance, to the extent possible, to enable self-assessment by countries, it doesn’t substitute for the assessment team’s own competence and independence. Therefore, in some cases, countries might opt for a mix of internal and external expertise.

Flexibility is appropriately exercised by the assessment team. As indicated, the indicators and sources of evidence, in most cases, should be interpreted in a flexible manner given the national situation and context. They are for illustration purposes, and the list is by no means closed. The guidance itself is not written in a prescriptive manner and the outcome statement is provided to indicate the “perspective” in which information should be collected and analysed.

Fairness is protected. As in all multi-stakeholder processes, there might be fear by some that the assessment process will be misused by others to gain undue power or influence, thereby leading them to “withdraw,” formally or not, from the process. This is why it is important to find a mechanism that ensures oversight over the different parties, as food control is always multi-sectoral. In some countries this will result in agreeing to conduct such assessments with an external party, such as FAO or WHO.

The tool is conceived for the assessment of a national food control system as a whole. Therefore, using the tool partially to specifically assess some key functions (such as import controls or domestic controls) is not straightforward and would require specific guidance. This will be elaborated on as a further publication, based on specific trials and pilots.
Adverse Health Effect: An undesirable or unwanted outcome in humans.
CAC/GL 77-2011

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.
CAC/GL 77-2011

Appropriate level of sanitary or phytosanitary protection (ALOP): The level of protection deemed appropriate by the Member establishing a sanitary or phytosanitary measure to protect human, animal or plant life or health within its territory.
WTO, 1995

Approval: See Registration

Audit: Is a systematic and functionally independent examination to determine whether activities and related results comply with planned objectives.
CAC/GL 20-1995

Authorization: See Registration

Based on risk: Means focused on and proportionate to an estimate of the probability and severity of an adverse effect occurring in consumers.
CAC/GL 71-2009

Certificates: Are those paper or electronic documents, which describe and attest to attributes of consignments of food destined for international trade.
CAC/GL 38-2001

Certification: Is the procedure by which official certification bodies or officially recognized certification bodies provide written or equivalent assurance that foods or food control systems conform to requirements. Certification of food may be, as appropriate, based on a range of inspection activities, which may include continuous on-line inspection, auditing of quality assurance systems, and examination of finished products.
CAC/GL 20-1995

Certifying bodies: Are official certification bodies and officially recognized certification bodies.
CAC/GL 38-2001
Certifying officers: Are officers authorized or recognized, by the exporting country’s competent authority, to complete and issue official certificates.
CAC/GL 38-2001

Competent authority(ies) - (CAs): Means the official government organisation/agency(ies) having jurisdiction.
CAC/GL 71-2009

Compliance and enforcement: Refers to the range of controls, procedures or other interventions undertaken by a competent authority or a third party on its behalf when monitoring or verifying food business operator compliance with official requirements including but not limited to, instigating any corrective measures to achieve compliance.
Own definition

Contaminant: Means any substance not intentionally added to food or feed for food producing animals, which is present in such food or feed as a result of the production (including operations carried out in crop husbandry, animal husbandry and veterinary medicine), manufacture, processing, preparation, treatment, packing, packaging, transport or holding of such food or feed, or as a result of environmental contamination. The term does not include insect fragments, rodent hairs and other extraneous matter.

Contamination: The introduction or occurrence of a contaminant in food or food environment.
CAC/RCP 1-1969

Control: Any form of control that the competent authority performs for the verification of compliance with feed and food law (and animal health rules).
Own definition

Control measure: Any action and activity that can be used to prevent or eliminate a food safety hazard or reduce it to an acceptable level.
CAC/RCP 1-1969

Control plan: Means a description established by the competent authorities containing information on the structure and organisation of the official control system, and of its operation and the detailed planning of official controls to be performed, over a period of time.
Own definition

Control system: Means a system comprising the competent authorities and the resources, structures, arrangements and procedures set up in a Member State to ensure that official controls are performed in accordance with the food safety regulations of the country.
Own definition

Documentary check: Means the examination of the official certificates, official attestations and other documents, including documents of a commercial nature, which are required to accompany the consignment under the feed or food law of the country.
Own definition
**Equivalence (equivalent):** Is the capability of different inspection and certification systems to meet the same objectives.

CAC/GL 26-1997

**Establishment:** Any building or area in which food is handled and the surroundings under the control of the same management.

CAC/RCP 1-1969

**FBO Risk categorization framework [D.1.3.4]:** Is a tool that help CAs classify the FBOs and food sectors in terms of potential risks.

Own definition

**Feed (feeding stuff):** Any single or multiple materials, whether processed, semi-processed or raw, which is intended to be fed directly to food producing animals.

CAC/RCP 54-2004

**Food:** means 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.


**Food business:** Means any undertaking, whether for profit or not and whether public or private, carrying out any of the activities related to any stage of production, processing and distribution of food.

Own definition

**Food business operator (FBO):** The person/company who undertakes, whether for profit or not, any activities related to any stage of the food chain.

FAO and WHO, 2012

**Food control:** A mandatory regulatory activity of enforcement by national or local authorities to provide consumer protection and ensure that all food during production, handling, storage, processing and distribution are safe, wholesome and fit for human consumption; conform to food safety and quality requirements; and are honestly and accurately labelled as prescribed by the law.

FAO and WHO, 2003

**Food hygiene:** Comprises conditions and measures necessary for the production, processing, storage and distribution of food designed to ensure a safe, sound, wholesome product fit for human consumption.


**Food law:** Includes acts, laws, regulations, and other instruments with legally binding force issued by public authorities, related to food in general, and to food safety in particular, and covering the protection of public health, the protection of consumers and conditions of fair trading. It covers any stage of production, processing and distribution of food, and also of feed produced for, or fed to, food producing animals.

Own definition based on: CAC/GL 26-1997
Food recall [A.1.3.1]: The action to remove food from the market at any stage of the food chain, including that possessed by consumers.

[Note on terminology: The term “withdrawal” is used widely in relation to food recall; however, the meaning of the term varies significantly among different countries and languages. For example, some countries use “withdrawal” to indicate the retrieval of a food item that did not reach consumers, while other countries use the same term to indicate the retrieval of a food item because of reasons unrelated to safety (e.g. quality). In addition, some other countries use “withdrawal” to indicate the retrieval of a food item by food business operators, in contrast to an action taken by the national authority. For the purpose of this Tool, withdrawal has the same meaning of food recall.]

FAO and WHO, 2012

Food safety: Assurance that food will not cause harm to the consumer when it is prepared and/or eaten according to its intended use.

CAC/RCP 1-1969

Food safety control system: The combination of control measures that, when taken as whole, ensures that food is safe for its intended use.

CAC/GL 69-2008

Food safety emergency: A situation, whether accidental or intentional, that is identified by a competent authority as constituting a serious and as yet uncontrolled foodborne risk to public health that requires urgent action.

CAC/GL 19-1995

Food safety emergency response: A process of assessing the risk, making risk management decisions, and communicating risks in the face of time constraints, and possible incomplete data and knowledge.

CAC/GL 19-1995

Foodborne pathogen: A pathogen present in food, which may cause human disease(s) or illness through consumption of food contaminated with the pathogen and / or the biological products produced by the pathogen.

CAC/GL 77- 2011

Good Hygiene Practices (GHP): All practices regarding the conditions and measures necessary to ensure the safety and suitability of food at all stages of the food chain.

CAC/RCP 58-2005

GOOD AGRICULTURAL PRACTICE IN THE USE OF PESTICIDES (GAP): Includes the nationally authorized safe uses of pesticides under actual conditions necessary for effective and reliable pest control. It encompasses a range of levels of pesticide applications up to the highest authorised use, applied in a manner which leaves a residue which is the smallest amount practicable. Authorized safe uses are determined at the national level and include nationally registered or recommended uses, which take into account public and occupational health and environmental safety considerations. Actual conditions include any stage in the production, storage, transport, distribution and processing of food commodities and animal feed.

**Hazard:** A biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect.


For the purpose of B.2.2:
An agent that has the potential to cause adverse health effects in exposed populations

WHO, 2012

**Hazard Analysis and Critical Control Point (HACCP):** A system which identifies, evaluates, and controls hazards which are significant for food safety.

CAC/RCP 1-1969

**Hazard characterization:** The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents which may be present in food.


**Hazard identification:** The identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.


**Identity check:** Means a visual inspection to verify that the content and the labelling of a consignment, including the marks on animals, seals and means of transport, correspond to the information provided in the official certificates, official attestations and other documents accompanying it.

Own definition

**Indicator:** Quantitative variable or qualitative factor that provides a simple and reliable means to measure achievement, to reflect the changes connected to activities, or to help assess the performance of a program or system.

CAC/GL 91-2017

**Inspection:** Is the examination of food or systems for control of food, raw materials, processing, and distribution including in-process and finished product testing, in order to verify that they conform to requirements.

CAC/GL 20-1995

**Label:** Means any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of food.

CODEX STAN 1-1985

**Labelling:** Includes any written, printed or graphic matter that is present on the label, accompanies the food, or is displayed near the food, including that for the purpose of promoting its sale or disposal.

CODEX STAN 1-1985
Less well-established FBO: May be any business from a street vendor to a small trader, or a start-up business with less experienced staff.

Licensing: See Registration

Lot: A quantity of a food material delivered at one time and known, or presumed, by the sampling officer to have uniform characteristics such as origin, producer, variety, packer, type of packing, markings, consignor, etc. A suspect lot is one which, for any reason, is suspected to contain an excessive residue. A non-suspect lot is one for which there is no reason to suspect that it may contain an excessive residue.

Notes:
(a) Where a consignment is comprised of lots which can be identified as originating from different growers, etc., each lot should be considered separately.
(b) A consignment may consist of one or more lots.
(c) Where the size or boundary of each lot in a large consignment is not readily established, each one of a series of wagons, lorries, ship’s bays, etc., may be considered to be a separate lot.
(d) A lot may be mixed by grading or manufacturing processes, for example.

CAC/GL 33-1999

Maximum Residue Limit for Pesticides (MRL): Is the maximum concentration of a pesticide residue (expressed as mg/kg), recommended by the Codex Alimentarius Commission to be legally permitted in or on food commodities and animal feeds. MRLs are based on GAP data and foods derived from commodities that comply with the respective MRLs are intended to be toxicologically acceptable.


Monitoring: Is a statistically based sampling, processing and analysis of samples to provide information on the occurrence and/or levels of chemical residues or microbiological hazards in pre-defined, sample populations. In general, the purpose of monitoring programmes is not direct enforcement action. Monitoring activities are particularly useful for discerning trends, when sampling is unbiased and random. Total Diet Studies are an example of chemical monitoring programmes.

Monitoring plan: A document detailing the sampling strategy, the purpose and scope, and all practical arrangements allowing to obtain results valid for monitoring purposes. Monitoring plans can target domestic food products, as well as imported or exported products. This will depend on the purpose of the monitoring plan: on exported products, this may be done upon request of the importing country; on domestic and imported food products, this can support exposure assessment to certain food safety hazards.
Depending on how they are conceived monitoring plans can also include results from own controls performed by FBOs.

**Own definition**

**Monitoring Programme (national) [B.2.1]:** For the purpose of the tool a national monitoring programme is a unified document putting together several complementary monitoring plans to ensure comprehensive information on occurrence and/or levels on a series of priority hazards at a national scale in a coherent manner.

**Own definition**

**National food control system:** The integration of mandatory regulatory approaches (i.e. official food control activities) with preventive and educational strategies that, along the entire food chain (including production, handling, storage, processing and distribution), ensure that food is safe, wholesome and fit for human consumption, conforms to food safety and quality requirements and is honestly and accurately labelled as prescribed by the law.

**Own definition based on: FAO and WHO, 2003**

**National IHR focal point:** Means the national centre, designated by each State Party, which shall be accessible at all times for communications with WHO IHR Contact Points under these Regulations.

**WHO, 2008d**

**Non biased sampling:** Refers to the random sampling of specified populations to provide information about the occurrence of residue non-compliances, typically on an annual, national basis. Compounds selected for non-biased sampling are usually based on risk profiles and the availability of laboratory methods suitable for regulatory purposes. The results of non-biased sampling are a measure of the effectiveness and appropriateness of the controls and practices within a wider segment of the production system.

**CAC/GL 71-2009**

**Notification [B.1.2.6]:** Information on imported food being provided to the competent authority as the food arrives in the importing country, or within 48 hours of its arrival.

**Own definition**

**Official certificates:** Are certificates issued by, or under the control of the exporting country’s competent authority, including by a certifying body recognized by the competent authority to issue such certificates. Certificates are generally issued to provide assurance concerning compliance with one or more legal requirements requested by the importing country.

**Own definition based on: CAC/GL 38-2001**

**Official control:** Means any form of control that the competent authority performs for the verification of compliance with food law, including animal health and animal welfare rules.

**Own definition**

**Official endorsement of food operations [B.1.1.3]:** It can be referred to with different wording in different countries (e.g. licensing, approval, etc.).

**Own definition**
Outcome [D.2.1.2]: Intended effects or results that contribute to achieving the national food control system objectives. Outcomes may be categorized at different levels, such as ultimate, high-level, intermediate, preliminary or initial.

CAC/GL 91-2017

Performance monitoring: A continuous or ongoing process of collecting and analysing data to compare how well the stated objectives and outcomes of the NFCS are achieved.

CAC/GL 91-2017

Pesticide: Means any substance intended for preventing, destroying, attracting, repelling, or controlling any pest including unwanted species of plants or animals during the production, storage, transport, distribution and processing of food, agricultural commodities, or animal feeds or which may be administered to animals for the control of ectoparasites. The term includes substances intended for use as a plant growth regulator, defoliant, desiccant, fruit thinning agent, or sprouting inhibitor and substances applied to crops either before or after harvest to protect the commodity from deterioration during storage and transport. The term normally excludes fertilizers, plant and animal nutrients, food additives, and animal drugs.


Pesticide residue: Means any specified substance in food, agricultural commodities, or animal feed resulting from the use of a pesticide. The term includes any derivatives of a pesticide, such as conversion products, metabolites, reaction products, and impurities considered to be of toxicological significance.


Placing on the market: Means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves.

Own definition

Pre-clearance [B.1.2.7]: Is a government-mandated process that relies on product verification information (e.g. sampling procedure details, analytical results) to be provided to the CAs prior to the lot arriving at the border. The imported food controls specify what information is required and who is responsible for providing it (i.e. exporting country, an independent recognized third party or the importer). The decision on accepting the lot can be made by the CA before the lot is actually shipped, thus minimizing deterioration of a perishable product.

Own definition

Pre-notification [B.1.2.6]: Information on imported food being provided to the competent authority prior to the food arriving in the importing country.

Own definition

Primary production: Means the production, rearing or growing of primary products including harvesting, milking and farmed animal production prior to slaughter. It also includes hunting and fishing and the harvesting of wild products.

Own definition
**Principal FBO [B.1.1.1]**: The country can define the term principal as needed. The criterion to determine what constitutes a “principal” FBO will be unique to the country’s circumstances and should be determined and documented.

*Own definition*

**Processing**: Means any action that substantially alters the initial product, including heating, smoking, curing, maturing, drying, marinating, extraction, extrusion or a combination of those processes.

*Own definition*

**Public health emergency of international concern**: Means an extraordinary event which is determined, as provided in these Regulations:

(i) to constitute a public health risk to other States through the international spread of disease and

(ii) to potentially require a coordinated international response”.

WHO, 2008d

**Qualitative risk assessment**: A Risk Assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties permits risk ranking or separation into descriptive categories of risk.

CAC/GL 30-1999

**Quality assurance (QA)**: All the planned and systematic activities implemented within the quality system and demonstrated as needed, to provide adequate confidence that an entity will fulfil requirements for quality.

CAC/RCP 58-2005

**Quantitative risk assessment**: A Risk Assessment that provides numerical expressions of risk and indication of the attendant uncertainties.

CAC/GL 30-1999

**Recall [A.1.3.1]**: See food recall

**Registration [B.1.1.1]**: Includes licensing, authorizations, approval, notification or any process that officially links FBOs with the competent authority.

*Own definition*

**Retail**: Means the handling and/or processing of food and its storage at the point of sale or delivery to the final consumer, and includes distribution terminals, catering operations, factory canteens, institutional catering, restaurants and other similar food service operations, shops, supermarket distribution centres and Wholesale outlets.

EU Regulation (EC) No 178/2002
**Risk**: A function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard(s) in food.

For the purpose of B.2.2:
The likelihood that an adverse event will occur during a specified period and the likely magnitude of its consequences.
WHO, 2012

**Risk analysis**: A process consisting of three components: risk assessment, risk management and risk communication.

**Risk assessment**: Is the evaluation of the likelihood and severity of adverse effects on public health (arising, for example, from the presence in foodstuffs of additives, contaminants, residues, toxins or disease-causing organisms). The assessment is a scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterization, (iii) exposure assessment, and (iv) risk characterization.
Own definition based on Codex Alimentarius Commission Procedural Manual and CAC/GL 20-1995

**Risk assessment policy**: Documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment such that the scientific integrity of the process is maintained.

**Risk-based**: See Based on risk

**Risk categorization framework [B.1.1.5]**: It is a supporting tool that allows to qualify and document the different risk categories that have been identified, and to subsequently insert the registered FBOs into a risk based inspection programme.
Own definition

**Risk characterization**: The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment.

**Risk communication**: The interactive exchange of information and opinions throughout the risk analysis process concerning risk, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, industry, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions.

**Risk estimate**: The qualitative and/or quantitative estimation of risk resulting from risk characterization.
Risk management: The process, distinct from risk assessment, of weighing policy alternatives, in consultation with all interested parties, considering risk assessment and other factors relevant for the health protection of consumers and for the promotion of fair trade practices, and, if needed, selecting appropriate prevention and control options. 


Risk management option (RMO): A specific action that could be implemented to mitigate risk at various control points throughout the food production to consumption continuum.

CAC/GL 77- 2011

Risk profile: The description of the food safety problem and its context.


Sample: One or more units selected from a population of units, or a portion of material selected from a larger quantity of material.

CAC/GL 33-1999

Sampling for analysis: Means taking feed or food or any other substance (including from the environment) relevant to the production, processing and distribution of feed or food or to the health of animals, in order to verify through analysis compliance with feed or food law or animal health rules.

Own definition

Sanitary and Phytosanitary (SPS) measure: Any measure applied:

(a) to protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease-carrying organisms or disease-causing organisms;

(b) to protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease-causing organisms in foods, beverages or feedstuffs;

(c) to protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or (d) to prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Sanitary or phytosanitary measures include all relevant laws, decrees, regulations, requirements and procedures including, inter alia, end product criteria; processes and production methods; testing, inspection, certification and approval procedures; quarantine treatments including relevant requirements associated with the transport of animals or plants, or with the materials necessary for their survival during transport; provisions on relevant statistical methods, sampling procedures and methods of risk assessment; and packaging and labelling requirements directly related to food safety.

WTO, 1995

Scientific evidence: Means information furnishing a level of proof based on the established and accepted methods of science.

WHO, 2008d
**Surveillance**: Means the systematic ongoing collection, collation, and analysis of information related to food safety and the timely dissemination of information for assessment and response as necessary.

Own definition based on:

- WHO, 2008d
- OIE Glossary For the purposes of the Terrestrial Code

**Testing**: Process to examine the specified characteristics of a sample.

CAC/GL 83-2013

**Traceability (product tracing)**: The ability to follow the movement of a food through specified stage(s) of production, processing and distribution.


**Transit**: The food destined for one country may have to “transit” or travel through another country although it is never imported nor offered for sale in the transit country. The country of transit may establish specific requirements (often pertaining to animal health or plant protection) and may require a transit certificate.

FAO, 2016

**Transparent**: Characteristics of a process where the rationale, the logic of development, constraints, assumptions, value judgements, decisions, limitations and uncertainties of the expressed determination are fully and systematically stated, documented, and accessible for review.

CAC/GL 30-1999

**Unprocessed products**: Means foodstuffs that have not undergone processing, and includes products that have been divided, parted, severed, sliced, boned, minced, skinned, ground, cut, cleaned, trimmed, husked, milled, chilled, frozen, deep-frozen or thawed.

Own definition

**Validation**: Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified outcome.

CAC/GL 69-2008

**Verification**: Activities performed by the competent authority and/or competent body to determine compliance with regulatory requirements.

CAC/RCP 58-2005

**Veterinary drug**: Means any substance applied or administered to any food producing animal, such as meat or milk producing animals, poultry, fish or bees, whether used for therapeutic, prophylactic or diagnostic purposes or for modification of physiological functions or behaviour.


**Withdrawal**: See Food recall
GLOSSARY OF TERMS STRICTLY PERTAINING TO PUBLIC HEALTH SURVEILLANCE

(used mainly in B.2.2 or related assessment criteria)

**Acute public health event**: Any event that represents an immediate threat to human health and requires prompt action, i.e. implementation of control or mitigation measures to protect the health of the public. It includes events that have not yet led to disease in humans but that have the potential to cause such disease through exposure to infected or contaminated food, water, animals, manufactured products or environments, or as a result of direct or indirect consequences of natural events, conflicts or other disruptions of critical infrastructure.

WHO, 2014

**Ad hoc studies**: Targeted public health studies designed to answer specific questions relating to foodborne diseases, e.g. total diet studies, burden of disease studies, source attribution studies.

WHO, 2017

**Agent**: A factor, e.g. microorganism, chemical substance or radiation, whose presence or excessive presence is essential for the occurrence of disease.

Adapted from Porta, 2014

**Analytical epidemiology**: The study of hypothesized causal relationships to make causal inferences. An analytical study is usually concerned with identifying or measuring the effects of risk factors or the health effects of specific exposures or interventions. This is in contrast to descriptive studies, which do not test causal hypotheses. Cohort studies and case–control studies are examples of analytical epidemiological studies.

Porta, 2014

**Case**: Any person who meets a case definition, either for surveillance purposes or during an outbreak investigation.

WHO, 2017

**Case definition**: A set of criteria (not necessarily diagnostic) that must be fulfilled in order to identify a person as having a particular disease or condition. Case definitions can be based on geographical, clinical, laboratory, or combined clinical and laboratory criteria.

Porta, 2014

**Evaluation**: The periodic assessment of the relevance, effectiveness and impact of activities in relation to the objectives of the surveillance and response system.

WHO, 2006a
**Event**: A manifestation of disease or an occurrence that creates a potential for disease. Events may be related to infections, zoonoses, breaches of food safety, or chemical, radiological or nuclear contamination, and transmission may be from person to person or via vectors, animals, goods, food or the environment.

WHO, 2014

**Event-based surveillance**: The organized collection, monitoring, assessment and interpretation of unstructured information about health events that may represent a risk to public health.

WHO, 2014

**Focal point**: A person who is nominated as the point of contact for an activity or process.

WHO, 2017

**Food chain**: The series of processes that food goes through; it includes primary production (including feeds, agricultural practices and environmental conditions), product design and processing, transport, storage, distribution, marketing, preparation and consumption.

CAC/GL 63-2007

**Foodborne disease**: Any disease of an infectious or toxic nature caused by the consumption of food.

WHO, 2008b

**Foodborne event**: Any event related to the occurrence of disease in humans that is caused by contaminated food (e.g. an outbreak of salmonellosis caused by improperly handled eggs) or that has the potential to expose humans to known or suspected hazards through food (e.g. accidental or intentional contamination of food with chemicals).

Adapted from WHO, 2008c

**Foodborne disease outbreak**: For common diseases (such as salmonellosis), the occurrence of two or more surveillance cases resulting from ingestion of the same food. For rare diseases, e.g. botulism, one case may be considered an outbreak.

WHO, 2008b

**Hazard assessment**: Identification of the hazard (or potential hazards) causing a foodborne disease event and of the associated adverse health effects.

WHO, 2012

**Indicator-based surveillance**: The regular, systematic collection, monitoring, analysis and interpretation of structured data, i.e. of indicators produced by a number of well identified, mostly health-based, formal sources.

WHO, 2014

**Laboratory-based surveillance**: A form of indicator-based surveillance of cases that have been confirmed by a laboratory test. The laboratories that perform the testing report the results to the surveillance system, as well as informing the clinicians who requested the tests.

WHO, 2017
**Monitoring:** The routine and continuous tracking of the implementation of planned surveillance activities and of the overall performance of the surveillance and response system.

WHO, 2006a

**Notifiable disease:** A disease that, because of its public health importance, must be reported to the public health authority under legislation or decree, in the pertinent jurisdiction when a diagnosis is made.

Porta, 2014

**Outbreak Response Team (ORT):** A team of people tasked with investigating and controlling the outbreak.

WHO, 2017

**Public health surveillance:** The systematic continuous collection, collation and analysis of data for public health purposes and the timely dissemination of public health information for assessment and public health response as necessary.

WHO, 2008a

**Response:** Any public health action (e.g. event monitoring, providing information to the public, field investigations and control or mitigation measures) triggered by the detection of a public health risk.

WHO, 2014

**Rapid risk assessment:** A systematic process for gathering, assessing and documenting information to assign to an event a level of risk to human health. Rapid risk assessment includes three components: hazard assessment, exposure assessment and context assessment. The rapid risk assessment provides the basis for deciding on action to be taken to manage and reduce the negative consequences of acute public health events.

WHO, 2014

**Risk:** The likelihood that an adverse event will occur during a specified period and the likely magnitude of its consequences.

WHO, 2012

**Sensitivity:** The proportion of actual cases in a population that is detected and reported through the surveillance system.

WHO, 2006a

**Specificity:** The proportion of persons without the disease in a population that are considered by the surveillance system as not having the disease. A surveillance system with low specificity would pick up false outbreaks, resulting in a waste of resources for their investigation.

WHO, 2006a

**Surveillance and response system:** The existing infrastructure, staff and processes used for surveillance of and response to communicable diseases.

WHO, 2017
**Syndrome:** A group of clinical signs and symptoms that consistently occur together, or a condition characterized by a set of associated clinical signs and symptoms.  
WHO, 2012

**Syndromic surveillance:** A method of surveillance that uses health-related data based on clinical observations rather than laboratory confirmation of diagnoses.  
WHO, 2008d
REFERENCES


### LIST OF CODEX DOCUMENTS REFERENCED IN THE TOOL

**Codex GUIDELINES**

Also available at: www.fao.org/fao-who-codexalimentarius/codex-texts/guidelines/en

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CAC/GL 33-1999  Recommended methods of sampling for the determination of pesticide residues for compliance with MRLs

CAC/GL 30-1999  Principles and guidelines for the conduct of microbiological risk assessment

CAC/GL 26-1997  Guidelines for the design, operation, assessment and accreditation of food import and export inspection and certification systems

CAC/GL 23-1997  Guidelines for use of nutrition and health claims

CAC/GL 20-1995  Principles for Food Import and Export Certification and Inspection


Codex CODES OF PRACTICE
Also available at:


CAC/RCP 54-2004  Code of Practice on Good Animal Feeding

CAC/RCP 1-1969  General Principles of Food Hygiene

Codex STANDARDS
Also available at:

CODEX STAN 234-1999  Recommended Methods of Analysis and Sampling

CODEX STAN 1-1985  General Standard for the Labelling of Prepackaged Foods
This introductory volume presents the FAO/WHO Food Control System Assessment Tool, providing background to its development and outlining its main scope and objectives. It presents a thorough review of the assessment Tool structure, breaking it down into its constitutive elements (dimensions, sub-dimensions, competencies and assessment criteria). Finally, it gives an overview of the assessment approach, from the ratings to the descriptive analysis supporting the allocation of scores. The volume also contains a glossary of useful terms and the list of Codex documents referenced in the Tool.