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FOOD CONTROL SYSTEM
ASSESSMENT TOOL

DIMENSION B

CONTROL FUNCTIONS

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ASSESSMENT TOOL

DIMENSION B

CONTROL FUNCTIONS

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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DIMENSION B focuses on the processes and the outputs of the national food control system. It revolves around the control functions that must be exercised by CAs to ensure food safety and quality along the food chain, and around the mechanisms that should be in place to appropriately manage food safety hazards, emerging risks and food emergencies. They encompass both inspection or oversight-type functions, in direct relation with FBOs, and monitoring and surveillance functions.

SUB-DIMENSION B.1

ROUTINE CONTROL ACTIVITIES OVER FOOD PRODUCTS

This sub-dimension reviews the control functions exercised by CAs at FBO level, be it domestic, import or export level to guarantee food safety and quality for national consumers and for sustainable trade.

Competency B.1.1 (Domestic controls) ensures that domestic controls (such as unscheduled inspections), performed at the level of FBOs, are planned and implemented in a way that ensures safety and quality of the products placed on the market. As a starting point, FBOs along the entire food chain should be registered for inspection and official control purposes. Official endorsement of food operations should be granted upon verification of the food safety management systems. A risk categorization framework should be in place as well as standard procedures for performing inspections of the same food category so that food control governance is consistent and better respected. Inspection resources should be deployed on an evidence base and with a robust risk-based approach to control food safety risk. Appropriate sampling should support verification of FBOs' food safety management systems. Traceability systems should be in place at FBOs to allow the identification of non-compliant lots and to support withdrawal or recalls if necessary. Food safety risks arising from informal food vending activities should also be taken into account and addressed. For a consistent application of food safety enforcement procedures, documentation containing enforcement sanctions and procedures should be available to the inspectors.

Competency B.1.2 (Import controls) assesses whether controls over imported food products are planned and implemented in a manner that ensures food safety and quality and that is in coherence with domestic controls. Importers (these need to be defined according to the context, but can include brokers and other categories) should be held primarily responsible for the safety of the food they are importing and should be identified through a registration system so that their compliance history is known and can be used for risk-based planning purposes. Border controls should be linked to domestic food control and a coherent risk-based programme for control measures should be in place. Decision-making on relevant control measures on consignments must be based on appropriate and timely information (notification, pre-notification and pre-clearance systems might be in place). At all border inspection posts (BIPs), effective collaboration must occur between CAs and other institutions, controls must be performed in a harmonized manner, and sufficient and appropriate inspection facilities should be available to allow proper inspections of food consignments.

Competency B.1.3 (Export controls) ensures that the export control system enables meeting the requirements of foreign markets; a specific authorization or licensing scheme should be in place for FBOs willing to export. Capacity to provide credible certificates should exist, to facilitate the clearance process while providing the required assurances, and they should not lend themselves to fraud. Certificates must respond to importing countries' required design features and should be issued by officers authorized by the CAs. In cases where more than one CA have authority to control exporting FBOs, and/or to provide certification, a coordinating mechanism should exist.

SUB-DIMENSION B.2

MONITORING, SURVEILLANCE & RESPONSE FUNCTIONS

This sub-dimension maps the control functions and mechanisms at the overall food supply level, necessary to identify, monitor, predict and handle food safety hazards and emerging risks and to deal with food emergencies.

Competency B.2.1 (Monitoring programmes in relation to the food chain) assesses whether the national food safety monitoring programme provides relevant information on the national situation for specific hazards, and contributes to trends analysis, risk assessment and the improvement of the food control system. The national food safety monitoring plan should be anchored on results of risk ranking and informed by the FBO risk categorization framework, which allows for better targeting of the premises identification and prioritization for sampling. To facilitate implementation, the plan should be developed with the collaboration of all relevant CAs, while human, financial and analytical resources must be identified and mobilized accordingly. The outputs of the national monitoring programme should be used to inform and review the food control policy and related strategies, and to propose suitable interventions. When a monitoring plan detects a potential risk to human health in the food chain, a mechanism should exist to rapidly inform the CA responsible for food-borne disease and response. In some countries, monitoring programmes are conceived and operated in a fragmented manner, without a national vision to ensure that planning, delivery and analysis of results eventually contribute to a national picture. This national convergence is an important element to assess.

Competency B.2.2 (Food-borne disease surveillance) evaluates the national surveillance system and its ability to ensure an effective management of FBD events and other acute public health events. Functional indicator-based disease surveillance (IBS) and event-based disease surveillance (EBS) systems should be in place to monitor trends and detect FBD outbreaks and other food-borne events.

Laboratory data coming from the IBS system should be used to assign etiology for disease syndromes and to support outbreak detection and risk profiling. Rapid risk assessments of acute public health events should be undertaken and suspected food-borne outbreak investigations should include analytical epidemiology and identification of the most likely source of the outbreak. Outbreak investigation results should be contributing towards identification of specific control measures.

Competency B.2.3 (Management of food safety emergencies) ensures that a coordinated management system can identify and respond to food safety emergencies and communicate effectively with all stakeholders, both at national and at international level. At the root, a national food safety emergency plan should be in place where all CAs involved in food safety emergency response are aware of their roles. A mechanism to gather and analyse information should be in place to facilitate incident identification while coordination should support efficient responses from relevant CAs. In the event of a food safety emergency, risk management responses should be implemented in a timely manner and, if needed, the risk analysis framework should be used to structure the response. Communication strategies and guidance should be available and the food safety emergency response plans pre-tested and reviewed after an emergency has occurred, to keep improving the food safety emergency response mechanism over time.



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B.1

ROUTINE CONTROL ACTIVITIES OVER FOOD PRODUCTS

COMPETENCY B.1.1

DOMESTIC CONTROLS

OVERALL OUTCOME	Routine controls performed at the level of FBOs are planned, managed and implemented in a way that ensures safety and quality of the products placed on the market.
B.1.1.1	All principal FBOs are registered for inspection and official control purposes.
B.1.1.2	All FBOs, including primary production establishments, are registered for inspection and official control purposes.
B.1.1.3	Where applicable/appropriate, CAs have verified the food safety management systems implemented by FBOs prior to official endorsement of food operations.
B.1.1.4	Periodic inspection plans developed by CAs are based on an articulated rationale and are implemented.
B.1.1.5	Inspection plans are based on a well-documented risk categorization framework.
B.1.1.6	There are documented procedures for performing inspections of the same food category.
B.1.1.7	As part of their approach to inspecting FBOs, the CAs regularly implement verifications and audits of food safety management systems.
B.1.1.8	The national inspection plan includes routine inspection at all registered farms.
B.1.1.9	Official controls implemented by various CAs at all levels of the food chain are organized to be continuous, joined-up, comprehensive and strategically complementary.
B.1.1.10	Clear documentation of official food standards and requirements are available to all official staff who implement compliance and enforcement work.
B.1.1.11	Clear documentation containing enforcement sanctions and procedures (including reference to legal instruments) is available to official control staff.
B.1.1.12	When an FBO is found to be non-compliant with legislation, the CA officially notifies the FBO of the need to implement corrective actions.
B.1.1.13	CAs follow up with FBOs that are found to be non-compliant to check on the implementation of corrective actions.
B.1.1.14	Authoritative and clear guidance on sampling techniques is available to inspectors and samples taken during inspections are appropriate.
B.1.1.15	CAs have appropriate controls in place to ensure that FBOs have effective traceability systems.
B.1.1.16	Mechanisms for withdrawal and recall of contaminated products are in place in collaboration with the food industry.
B.1.1.17	Where appropriate, there are official controls in place for informal street-food vending to reduce food safety risks for consumers.

COMPETENCY B.1.2 IMPORT CONTROLS

OVERALL OUTCOME	Controls over imported food products are planned and implemented in a manner that ensures food safety and quality, in coherence with domestic controls (Ref. CAC/GL 47-2003 and Risk-based imported food control manual, FAO 2016).
B.1.2.1	Importers are identified through a registration system and importer compliance profiles are established over time.
B.1.2.2	Good importing practices have been developed and published and are used as the basis for import controls.
B.1.2.3	CAs design a coherent risk-based import control programme based on relevant information and responsive to evolving situations.
B.1.2.4	The risk-based import control programme is operated as planned, taking into account available resources.
B.1.2.5	Detailed procedures are in place for border controls, are available to all staff of BIPs and are implemented.
B.1.2.6	A system allowing notification (and/or pre-notification) for imported food consignments is in place and is supported by clear documentation requirements to be submitted by importers.
B.1.2.7	A system for the import of products requiring particular attention is in place, supported by clear documentation requirements.
B.1.2.8	Sufficient inspection facilities are available to inspection staff, of appropriate design, layout and capacity, in the relevant sites.
B.1.2.9	The collaborations that occur between CAs and other institutions at the BIPs are effective and border controls are linked to domestic food control.

COMPETENCY B.1.3 EXPORT CONTROLS

OVERALL OUTCOME	The export control system enables meeting the requirements of export foreign markets.
B.1.3.1	A coordinating mechanism is set up for cases where more than one CA has authority to control and provide certification to FBOs wishing to export, and where other stakeholders are involved.
B.1.3.2	CAs have the capacity to support the requirements of importing countries.
B.1.3.3	A specific authorization or licensing scheme is in place for specific FBOs targeting exports.
B.1.3.4	Certificates respond to required design features as indicated by importing countries and are issued by officers authorized by the CAs (qualified and fully trained).
B.1.3.5	CAs have a system in place to identify and prevent fraudulent certificates and provide clear guidance in case of specific situations related to certification.

B.1.1**DOMESTIC CONTROLS****OVERALL OUTCOME**

Routine controls performed at the level of FBOs are planned, managed and implemented in a way that ensures safety and quality of the products placed on the market.

B.1.1.1

ASSESSMENT CRITERION: All principal FBOs are registered for inspection and official control purposes.

GUIDANCE

Ideally, all FBOs should be registered, to facilitate oversight by CAs. They are then known and can be factored into the risk categorization models, inspection visit planning, etc. However, it is recognized that for some governments it is difficult to ensure that all FBOs are actually registered. Registration includes licensing, authorizations, approval, notification or any process that officially links FBOs with the CAs.

In that case, CAs should ensure that at least all **principal** FBOs are registered for inspection and official control purposes. Each 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 documented. To this end, there should be a system in place for prioritizing principal FBOs based on sound evidence, or possibly on risk. The legal requirement for being registered should preferably be under the food law. It might happen that this is to be found under other laws (e.g. trade) but in that case, CAs dealing with food control should have access to that registration information, or to those parts that are required for food control purposes.

Note: AC B.1.1.1 and AC B.1.1.2 are both exploring the notion of registration of FBOs along the food chain – B.1.1.1 in a more basic manner and B.1.1.2 in a more comprehensive manner.

POSSIBLE OUTCOME

The principal FBOs are within the regulatory control of the CAs.

POSSIBLE INDICATORS

- > Total number of registered FBOs versus total number of FBOs.
- > Criteria/rationale used to determine what defines principal FBOs in the context of the country – if this concept is used in the country.
- > System in place for prioritizing which FBOs are officially linked with the CAs.

SOURCES OF EVIDENCE

- > List of registered FBOs.

SEE ALSO

A.1.3.7 [Legislation includes a mechanism that enables CAs to identify all FBOs throughout the food chain]

B.1.1.2

ASSESSMENT CRITERION: All FBOs, including primary production establishments, are registered for inspection and official control purposes.

**GUIDANCE**

To enable oversight by CAs, all FBOs, including primary production establishments (e.g. farms), should be registered by CAs. This is the basis for subsequent risk categorization of establishments as well as for inspection planning. It is recognized that at initial stages of development not all countries are in a position to demonstrate that all FBOs along the entire food chain continuum are under the regulatory control of CAs. Nevertheless, more advanced systems should be able to demonstrate, through registration, that the FBO community in its entirety, as defined in the law, is known and accessible by CAs.

Note: AC B.1.1.1 and AC B.1.1.2 are both exploring the notion of registration of FBOs along the food chain – B.1.1.1 in a more basic manner and B.1.1.2 in a more comprehensive manner.

POSSIBLE OUTCOME

FBOs are within the regulatory control of the CAs along the entire food chain continuum.

POSSIBLE INDICATORS

- > Total number of registered FBOs versus total number of FBOs.
- > System in place for prioritizing which FBOs are officially linked with the CAs.

SOURCES OF EVIDENCE

- > List of registered FBOs.

SEE ALSO

A.1.3.7 [Legislation includes a mechanism that enables CAs to identify all FBOs throughout the food chain]

B.1.1.3



ASSESSMENT CRITERION: Where applicable/appropriate, CAs have verified the food safety management systems implemented by FBOs prior to official endorsement of food operations.

GUIDANCE

Modern food control governance requires FBOs to take full legal responsibility for the safety of the food that they produce or place on the market. FBOs are expected to implement valid food safety management systems based on the indications provided in the Codex General Principles for Food Hygiene (CAC/RCP 1-1969) as a basis for their own controls during the whole set of food production processes occurring on their premises.

Depending on legislation, specific (or higher-risk) categories of FBOs could be requested to use HACCP, or an HACCP-based system, for their own controls (Ref. para 5 and 25 of CAC/GL 26-1997). This food safety management system should be officially endorsed by CAs prior to commencement of food producing operations, as part of the approval or licensing system, and then periodically revised (Ref. para 52, 3rd point, and 54 of CAC/GL 82-2013). The categories of food businesses requiring such official endorsement of food operations should be based on risk.

Assuming that the food safety management system is considered appropriate, the official recognition should continue. Otherwise, official endorsement of food production at the premises should be altered accordingly, and appropriate control measures should be taken to ensure food safety.

Note: While AC B.1.1.1 and B.1.1.2 are considering registration in a more or less exhaustive manner for the food chain, AC B.1.1.3 focuses on the type of analysis that supports endorsement of food operation.

POSSIBLE OUTCOME

Safe production of food by FBOs is supported by valid food safety management systems.

POSSIBLE INDICATORS

- > Approval or licensing (or any equivalent) system in place.
- > Evidence of periodic revisions taking place.
- > Proceedings of the official endorsement process.

SOURCES OF EVIDENCE

- > Documentary evidence of CAs' approval before official recognition.
- > Documentary evidence that CAs regularly verify that FBOs have the appropriate food safety management systems in place (inspection/audit reports, correspondence with FBOs, etc.).

B.1.1.4

ASSESSMENT CRITERION: Periodic inspection plans developed by CAs are based on an articulated rationale and are implemented.

**GUIDANCE**

Inspection plans may be based on an articulated rationale, including elements of evidence and other information such as, if available, a very basic and qualitative risk categorization model for food businesses. Information such as results of previous inspections, size of premises, number of premises and staffing resources may typically be considered for this qualitative approach to risk categorization. Each CA with a mandate for inspection should be able to present a periodic (e.g. annual) inspection plan, or its equivalent.

It is important that transparent criteria for targeting the FBOs are applied – for example, that principal and “high-risk” FBOs be given priority in inspection plans. (In the absence of a risk categorization model, “sensitive” FBOs should be identified.)

The deployment of inspectors should be planned rather than ad hoc. CAs should leverage impact for food controls by deploying the limited staff and other resources that are available on a logical basis. To this purpose, staff numbers and qualifications should be taken into account at the planning stage.

Once plans are formulated, they should be implemented. Their implementation, along with any issues faced in the course of action, should feed into revisions and improvement of such plans.

These plans should be logically connected with the operational food control plans developed by the relevant CAs to ensure that policy objectives are eventually met.

Note: AC B.1.1.4 and AC B.1.1.5 are both related to the existence of simple (B.1.1.4) or more sophisticated (B.1.1.5) approaches to risk categorization of FBOs as a basis for inspection planning.

An example of an approach to develop this plan is given below:

1	SIZE OF PREMISES (I.E PRODUCTION).	Principal / Medium / Small / Micro PREMISES
2	SENSITIVITY OF FOOD PRODUCT.	High / Medium / Low SENSITIVITY
3	ALLOCATION OF INSPECTION ATTENDANCE TIME TO PREMISES AGAINST "BROAD-RISK" CATEGORIES.	<i>(Example provided here)</i> > High-risk 60% > Medium-risk 30% > Low-risk 10%
4	NUMBER OF REGISTERED / LICENSED FBOs.	The number of premises according to risk allocation. [Premises where government intends to make inspections during the period in question] > High-risk: x FBOs > Medium-risk: y FBOs > Low-risk: z FBOs
5	STAFFING RESOURCES AVAILABLE FOR INSPECTION (TIME).	<i>(Example provided here)</i> > Full-time inspection units (FTIUs) (e.g. 40 hours per week x 1 inspector = 1 FTIU. 40 working weeks per year (each full-time inspector) = 40 FTIU p.a./per inspector > 50% time available for inspection (after admin. time, travel time, reporting time) = 20 FTIU p.a. is available for each inspector > Number of full-time inspectors x 20 FTIU = available time for inspections
6	ALLOCATION OF INSPECTION TIME TO INDIVIDUAL PREMISES.	Rational allocation of available time for inspection taking into account: > Risk classification > Throughput > History of premises, capacity of the management
7	OTHER REQUIRED RESOURCES AND AVAILABILITY. (TRANSPORT AND ACCOMMODATION).	> Inventory of transportation resources (vehicles, fuel, maintenance, etc.) for food inspector cadres > Calculation of accommodation costs for food inspector cadres > Budget for accommodation and transport for food inspector cadres
8	A VALID PLAN FOR INSPECTION ATTENDANCE AT HIGH-RISK AND PRINCIPAL PREMISES.	A plan for attendance at registered/licensed premises is documented, available, implemented and in operation according to the documented plan, and for at least the following classifications of premises: > Principal premises (see 1 above) > High-risk premises (see 2 above)

POSSIBLE OUTCOME

Inspections resources are deployed on an evidence basis.

POSSIBLE INDICATORS

- > Rationale for the development of the plan (objective elements taken into account to support the rationale, including, for example, results of previous inspections).
- > Evidence that the annual inspection plan was implemented.
- > Other documentation that shows that CAs make the effort to measure and understand the human resources at their disposal for food control purposes in order to make rational work plans.

SOURCES OF EVIDENCE

- > Annual inspection plan.
- > The report (or data workings) of how the multi-annual plan or the annual plan for inspections and sampling have been calculated.

SEE ALSO

- A.1.1.2** [Food control strategic plans are prepared by CAs and translate into action the overarching objectives set out in the food safety and quality policy]
- A.1.3.7** [Legislation includes a mechanism that enables CAs to identify all FBOs throughout the food chain]
- A.3.1.1** [A duty is placed upon the State to ensure that CAs have access to sufficient and suitably skilled personnel with adequate qualification and ability]

B.1.1.5

ASSESSMENT CRITERION: Inspection plans are based on a well-documented risk categorization framework.

**GUIDANCE**

Inspection resources available to CAs are generally limited and should be deployed in a manner that assures greatest impact in terms of consumer protection, through control of the most significant risks. This should be reflected in the inspection plan, using a well-documented risk categorization framework for food businesses.

A risk categorization framework (see **D.1.3.4**) is a supporting tool that makes it possible 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. Of course, other risks should not be ignored, but the inspection resources should be deployed in proportion to the identified risks.

Sufficient information must be available to identify the most significant risks through a risk ranking process, and to identify high-risk foodstuffs and high-risk FBOs – including, for example, using results of previous inspections (Ref. para 81 of CAC/GL 82-2013).

Inspection plans should rationally and proportionally ensure that these priority risks are met with inspection resources.

Note: AC B.1.1.4 and AC B.1.1.5 are both related to the existence of simple (B.1.1.4) or more sophisticated (B.1.1.5) approaches to risk categorization of FBOs as a basis for inspection planning.

POSSIBLE OUTCOME

CAs' resources are deployed with a robust risk-based approach to control food safety risks.

POSSIBLE INDICATORS

- > The risk-based approach is written into policy and strategy documents.
- > There is a documented process for risk ranking of FBOs.
- > Inspection plans reflect considerations of the risk categorization framework.
- > Inspection resources are deployed in proportion to the identified risks (documentary evidence, audits, etc.).

SOURCES OF EVIDENCE

- > Policy and strategy documents.
- > Inspection plans.
- > Audits.

SEE ALSO

- A.1.3.4** [Legislation introduces the principle of risk analysis and this is used as a basis for establishing food safety measures]
- D.1.3.3** [When necessary, CAs use risk profiles to guide and inform the deployment of resources into official controls]
- D.1.3.4** [CAs have collaborated to produce a risk categorization framework of FBOs]

B.1.1.6

ASSESSMENT CRITERION: There are documented procedures for performing inspections of the same food category.

**GUIDANCE**

Consistency in the institutional approach to food inspections and audits of the same food category is important. All inspections of the same food category should be based on structured and consistent guidelines (Ref. para 70, 2nd point, of CAC/GL 82-2013) – for example, using checklists for GHP/GMP at premises inspections – and should primarily review conformity with general principles of food hygiene provisions. This consistent and constant message will assist the food industry staff to become familiar with the priorities as seen by the CAs, and will assist the food industry staff to respond positively to the needs of the CAs. It is important that administrative procedure be in place to document the process and the findings (Ref. para 49 of CAC/GL 82-2013).

Controls should cover (Ref. para 52 of CAC/GL 82-2013):

- i. Establishments, installations, equipment, personnel and material.
- ii. Products, from raw materials to finished products, including intermediate products.
- iii. Preventative controls such as Good Agricultural Practices (GAPs), Good Hygiene Practices (GHPs), Good Manufacturing Practices (GMPs) and, if applicable, food safety management systems (e.g. HACCP-based).

POSSIBLE OUTCOME

Enforcement of requirements for GHP/GMP is consistent and there is increased confidence in the system of food control governance.

POSSIBLE INDICATORS

- > The scope of food inspections has been standardized (especially regarding GHP/GMP) and kept at the forefront of the inspection process.
- > CAs have standard procedures for performing HACCP/GHP/GMP inspections and documenting the findings.

SOURCES OF EVIDENCE

- > Documented standard procedures.

SEE ALSO

A.3.2.3 [CAs supply or facilitate periodic update training events for staff with responsibilities in food control]

B.1.1.7

ASSESSMENT CRITERION: As part of their approach to inspecting FBOs, the CAs regularly implement verifications and audits of food safety management systems.

GUIDANCE

Modern food control governance requires FBOs to take full legal responsibility for the safety of the food that they produce. FBOs are therefore expected to implement “own controls” – i.e. valid food safety management systems and prevention measures to control the safety of their food production (Ref. para 11 and 19 of CAC/GL 82-2013). HACCP is an approach being widely used among food businesses worldwide. Codex, as part of the General Principles for Food Hygiene (CAC/RCP 1-1969), has provided guidelines on the HACCP system.

Beyond elements mentioned in B.1.1.6, control approaches should also entail a blend of approaches such as (Ref. para 53 and 80 of CAC/GL 82-2013):

- i. Inspection, verification and audit, including onsite visits;
- ii. Market surveillance;
- iii. Sampling and analysis;
- iv. Examination of written records;
- v. Documentation of observations and other findings;
- vi. Examination of the results of any verification systems operated by the establishment.

POSSIBLE OUTCOME

CAs have evidence that FBOs have adopted risk-based “own controls” based on HACCP principles.

POSSIBLE INDICATORS

- > Audits of HACCP and other food safety management systems are recorded.
- > Approaches used include:
 - i. Inspection, verification and audit, including onsite visits;
 - ii. Market surveillance;
 - iii. Sampling and analysis;
 - iv. Examination of written records;
 - v. Documentation of observations and other findings;
 - vi. Examination of the results of any verification systems operated by the establishment.

SOURCES OF EVIDENCE

- > Documentation of verifications and/or audits of “own controls” adopted by FBOs.

B.1.1.8

ASSESSMENT CRITERION: The national inspection plan includes routine inspection at all registered farms.

**GUIDANCE**

Food safety begins at farm level, and in some cases in the industries that supply the farming sector, such as the animal feed industry or suppliers of agricultural chemicals. The concept of food safety “from farm to fork” must include the duty of relevant CAs to ensure food safety at farm level (“upstream”) and not only at production (“downstream”).

To allow controls to happen, primary production establishments should therefore be identified and registered, and depending on the level of risk, there should be provision for suitable inspection regimes.

In many developing countries, the primary sector is still informal and the integration of the early steps of the food chain happens later as systems mature. However, this may vary by region and country.

Note: There may be countries where controls over primary production only happen in connection to exports. For the purpose of this assessment criterion, and in order to be considered as fully achieved, these controls, while risk-based, should also target production for the domestic market.

POSSIBLE OUTCOME

Where appropriate, official food controls are exercised at an early stage of the food chain and this is linked to more efficient controls downstream.

POSSIBLE INDICATORS

- > Primary production establishments (e.g. farms, fishing vessels and aquaculture, animal feed industry, agrochemicals suppliers) have been identified.
- > Primary production establishments are included in the national inspection plan.

SOURCES OF EVIDENCE

- > The national inspection plan.
- > List of registered primary production establishments.

SEE ALSO

C.1.1.3 [There are formal attempts to identify which specific food controls are often poorly carried out by FBOs and these are addressed in the capacity development activities as conceived and arranged by, or in collaboration with, the CAs]

B.1.1.9

ASSESSMENT CRITERION: Official controls implemented by various CAs at all levels of the food chain are organized to be continuous, joined-up, comprehensive and strategically complementary.

GUIDANCE

Different CAs are usually responsible for different levels of the food production chain. The institutional set-up should ensure that all responsibilities outlined in official texts are clear, and that gaps are avoided and duplications minimized. At operational level, good communication and coordination among CAs should exist to ensure that the mandates related to control measures are effectively implemented. This should be supported by formal communication procedures, which will help to ensure that official controls for the streams of production and processing (value chains) are strategically linked and are efficient. Examples for this would be controls on veterinary drugs and pesticide residues and contaminants originating from fertilizers connecting primary production with further steps in the food chain.

This also includes joint planning between the CAs at the central level, to ensure coherent national plans are developed, and effective implementation at local level (for de-concentrated and/or decentralized services) to ensure proper coverage of FBOs. When a national strategic food control plan exists, this provides a conceptual framework for such integrated work. Proper coordination and communication within and among CAs are conducive to the implementation of such work, which is the focus of this assessment criterion.

POSSIBLE OUTCOME

CAs implement coordinated “farm to fork” controls.

POSSIBLE INDICATORS

- > Examples of communication and coordination among CAs at both central and decentralized or de-concentrated level (e.g. common programmes, transfer of information, integration of information stemming from other CAs into inspection programme and approaches).
- > Formal agreements (such as MoUs) between CAs regarding roles and operations.
- > Formal joint standing committee for food safety, with specific reference to inspection coordination.
- > CAs’ communication ensures proper coverage of FBOs.
- > Existence of a forum for ensuring coordination and collaboration for official controls.

SOURCES OF EVIDENCE

- > Records of correspondence/communication happening at central and local level to ensure a coherent national planning.
- > MoUs.
- > Mandates of joint standing committees.

SEE ALSO

- A.1.1.2** [Food control strategic plans are prepared by CAs and translate into action the overarching objectives set out in the food safety and quality policy]
- A.1.2.2** [A formal communication mechanism is in place between CAs and other stakeholders involved in food control, to exchange relevant information over the entire food chain, from primary production to human health]

B.1.1.10

ASSESSMENT CRITERION: Clear documentation of official food standards and requirements are available to all official staff who implement compliance and enforcement work.

GUIDANCE

A principal function of the CAs is to verify that food produced by FBOs is safe for consumers and complies with regulations and official requirements. Staff require easy access to food regulations, standards and requirements, as well as other supporting documentation (internal notes, etc.), to support their judgments when performing inspections and audits. This should also include relevant guidance for sampling if necessary (Ref. para 70 of CAC/GL 82-2013).

POSSIBLE OUTCOME

Consistent understanding of food standards and requirements is achieved.

POSSIBLE INDICATORS

- > Formal and clear documentation on official food control activities for the use of inspectors, officers, and enforcement staff (produced by the CAs responsible for food control from farm to fork).
- > Accessibility of the documentation to the inspectors.

SOURCES OF EVIDENCE

- > Documentation on official food operations (internal notes, guidance for sampling, etc.).
- > Interviews with staff.

B.1.1.11

ASSESSMENT CRITERION: Clear documentation containing enforcement sanctions and procedures (including reference to legal instruments) is available to official control staff.

GUIDANCE

While performing their official control duties, situations will arise where inspectors experience non-compliance with legislation or where a self-food-control system implemented by a FBO is considered to be failing. Staff require formal and clear documentation and operational guidance* to outline enforcement and other administrative procedures (Ref. para 49 and 80 of CAC/GL 82-2013), including

reference to legal instruments, covering a set of sanctions to control unsafe food or non-compliant incidents. Staff should also be trained in the implementation of enforcement work. The sanctions (as outlined) should be supported institutionally, legally and procedurally within the context of the judicial process of the country, which is available and accessible by the CAs. The documented sanctions should be available to all stakeholders, including FBOs and the private sector and consumers.

***Note:** It is important to differentiate documentation and operational guidance directed at CAs' staff, from "codes of practice" or other formal guidance material directed at FBOs or consumers.

POSSIBLE OUTCOME

Food safety enforcement procedures are consistently applied.

POSSIBLE INDICATORS

- > Documentation exists regarding food safety enforcement sanctions and procedures for appropriate food safety inspectors and enforcement officers.
- > Documentation is accessible to official staff.
- > The sanctions as outlined are supported institutionally, legally and procedurally.
- > The documented sanctions are available to all stakeholders, including FBOs and the private sector and consumers.

SOURCES OF EVIDENCE

- > Documentation on food safety enforcement sanctions and procedures.

SEE ALSO

A.1.2.7 [Legislation provides an array of effective enforcement provisions as well as the right to appeal decisions made by the CAs]

B.1.1.12

ASSESSMENT CRITERION: When an FBO is found to be non-compliant with legislation, the CA officially notifies the FBO of the need to implement corrective actions.



GUIDANCE

Non-compliant food should be stopped from being traded. The duty of the CA is to enforce legislative standards or requirements and to ensure that FBOs implement control measures. This can include: (i) enforcing immediate rectification of the non-compliance and control of affected foodstuffs; or (ii) identifying a reasonable time

frame for the corrective action to be implemented to the satisfaction of the food control inspector, for situations where the non-compliance is not immediately critical.

In high-risk scenarios of non-compliance, appropriate official action over food production should be implemented to minimize the risk to consumers. Risks associated with non-compliant foods should be evaluated and appropriate action taken, which means that the food could be disposed of, treated appropriately or redirected to other uses. For instance, if necessary, food production can be stopped, until a repair or rectification can be implemented (Ref. para 39, 9th point, and 81 of CAC/GL 82-2013).

POSSIBLE OUTCOME

CAs ensure that FBOs implement corrective actions.

POSSIBLE INDICATORS

- > Evidence that official enforcement actions was taken after instances of non-compliance (e.g. percentage of non-compliant FBOs for which enforcement action was taken).
- > Direct enforcement action taken in case of immediate danger.

SOURCES OF EVIDENCE

- > Records of correspondence on corrective actions.

B.1.1.13



ASSESSMENT CRITERION: CAs follow up with FBOs that are found to be non-compliant to check on the implementation of corrective actions.

GUIDANCE

Non-compliance is sometimes repeated by lax or careless FBOs. Some corrective actions may also not be sufficient to ensure full control over food. Any non-compliance that has been subjected to some form of official control measure should be re-visited and re-checked at a suitable time (Ref. para 50, 6th point, 57, 4th point, and 81 of CAC/GL 82-2013). In the event that corrective actions have failed, or were never implemented, appropriately strong enforcement measures must be implemented immediately by the CA to ensure food safety and quality.

POSSIBLE OUTCOME

FBOs are required by CAs to implement corrective actions.

POSSIBLE INDICATORS

- > CAs follow up to ensure that non-compliant FBOs have implemented corrective actions.
- > CAs ensure that the corrective actions were effective.
- > Non-compliances and subsequent enforcement actions are documented.

SOURCES OF EVIDENCE

- > Official control records for several FBOs.
- > Documentary evidence of CAs checking on implementation of corrective actions and their effectiveness.
- > Interviews with inspectors or officials who have responsibility for food controls in FBOs.

B.1.1.14

ASSESSMENT CRITERION: Authoritative and clear guidance on sampling techniques is available to inspectors and samples taken during inspections are appropriate.

**GUIDANCE**

Sampling can be used to support inspection activities. It can be triggered either by suspicion of non-conformities or to support the implementation of the national monitoring programme (see B.2.1). In any event, sampling must be implemented in a robust way to ensure appropriateness of subsequent analytical results. It is therefore important that:

- i. Relevant equipment is available to inspectors to implement sampling operations;
- ii. Sufficient guidance on how to take (and transport) samples is provided to inspectors;
- iii. Inspectors implement this guidance in an appropriate manner.

POSSIBLE OUTCOME

Sampling supports inspection of FBOs' food safety management systems.

POSSIBLE INDICATORS

- > Relevant sampling equipment is available to inspectors.
- > Guidance on how to take (and transport) samples is provided to inspectors.
- > Samples are taken appropriately (e.g. no evidence of reports by laboratories indicating inappropriate sampling).

- > Sample records are reviewed (including size, type, temperature, etc.), from sample collection to analysis, to ensure that all samples were taken appropriately.

SOURCES OF EVIDENCE

- > Sample records (including size, type, temperature, etc.) from sample collection to analysis.
- > Interviews with inspectors.
- > Sampling equipment.
- > Guidance on how to take (and transport) samples.

SEE ALSO

- A.2.2.5** [Suitable sampling equipment, space and facilities (such as temperature-controlled storage and infrastructure for transportation of samples to laboratories), are provided for monitoring or surveillance activities]
- B.2.1.5** [The national monitoring programme takes into consideration available human, financial and analytical resources]

B.1.1.15**ASSESSMENT CRITERION: CAs have appropriate controls in place to ensure that FBOs have effective traceability systems.****GUIDANCE**

Traceability can:

- Contribute to the protection of consumers against food-borne hazards and deceptive marketing practices;
- Facilitate trade on the basis of accurate product descriptions.

The traceability systems (or product-tracing systems) may apply to all or specified stages of the food chain, from production to distribution. These systems should be able to identify, at any specified stage of the food chain, where the food came from (one step back) and where the food went to (one step forward) (Ref. to CAC/GL 60-2006). Traceability is a fundamental tool in the event of food safety emergencies or incidents but also in the case of fraud. It allows for tracing unsafe or fraudulent food (one step forward, or commercially “downstream”) and for detecting the source of unsafe or fraudulent food (one step backward, or commercially “upstream”). This is facilitated by source and destination information that should be provided by the FBOs involved. “Upstream information” should include details of food/feed batches or consignments or ingredients – most importantly if in bulk – which

include the nature and details of the food, feed or ingredients, the date of transfer, the name and address of the FBO that is the source of the batch (or even further up the chain, if possible). “Downstream information” should include details of food/feed batches or consignments or ingredients – most importantly if in bulk – which include the nature and details of the food, feed or ingredients, the date of transfer, the name and address of the FBO to which the batch was consigned. Traceability systems need to support identification of quantities of product affected by the non-conformity. They should be connected to the food safety emergency management plan and systems to gather and retrieve information, and implement a response (see **B.2.3.1**, **B.2.3.2** and **B.2.3.4**).

POSSIBLE OUTCOME

Traceability systems in place at FBOs allow the identification of non-compliant lots and support withdrawal or recalls if necessary.

POSSIBLE INDICATORS

- > Records kept by FBOs of commercial movement of food (or other materials kept in the vicinity of food production, ingredients, etc.) “one step backward” and “one step forward”.
- > Evidence of CAs enforcing the requirement to keep records of food movement and quantities involved at least one step back and one step forward.
- > Capacity by CAs to produce “on demand” statistics regarding actions taken on recalls and trace back of issues.

SOURCES OF EVIDENCE

- > Documentation on the CAs’ requirements regarding traceability.
- > Documentary evidence of CAs enforcing these requirements.
- > CA records on traceability check/verification of adequate data collection.

SEE ALSO

- B.1.1.16** [Mechanisms for withdrawal and recall of contaminated products are in place in collaboration with the food industry]
- B.2.3.1** [A suitable national food safety emergency plan has been developed in a participatory way and food safety emergencies have been defined to serve as a trigger for escalating appropriate response]
- B.2.3.2** [Mechanisms to gather and analyse information are in place to allow incident identification]
- B.2.3.4** [Functional arrangements are in place for communication and implementation of response in the event of a food safety emergency]

B.1.1.16

**ASSESSMENT CRITERION: Mechanisms for withdrawal and recall of contaminated products are in place in collaboration with the food industry.****GUIDANCE**

There should be mechanisms in place to ensure that timely withdrawal or recall happens, following the identification of a contaminated product. While these mechanisms should be proposed by the FBOs with validation by the CAs, implementing recalls is primarily the FBOs' responsibility, while keeping the CAs fully informed. Withdrawal and recall mechanisms should be planned, tested and documented (Ref. para 62 and 63 of CAC/GL 82-2013). (FAO and WHO, 2012).

These mechanisms are based on traceability systems to allow, **as a first step**, identifying where the product has been distributed (tracing forward) and stopping its distribution. Contact with all clients (industry) is essential to inform them of expected actions that they should take to withdraw or recall products. A list of all clients should be provided to CAs. This should be implemented by the FBO who is responsible for the recall. If the FBO cannot be identified, or if no FBO has this capacity, CAs should undertake this task themselves.

A second step (tracing backward) should also allow identifying any other product that might also be involved (a common ingredient, for example). This should also involve joint work with the responsible FBO. All these steps and actions should be properly documented by both the CAs and the FBOs.

As a third step, verification should be undertaken by CAs to check that all products have indeed been traced, withdrawn from the market and appropriately dealt with to ensure consumer protection (i.e. reprocessed, relabelled, disposed of, etc.) CAs should also ensure that FBOs have taken the necessary steps to inform consumers when appropriate.

POSSIBLE OUTCOME

Distribution of non-compliant food products is contained.

POSSIBLE INDICATORS

- > Recall and withdrawal plans, reviewed by CAs, available in the private sector.
- > Simulations of recall and withdrawal.
- > Functional traceability system in place.
- > Systems in place to inform consumers.
- > Verification measures undertaken by CAs to confirm effectiveness of recalls.

SOURCES OF EVIDENCE

- > Recall and withdrawal plans.
- > Records of past emergencies and indications of lessons learned.
- > List of all clients (industry).

SEE ALSO

- A.1.3.9** [Legislation includes an obligation to ensure food traceability from farm to fork]
B.1.1.15 [CAs have appropriate controls in place to ensure that FBOs have effective traceability systems]

B.1.1.17

ASSESSMENT CRITERION: Where appropriate, there are official controls in place for informal street food vending to reduce food safety risks for consumers.

**GUIDANCE**

Government should consider including informal street food vending in their control plans, if appropriate. Informal street food vending activities are generally conducted by operators with a limited understanding of food hygiene, who utilize low-investment facilities and equipment and ply their trade in places where conditions are generally uncontrolled (such as no place to wash hands, no toilets, no roof coverage or protection from the elements such as sun, dust, rain, fumes, uncontrolled pests). Such scenarios present a risk that food hazards may manifest without sufficient control. It is recognized that this sector is notoriously difficult to control consistently and, although some governments completely ban informal food vending activities, other governments do not feel they have the political mandate to do so. A combination of control and educational strategies for vendors, through their associations, supported by consumer awareness-raising activities, usually works better than controls alone. This should be supported by good knowledge and understanding of the sector by local CAs, to appropriately target priority interventions and messages to be delivered.

FAO/WHO regional coordination committees have proposed regional guidelines putting forward hygiene codes that can be used to develop an appropriate approach to inspecting street foods and street food vendors (CCAFRICA (CAC/GL 22R-1997, Regional Guidelines for the Design of Control Measures for Street-Vended Foods (Africa), CCASIA (CAC/RCP 76R-2017 Regional Code of Hygienic Practice for Street-Vended Foods in Asia), CCLAC (CAC/RCP 43R-1995 Regional Code of

Hygienic Practice for the Preparation and Sale of Street Foods (Latin America and the Caribbean)), and CCNEA (CAC/RCP 71R-2013 Regional Code of Practice for Street-Vended Foods (Near East)) (FAO, 2009a, 2009b; WHO, 1996).

POSSIBLE OUTCOME

Food safety risks arising from informal food vending activities are appropriately mitigated.

POSSIBLE INDICATORS

- > Legal instruments allowing such controls to take place.
- > Policy for informal foods that includes technical guidelines, codes of practice and stipulations for people involved in preparing and selling street food.
- > Results of controls being implemented.

SOURCES OF EVIDENCE

- > Informal food policy/legal provisions.
- > Records of controls.
- > Interviews with CAs responsible for urban public health or environmental health.

SEE ALSO

- C.1.1.1** [The CAs assess FBOs' capacity development needs to inform and plan awareness campaigns, training and educational programmes]
- C.1.1.2** [Where needs are identified, capacity development activities are leveraged or directly implemented by CAs to improve the understanding of a range of FBOs (primary producers, processors, small traders, food vendors, etc.) regarding the requirements of food regulations]

B.1.2**IMPORT CONTROLS**

Controls over imported food products are planned and implemented in a manner that ensures food safety and quality, in coherence with domestic controls (Ref. CAC/GL 47-2003 and Risk-based imported food control manual, FAO 2016).

OVERALL OUTCOME**B.1.2.1**

ASSESSMENT CRITERION: Importers are identified through a registration system and importer compliance profiles are established over time.

**GUIDANCE**

At the basis of a risk-based control system for imported food controls, there should be timely access to relevant and organized information about a food product, its source country and the importer's compliance history. To build a base of such information, it is necessary to have a system that allows identifying importers (Ref. para 37 of CAC/GL 47-2003), connecting them with:

- i. Records of compliance of their consignments;
- ii. Record of their compliance with Good Importing Practices (GIP);
- iii. Reliability of the foreign supplier verification programmes.

The system might vary with regard to its name (e.g. registration, authorization, licensing) and may include an official endorsement of the food safety management system of importers, in a similar manner as for domestic FBOs (Ref. para 38 of CAC/GL 47-2003). In some countries, this would result in the issuance of licences based on compliance with GIPs, for example, while in other countries permits would be issued in relation to specific imports (e.g. high-risk foods). On this basis, CAs are able to develop importers' profiles to trace compliance history and to develop a database on importers to inform a risk categorization process.¹

POSSIBLE OUTCOME

Importers' compliance history is known and can be used for risk-based planning purposes.

¹ For more detailed guidance see also: FAO (2016), Section 2

POSSIBLE INDICATORS

- > Existence of a risk-based control system for importers (registration, authorization, licensing, permits, etc.).

SOURCES OF EVIDENCE

- > Registry of importers available and updated with information on:
 - i. Importers' compliance history.
 - ii. Compliance with GIP.
 - iii. Reliability of the foreign supplier verification programmes.

SEE ALSO

- B.1.2.3** [CAs design a coherent risk-based import control programme based on relevant information and responsive to evolving situations]
- C.1.1.3** [There are formal attempts to identify which specific food controls are often poorly carried out by FBOs and these are addressed in the capacity development activities as conceived and arranged by, or in collaboration with, the CAs]

B.1.2.2



ASSESSMENT CRITERION: Good importing practices have been developed and published and are used as the basis for importer controls.

GUIDANCE

Good Importing Practices (GIPs) set up the basic requirements that importers should meet. As such, they are a useful reference for both CAs and importers to regulate food safety and quality of imported foods. They should cover basic hygiene measures in relation to storage conditions, buildings, equipment and personnel in coherence with the Codex general principles for food hygiene. Requirements for importing products, procedures for maintaining documents, reception and assessment of the imported product should also be included, as well as the basis for importers to set up their own control approach.² Vulnerability assessment should also be incorporated as a preventative approach against fraud.

While these GIPs support the growth of a professionally responsible subset of FBOs, they are also the basis for CAs to control the importers, as for any other FBO category.

² For more detailed guidance see also: FAO (2016), Section 2

POSSIBLE OUTCOME

Importers are held primarily responsible for the safety of the food they are importing.

POSSIBLE INDICATORS

- > A set of good importing practices (GIPs) has been developed, in coherence with the Codex general principles for food hygiene, and includes:
 - i. Requirements for importing products;
 - ii. Basic hygiene measures re: storage conditions, buildings, equipment and personnel;
 - iii. Vulnerability assessments against fraud;
 - iv. Reception and assessment of the imported product;
 - v. Maintaining of documents;
 - vi. Basis for importers to set up their own control approach.
- > FBOs are knowledgeable of these GIPs.

SOURCES OF EVIDENCE

- > GIPs.
- > Inspection reports of importers based on the GIPs.
- > Interviews with FBOs.

B.1.2.3

ASSESSMENT CRITERION: CAs design a coherent risk-based import control programme based on relevant information and responsive to evolving situations.

**GUIDANCE³**

Structured control programmes are necessary to ensure that a course of action is designed to achieve the intended objectives and, through a logical sequence, to regularly assess if the results delivered actually ensure the desired outcomes. When the import control programme is risk-based it also enables authorities to deploy their inspection resources where the greatest risks are, thus maximizing benefits (Ref. para 24 of CAC/GL 26-1997).

³ For more detailed guidance see also: CAC/GL 47-2003, Section 4 and 5 of the Appendix

Risk profiles for imported food are a basic tool to build these risk-based programmes. Examples of information that risk profiles should take into account include:

- i. Information about type of product and its “inherent” risk;
- ii. Country of origin and reliability of export certification;
- iii. Importer’s reliability, including own-control system and/or use of certification processes for consignments (Ref. para 45 of CAC/GL 82-2013);
- iv. Information stemming from rejection, INFOSAN, RASFF, etc.

To prepare imported food risk profiles, information should be retrieved from sources such as:

- i. Risk ranking processes (see D.1.3.2);
- ii. Risk profiles (see D.1.3.3);
- iii. Importers’ profiles (see B.1.2.1), including information stemming from importers’ registration/licensing processes, controls showing their implementation of good importing practices and results from controls over previous import processes;
- iv. Source country export controls (see C.2.1), e.g. via audits, recognition or other equivalence agreements (for specific guidelines for the conduct of foreign official inspection systems refer to the Annex of CAC/GL 26-1997).

To determine the risk-based programme, different levels of risk can be associated to different types of inspection regime, ranging from simple documentation review and visual inspection of consignment (identity check), up to sampling and analysis, with given frequencies⁴ (Ref. para 4, 22 and 24 of CAC/GL 47-2003). As far as possible, requirements should be applied equally to domestically produced and imported food (Ref. para 5 of CAC/GL 47-2003).

This programme should also show a capacity to adapt to evolving circumstances as an intrinsic feature – such as, for example, enhanced or reduced intensity of controls based on results of previous controls (Ref. para 81, 1st point, of CAC/GL 82-2013 and Section 6 of the Appendix of CAC/GL 47-2003).

POSSIBLE OUTCOME

CAs’ resources for control of imported food consignments are used at maximum efficiency for the protection of health and economic interests of consumers.

POSSIBLE INDICATORS

- > Existence and content of imported food profiles, and sources of information for these profiles.

⁴ For more detailed guidance see also: FAO (2016), Section 2

- > Existence of a risk-based control programme, differentiating measures according to product risks.
- > Degree of reactivity to risk or new circumstances of this programme.

SOURCES OF EVIDENCE

- > Imported food profiles.
- > Imported food control programme.
- > Annual report of activity.

SEE ALSO

- B.1.2.1** [Importers are identified through a registration system and importer compliance profiles are established over time]
- C.2.1.1** [The CAs support the development of bilateral or regional trading relationships with an open and pro-active communication approach on food safety and quality regulations, as well as on control measures and documentation requirements]
- C.2.1.2** [Trading partners have easy access to up-to-date information regarding food safety and quality requirements and controls]
- C.2.1.4** [CAs of importing and exporting countries have capacity to reach and maintain cooperative arrangements and agreements regarding control measures for specific categories of food products to allow trade]
- D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]
- D.1.3.3** [When necessary, CAs use risk profiles to guide and inform the deployment of resources into official controls]

B.1.2.4

ASSESSMENT CRITERION: The risk-based import control programme is operated as planned, taking into account available resources.

**GUIDANCE⁵**

Imported food control programmes generally entail some degree of control at the border, whether documentary check, visual check and verification of identity and apparent integrity (e.g. no sign of thawing, no filth or insect/rodent damage, organoleptic verification), or sampling for laboratory analysis. Inspectors must therefore be present and able to perform whatever level of control is expected from them, depending on the type of commodity imported. Staff numbers should also be matched with the requested skills and competences, in particular for specific high-risk products. It may be strategic to review staff allocations with regard to the

⁵ For more detailed guidance see also: FAO (2016), Section 4

volume and types of food imported at specific BIPs. If staff allocations cannot cover all BIPs, some policy decisions should be made based on risk – restrictions in the type of food that can be imported at specific BIPs, collaborations with other CAs for delegation of specific tasks, etc. This could also be reflected in further iterations of the control programme.

POSSIBLE OUTCOME

The tasks and procedures associated with inspection of food consignments are performed as planned to allow the programme to meet its objectives.

POSSIBLE INDICATORS

- > Presence of qualified staff at BIPs allocated according to import volume and types of controls.
- > Rationale used to distribute staffing.
- > Evidence that staff are empowered to carry out import controls as planned.
- > Reviews and iterations over time of the imported food control programme.
- > Content of the delegation or MoU s between CAs involved in border controls.

SOURCES OF EVIDENCE

- > Imported food control programme (with possible annual revisions).
- > Annual reports.
- > Staff interviews.
- > MoUs or similar delegation agreements.

B.1.2.5

ASSESSMENT CRITERION: Detailed procedures are in place for border controls, are available to all staff of BIPs and are implemented.

GUIDANCE

Within the overall programme for import controls that should be risk-based, staff should not be left without specific guidance about how to operate and make decisions within their authority. Standard operating procedures should be developed to support staff (Ref. para 70 of [CAC/GL 82-2013](#) and para 14 and 27 of [CAC/GL 47-2003](#)) through critical processes such as:

- i. Document review and certification validation;
- ii. Decision to inspect or not inspect a consignment;
- iii. Processes for consignment inspection;

- iv. Decision to release (or not release) a consignment;
- v. Implementation of specific sampling programmes;
- vi. Detailed consignment sampling guidance;
- vii. Guidance in case of non-conformity (including different options such as bringing product into conformity, disposal, re-processing, diversion to another use, return to supplier, re-export, etc.).

If the authorities operating food importation inspections do not operate according to the same standards, rules and procedures at all BIPs, traders soon discover which BIPs are the easiest to traverse with food consignments that are of lesser quality or of greater food safety risk. Some BIPs might be dedicated to high-risk foods; in these cases complex procedures, requiring specific training or equipment are necessary for the clearance of consignments of such foods.

In addition, staff should have knowledge of the IHR ports of entry core capacity requirements (WHO, 2005).

POSSIBLE OUTCOME

Controls are performed in a harmonized manner at all BIPs and are coherent among CAs.

POSSIBLE INDICATORS

- > Evidence of procedures being physically available at BIPs:
 - i. Document review and certification validation;
 - ii. Decision to inspect or not inspect a consignment;
 - iii. Processes for consignment inspection;
 - iv. Decision to release (or not release) a consignment;
 - v. Implementation of specific sampling programmes;
 - vi. Detailed consignment sampling guidance;
 - vii. Guidance in case of non-conformity (disposal, re-processing, etc.).
- > Evidence showing action taken according to the guidance.

SOURCES OF EVIDENCE

- > Documented procedures.
- > Visual observation of course of action by inspectors.

B.1.2.6



ASSESSMENT CRITERION: A system allowing notification (and/or pre-notification) for imported food consignments is in place and is supported by clear documentation requirements to be submitted by importers.

GUIDANCE

CAs need to receive specific information about the imported food consignment in a timely manner in order to decide how to proceed, according to the established procedures for the specific type of food and its origin (Ref. para 21 of CAC/GL 47-2003). This is accomplished through:

- > **Pre-notification** = information on imported food being provided to the CA prior to the food arriving in the importing country; and/or
- > **Notification** = information on imported food being provided to the CA as the food arrives in the importing country or within 48 hours of its arrival.

(Pre-)Notifications could be supported by a standard form that identifies the nature of the consignment (what kind of food), the consignor and consignee, the intended destination of the food product, the inspection status of the food in question, and all other information that the CA requires. This needs to correspond to established requirements, such as the types of certificates that should accompany the consignments, including for non-food safety specific issues (e.g. animal health or plant health certificates).

Importers need to know what type of information they should provide without any ambiguity and inspectors should in turn not be “chasing” missing information, nor take into consideration other information (e.g. other types of certificates) in addition to, or in lieu of, the ones that are required.

A system must be in place to channel the information on (upcoming) consignments to the relevant CA(s) in appropriate timelines to allow a relevant course of action in coordination with other CAs or institutions (e.g. customs).

- > Pre-notification is preferable where individual food shipments are assessed to identify high-risk lots that might be the subject of inspection, and to recommend refusal for unacceptable shipment. This allows CAs to review documentation submitted in advance, and, if necessary, to plan and prepare for sampling, quarantine and/or any other strategic official controls that may be deemed essential.
- > Notification, on arrival or within 48 hours of arrival, is suitable for low-risk products and when a product is detained for inspection at the importer’s storage facility.⁶

⁶ For more detailed guidance see also: FAO (2016), Section 2

POSSIBLE OUTCOME

Decision-making on relevant control measures on consignments is based on appropriate and timely information.

POSSIBLE INDICATORS

- > Every consignment of imported food is formally pre-notified or notified.
- > CAs can demonstrate that the system is being implemented (with evidence of timely (pre)notifications).
- > Importers are informed on/have access to the type of information they should provide for importing.
- > There is a set of established documentation requirements (e.g. types of certificates that should accompany the consignments).
- > No serious issues have been raised by recent importers of food.

SOURCES OF EVIDENCE

- > Notifications/pre-notifications.
- > Standard format form for (pre)notification, that identifies:
 - i. Nature of the consignment (type of food);
 - ii. Consignor and consignee;
 - iii. Intended destination of the food product;
 - iv. Inspection status of the food in question.
- > Written documentation/information requirements.
- > Point of view of recent/new importers (a limited questionnaire could be arranged).

B.1.2.7

ASSESSMENT CRITERION: A system for the import of products requiring particular attention is in place, supported by clear documentation requirements.

**GUIDANCE**

Some food products need particular attention, either: (i) because of their level of risk; or (ii) because they are highly perishable and cannot tolerate delays in treatment of the information at the border. In these cases, it is essential to have a system in place that allows CAs to receive advanced information and documentation and that mandates them to react promptly (e.g. prior to the lot being shipped) (Ref. para 16 of CAC/GL 47-2003).

An example of such a system is the “pre-clearance” approach, which 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. (Ref. para 19 and 20 of CAC/GL 47-2003).

It should be noted that laboratory results outside of a pre-established process should not be used as part of the decision process as it is impossible to validate that information.⁷

POSSIBLE OUTCOME

Decision-making on relevant control measures for consignments is based on appropriate and timely information.

POSSIBLE INDICATORS

- > Pre-clearance system in place.
- > Evidence that the system is being used and is functional.
- > Set of established documentation/information requirements.

SOURCES OF EVIDENCE

- > Documented pre-clearance requests.
- > Written documentation/information requirements.
- > Point of view of recent/new importers (a limited questionnaire could be arranged).

B.1.2.8



ASSESSMENT CRITERION: Sufficient inspection facilities are available to inspection staff, of appropriate design, layout and capacity, in the relevant sites.

GUIDANCE

When food (or a consignment that is potentially food) is imported, the good must generally be inspected at some level, whether through documentary check, visual check, or sampling for laboratory analysis. This means that inspectors must have access to the commodities and facilities to inspect food goods (Ref. para 38 of CAC/GL 26-1997). In some cases, inspectors may need to physically detain consignments, either for inspection reasons or for enforcement reasons. Facilities have to be made

⁷ For more detailed guidance see also: FAO (2016), Section 2

available to examine consignments, to take samples and to physically detain certain consignments. Some specific products, such as high-risk products (that warrant specific physical inspection or sampling procedures) or perishable products, require specific facilities (cold chain, temperature-controlled inspection room) and equipment. For strategic reasons, if some foods require specific sampling facilities that cannot be available at all BIPs, a system of dedicated BIPs may be put in place and communicated to the importers. Facilities for safe disposal of non-compliant food should also be available⁸ (Ref. para 22 in the Appendix of *CAC/GL 47-2003*).

POSSIBLE OUTCOME

Appropriate inspection facilities allow proper inspection of food consignments.

POSSIBLE INDICATORS

- > Facilities are available to:
 - i. Examine consignments;
 - ii. Take samples;
 - iii. Physically detain certain consignments.
- > A system of dedicated BIPs that have specific sampling facilities (i.e. for high-risk food products and perishable products) is in place and has been communicated to the importer community.
- > Facilities are available for safe disposal of non-compliant food.

SOURCES OF EVIDENCE

- > List of inspection facilities.
- > Observations from assessors.

SEE ALSO

- A.2.1.6** [The financial resources required to purchase, renew and maintain essential infrastructure and equipment (office, logistic, transportation, IT, etc.) are financially secured in CAs' budgets]
- A.2.1.7** [Funding for the sampling activities related to monitoring of priority food safety risks, as well as human health surveillance relevant to FBDs, is financially secured in the CAs' budgets]
- A.2.2.1** [Food control services are provided with suitable accommodation and with special facilities at all locations where official food control work is carried out]
- A.2.2.4** [Staff operating inspection, monitoring and surveillance activities have access to reliable modern technologies for rapid communication in central and local offices]
- A.2.2.5** [Suitable sampling equipment, space and facilities (such as temperature-controlled storage and infrastructure for transportation of samples to laboratories), are provided for monitoring or surveillance activities]

⁸ For more detailed guidance see also: FAO (2016), Section 4

B.1.2.9



ASSESSMENT CRITERION: The collaborations that occur between CAs and other institutions at the BIPs are effective and border controls are linked to domestic food control.

GUIDANCE

Importation of food requires that checks of different types be conducted by different government authorities. In addition to food safety and quality controls, the Customs Authority usually charges duty tax on goods that will be imported and sold. Security checks are also necessary, because items being imported for illegal purposes could be hidden inside any consignment, including food. Inspections of food products also commonly include checks for other purposes such as plant and animal health. These checks might be performed by CAs that also have a mandate on food safety – or not. Regarding controls over food products, when several CAs are called to inspect and check the imported consignments, the institutional framework should allow an efficient degree of integration and coordination (Ref. para 6 of CAC/GL 47-2003 and para 19 of CAC/GL 26-1997). To do this efficiently and effectively, formal agreements and MoUs are useful tools to ensure different CAs and other partner authorities know their responsibilities and the procedures required. The implementation of these agreements should be monitored and periodically reviewed (Ref. para 54 of CAC/GL 26-1997).

It is also very important that import controls be well connected to the domestic control system through early warning functions and traceability to ensure, for example, removal from the domestic market of unsafe imported products that would have been cleared for distribution. In other instances, where the risk-based planning indicates that the product is low-risk, countries might opt for a “light regime” of border checks (e.g. documentation checks only), while including the product in the scope of monitoring plans for food products available at domestic level, or programmes of inspection at retail level. In this case, communication and coordination between CAs in charge of import controls and CAs in charge of domestic controls must ensure that there is mutual awareness of choices made and that these complementarities are well reflected in each CAs programme of work.⁹ It is also very important that information collected or generated by the different CAs is communicated and used by all in a feedback loop to improve programme targeting, allow adjustments and modify control strategies (e.g. a product initially identified as low-risk and integrated into domestic market monitoring strategies might requalify as mid-risk and need to be addressed with a different approach – for example, border controls).

⁹ For more detailed guidance see also: FAO (2016), Section 2

POSSIBLE OUTCOME

The combined output of the CAs and other institutions collaborating at BIPs effectively supports the needs of official food controls.

POSSIBLE INDICATORS

- > Clear understanding and official collaborations between the partner authorities and CAs are established, implemented and periodically reviewed.
- > There is evidence of connection of import control to the domestic control system through:
 - i. Early warning functions;
 - ii. Traceability systems;
 - iii. Inclusion of low-risk imported products into the domestic monitoring activities or inspection programme at retail;
 - iv. Communication, coordination and mutual awareness of choices between CAs in charge of import controls and CAs in charge of domestic controls.
- > Little or no complaints about lack of efficiency between authorities at BIPs.

SOURCES OF EVIDENCE

- > Records of formal agreements between relevant authorities (e.g. food safety and quality controls, Customs Authority, security checks).
- > Formal reports by the authorities responsible for food checks and inspections at importation of commercial consignments of food.
- > Any register of complaints from commercial importers.

SEE ALSO

- A.1.2.2** [A formal communication mechanism is in place between CAs and other stakeholders involved in food control, to exchange relevant information over the entire food chain, from primary production to human health]
- A.1.2.3** [Legislation includes coordination mechanisms that enable CAs to develop a common vision of food control, to facilitate multi-sectoral planning and implementation of food control measures, and to promote communication]

B.1.3**EXPORT CONTROLS****OVERALL OUTCOME**

The export control system enables meeting the requirements of export foreign markets.

B.1.3.1

ASSESSMENT CRITERION: A coordinating mechanism is set up for cases where more than one CA has authority to control and provide certification to FBOs wishing to export, and where other stakeholders are involved.

GUIDANCE

When multiple CAs are involved in providing certification services, multiple or redundant certificates might be issued as a result of this situation. To streamline this process and improve efficiency and effectiveness, a single certificate could be issued, covering multiple attestations by the recognized authorities (i.e. a certificate including attestations on plant health and food safety, or animal health and food safety) (Ref. para 8, point G, 29 and 31 of [CAC/GL 38-2001](#)). Another solution is that a single authority issues the certificate on the basis of the information received from other official bodies. This mechanism could also facilitate contacts with CAs from importing countries for a better understanding of specific requirements for exports. In addition, to establish official certificates, CAs must sometimes rely on provision of information by other stakeholders, such as laboratories for analytical results, or other certification bodies. It is important that a mechanism allows access to services or information in a timely manner, where and when needed (Ref. para 39 of [CAC/GL 26-1997](#)). This also means that these services are available at major points. Exports should not be impaired by a delayed certification service (Ref. para 19 of [CAC/GL 26-1997](#)).

POSSIBLE OUTCOME

Government stakeholders involved in export controls and certification are providing an efficient and effective service to exporters.

POSSIBLE INDICATORS

- > Existence of a single certificate with multiple attestations for exporters (e.g. plant health and food safety, or animal health and food safety).
- > Availability of certification services at major points (e.g. laboratories for analytical results or other certification bodies).

- > Coordination among certification bodies and other relevant stakeholders (e.g. laboratories).
- > Communication with CAs from importing countries.
- > Satisfaction from trading partners that their certification requests are being met.
- > Records of rejection due to inadequate certification.

SOURCES OF EVIDENCE

- > Single certificate format/template (covering multiple attestations by the recognized authorities).
- > Records of communication among certification bodies and other relevant stakeholders (e.g. laboratories).
- > Interviews with trading partners.

B.1.3.2

ASSESSMENT CRITERION: CAs have the capacity to support the requirements of importing countries.

**GUIDANCE**

Foreign trading partners importing commodities will have varying sets of requirements, including when equivalence or mutual agreements are in place. This can involve, for example:

- i. Specific licensing (see **B.1.3.3**) and control of premises for export, implemented by the CAs of the exporting country and subject to periodic reviews by the importing trading partner.
- ii. Implementation of specific monitoring plans by the CAs of the exporting country, whose results should be shared with the importing trading partner (such as monitoring of production environmental conditions or other specific hazard/commodity pairs monitoring programmes).

In more general terms, this would cover verification by the authorities of the exporting country, or visitation, inspection and verification by authorities of the importing country. Importing countries may make their own inspections and verification or may rely upon verification by the national food control authority. Importing countries may be monitoring food importations by means of laboratory analysis.

Trade agreements for exportation may depend upon the capacity to demonstrate that sufficient CA oversight is in place on specific hazard/commodity pairs, or on specific contaminants, or on general conditions of production (including, for example, on environmental contamination in specific value chains, like aquaculture). In particular, this can happen through provision of consolidated and transparent results and by using, for example, specific monitoring plans.

POSSIBLE OUTCOME

Importers are confident that FBOs authorized for export are meeting their requirements.

POSSIBLE INDICATORS

- > CAs implement specific monitoring programmes for export commodities.
- > Sufficient CA oversight is in place on specific hazard/commodity pairs, or on specific contaminants, or on general conditions of production.
- > There is exchange of information and provision of data on effectiveness of controls with foreign CAs (also measured through monitoring programmes).
- > Equivalence agreements are in place.
- > There is actual investment in capacity for equivalence or for implementing alternative food control measures that can be agreed with trade partners or potential trade partners.
- > Importing countries have rising confidence in the official food controls of the exporting country.

SOURCES OF EVIDENCE

- > Mutual agreements on equivalence of food control methods.
- > Trade agreements.
- > Records of exchanged information and provision of data.

SEE ALSO

C.2.1.1 [The CAs support the development of bilateral or regional trading relationships with an open and pro-active communication approach on food safety and quality regulations, as well as on control measures and documentation requirements]

B.1.3.3

ASSESSMENT CRITERION: A specific authorization or licensing scheme is in place for specific FBOs targeting exports.

GUIDANCE

Specific foods may be required to be produced in establishments specifically authorized or licensed for exports by the CA(s). This will entail a functional inspectorate fully qualified on specific requirements for exports. The exporting country may decide to adopt this type of measure independently of the specific request by the foreign importing countries – for example, for commodities that present a higher risk or that are strategic for exports.

POSSIBLE OUTCOME

Food for export is produced in conditions that allow for meeting export requirements.

POSSIBLE INDICATORS

- > The country can support the process and typical requirements of importing countries in terms of verification (or re-verification) of food standards at premises seeking (or re-seeking) export approval. (Examples of the process will need to be presented and checked).
- > An inspectorate is present that is fully qualified on specific requirements for exports.

SOURCES OF EVIDENCE

- > Licences/authorizations of establishments authorized for export.
- > Interviews with importing country authorities. (Are they content with the framework for the procedure?).

B.1.3.4

ASSESSMENT CRITERION: Certificates respond to required design features as indicated by importing countries and are issued by officers authorized by the CAs (qualified and fully trained).

**GUIDANCE**

Certificates should:

- i. Refer unambiguously to the certifying body and other parties involved in providing specific attestations. In this case, they should be constructed such that each part of the certificate clearly refers to that party (laboratory, producing establishment, certifying body, other authority) (Ref. para 22 of CAC/GL 38-2001).
- ii. Clearly describe the commodity and consignment it refers to, indicating:
 - > Name of food (using world custom organization when appropriate).
 - > Name of product (refer to Codex standards if available).
 - > Quantity in appropriate units.
 - > Description of the commodity and consignment (lot identifier, means of transport, date coding or security seal coding).
 - > Identity, name and address of producer and/or storage establishment and their approval number.
 - > Name and contact details of exporter and importers.
 - > Country of dispatch (or parts thereof, where these relate to specific attestations – e.g. animal or plant health).
 - > Country of destination. (Ref. para 23 of CAC/GL 38-2001).

- iii. Clearly refer to those official requirements for which the certificate is issued.
- iv. Contain all the necessary attestations so that there is no need to re-endorse or re-attest the certificate at a later stage (Ref. para 8, point G, and 29 of CAC/GL 38-2001).
- v. Be in a language understood by the certifying officer, in transit countries and by the receiving country. When necessary, official translations can accompany the certificate.

Certificates should only be issued by officers who are specifically designated for that (Ref. para 25 of CAC/GL 38-2001). These officers should have no commercial conflict of interest vis-à-vis the consignment for which they are providing certification. They should also be conversant with the requirements of the importing country (required standards, whether on product or process) and have access to all necessary information – for example, the requirements, information or guidance notes produced by the CAs explaining the criteria that the product must meet before being certified. They should only attest matters that are within their own knowledge, or that have been separately attested by another competent authority. Finally, they should only certify to circumstances that can be verified directly by documentation provided between the dates of production and of issuance of certificate (Ref. para 28 of CAC/GL 38-2001 and para 43, 47 and 48 of CAC/GL 26-1997).

An example of a generic model of an official certificate can be found in the Annex of CAC/GL 38-2001.

POSSIBLE OUTCOME

Certificates facilitate the clearance process while providing the required assurances.

POSSIBLE INDICATORS

- > Examples of certificates used that:
 - i. Refer unambiguously to the certifying body and other parties involved in providing specific attestations.
 - ii. Clearly describe:
 - Commodity and consignment referred to, indicating name of food (*using world custom organization when appropriate*).
 - Name of product (*referring to Codex standard if available*).
 - Quantity in appropriate units.
 - Commodity and consignment details (*lot identifier, means of transport, date coding or security seal coding*).
 - Identity, name and address of producer and/or storage establishment and their approval number.
 - Name and contact details of exporter and importers.
 - Country of dispatch and country of destination.

- iii. Contain all the necessary attestations so that there is no need to re-endorse or re-attest the certificate at a later stage.
 - iv. Are in a language understood by the certifying officer, in transit countries and receiving country.
- > Process for designation of certifying officers.
 - > Certifying officers having access to all necessary documentation/information (e.g. importing country requirements, information or guidance notes on the criteria that the product must meet before being certified).

SOURCES OF EVIDENCE

- > Copies of certificates.
- > List of certifying officers in CAs.
- > Documentation/guidance relating to certification requirements/criteria.

SEE ALSO

C.2.1.1 [The CAs support the development of bilateral or regional trading relationships with an open and pro-active communication approach on food safety and quality regulations, as well as on control measures and documentation requirements]

B.1.3.5

ASSESSMENT CRITERION: CAs have a system in place to identify and prevent fraudulent certificates and provide clear guidance in case of specific situations related to certification.

**GUIDANCE**

The integrity of an export system, and the credibility of the CAs themselves, depend upon a reliable and secure system of certification. The general principles of certification should be adhered to. Each issued blank certificate should be given a unique ID number and its issuance details recorded permanently. Each issued certificate should be reconciled periodically. Certificates could use specific security features (watermarked paper in the case of paper certificates, or secure lines and systems for electronic certificates) (Ref. para 22, 2nd point, of CAC/GL 38-2001). Copies of official stamps and marks should be provided to the importing country authorities, to complement the maintenance of a record of certificates provided. When certificates have been lost or damaged, when they contain errors, or when the original information is no longer correct, replacement certificates may be issued. They must be clearly marked to indicate that they are replacing the original certificate, indicating its number. The original certificate should be cancelled and returned to the issuing authority (Ref. para 42 of CAC/GL 38-2001).

Certificates may also be revoked. This should be done as soon as possible and the exporter should be informed accordingly. The number of the original certificate should be referenced and details should be provided with regard to the reason for the revocation. The importing country should be informed if the product has already been exported and the original certificate should be returned to the issuing authority (Ref. para 43 of CAC/GL 38-2001). If certificates are found to be invalid because they contain incorrect or incomplete information or attestations, the CA responsible for certification in the exporting country and the authorities in the importing country should communicate in a timely fashion and either issue a replacement certificate or revoke the certificate (Ref. para 44 of CAC/GL 38-2001).

When there are suspicions of fraud, an investigation should be quickly launched and there should be full cooperation with authorities of the importing country to identify those responsible and take appropriate legal action (Ref. para 50, 2nd point, and para 81 of CAC/GL 82-2013 and para 8, point H, 45 and 46 of CAC/GL 38-2001).

POSSIBLE OUTCOME

Certificates provided do not lend themselves to fraud.

POSSIBLE INDICATORS

- > Certificates use specific security features (e.g. watermarked paper for paper certificates, or secure lines and systems for electronic certificates).
- > Investigations are quickly launched when there are suspicions of fraud and there is full cooperation with authorities of the importing country.
- > Replacement certificates are clearly marked to indicate that they are replacing the original certificate, indicating its number (and the original certificates are returned to the issuing authority).
- > CAs responsible for certification in the exporting country and CAs in the importing country communicate in timely fashion if certificates are found to be invalid and should be replaced or revoked.
- > Examples exist of practices related to replacement or revoked certificates.

SOURCES OF EVIDENCE

- > Copies of replacement certificates.
- > Documentation pertaining to past investigations regarding fraud.
- > Records of communication among CAs responsible for certification in the exporting country and CAs in the importing country.



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B.2

MONITORING, SURVEILLANCE & RESPONSE FUNCTIONS

COMPETENCY B.2.1 MONITORING PROGRAMMES IN RELATION TO THE FOOD CHAIN

OVERALL OUTCOME	The national monitoring programme informs CAs on the situation for specific food safety or quality issues, supports trends analysis and risk assessment and contributes to improve targeting of interventions with a risk-based approach.
B.2.1.1	A monitoring plan is in place to detect and/or monitor issues related to food safety or quality in the food chain.
B.2.1.2	The risk ranking processes drive the development of the national food safety and quality monitoring programme.
B.2.1.3	All relevant CAs have collaborated to facilitate the planning, ongoing implementation, operation and analysis of the national monitoring programme.
B.2.1.4	The national monitoring programme is informed by an FBO risk categorization framework.
B.2.1.5	The national monitoring programme takes into consideration available human, financial and analytical resources.
B.2.1.6	The outputs of the national monitoring programme are used to review/inform food control policies and strategies and to propose suitable interventions/measures.
B.2.1.7	A mechanism to rapidly inform the other CAs responsible for FBD surveillance and response is in place when a monitoring plan detects a potential risk to human health in the food chain.

COMPETENCY B.2.2 FOOD-BORNE DISEASE SURVEILLANCE

OVERALL OUTCOME	The national surveillance system ensures an effective detection of FBD and contributes to the management of food safety events, including outbreaks and emergencies.
B.2.2.1	There is a fully functional Indicator-Based Surveillance (IBS) system in place that can successfully monitor trends and detect FBD outbreaks.
B.2.2.2	There is a fully functional Event-Based Surveillance (EBS) system in place that is capable of detecting food-borne events.
B.2.2.3	There is an IBS system that includes laboratory analysis to assign aetiology for suspected FBDs (particularly diarrhoeal disease), investigate hazards in foods linked to cases and outbreaks, understand trends in FBD and increase the sensitivity and specificity of outbreak detection.
B.2.2.4	Capacity to undertake rapid risk assessments of acute public health events exists at the national and subnational levels.
B.2.2.5	Capacity for multidisciplinary and inter-sectoral subnational outbreak response exists and analytical epidemiology is being applied during outbreak investigations.
B.2.2.6	Multi-sectoral collaboration facilitates rapid information exchange and support with laboratory testing during FBD outbreak investigation.

COMPETENCY B.2.3 MANAGEMENT OF FOOD SAFETY EMERGENCIES

OVERALL OUTCOME	A coordinated management system scans, identifies and responds to food safety emergencies and communicates effectively with all stakeholders (national, international).
B.2.3.1	A suitable national food safety emergency plan has been developed in a participatory way and food safety emergencies have been defined to serve as a trigger for escalating appropriate response.
B.2.3.2	Mechanisms to gather and analyse information are in place to allow incident identification.
B.2.3.3	A functional central coordination mechanism includes all relevant CAs to address food safety emergencies.
B.2.3.4	Functional arrangements are in place for communication and implementation of response in the event of a food safety emergency.
B.2.3.5	Strategies and guidance for communicating with partners, stakeholders, general public and international organizations are in place.
B.2.3.6	Food safety emergency response plans are pre-tested and reviewed after an emergency has occurred.
B.2.3.7	When appropriate, the risk analysis framework is used to structure the response to food safety emergencies.

B.2.1**MONITORING PROGRAMMES IN RELATION TO
THE FOOD CHAIN****OVERALL OUTCOME**

The national monitoring programme informs CAs on the situation for specific food safety or quality issues, supports trends analysis and risk assessment and contributes to improve targeting of interventions with a risk-based approach.

B.2.1.1

ASSESSMENT CRITERION: A monitoring plan is in place to detect and/or monitor issues related to food safety or quality in the food chain.

GUIDANCE

At least one monitoring plan covering the relevant portions of the national territory for a given hazard or fraud issue has been designed, is implemented and generates periodic reports. This may focus, for example, on a specific hazard/commodity pair, or a given hazard common to a group of food products, or a specific fraud issue related to a product or a group of products and/or environmental production conditions for a given commodity/group of products. The monitoring programme may be based on a set of qualitative and quantitative considerations and evidence stemming from, for example, routine inspection programmes (Ref. para 51 of CAC/GL 82-2013). If the plan is well implemented, it could contribute to the creation of a database to allow progressive movement towards a risk-based approach and/or to detect emerging risks or fraudulent behaviours, leading to the revision of the control system or the plan in force.

Note 1: For the purpose of this assessment criterion, it is acceptable that the decision-making process leading to the definition of the monitoring plan is not necessarily risk-based from a national perspective (e.g. it may be to satisfy the requirements of an export market). It should, however, have relevance at national level (where relevant to the specific hazard/commodity combination) and involve different CAs, if relevant.

Note 2: AC B.2.1.1 and B.2.1.2 are both exploring the existence of monitoring programmes, while B.2.1.3, B.2.1.4 and B.2.1.5 describe their conception in a more comprehensive manner.

POSSIBLE OUTCOME

For one or more food safety or quality issues, a national situation can be characterized and trends can be analysed.

POSSIBLE INDICATORS

- > Existence of a (simple and limited) documented monitoring programme.

SOURCES OF EVIDENCE

- > Records of implementation of the monitoring programme.
- > Documentation, datasets, rationale used to decide on existence and structure of the programme.

B.2.1.2

ASSESSMENT CRITERION: The risk ranking processes drive the development of the national food safety and quality monitoring programme.

**GUIDANCE**

The majority of food safety hazards should be contained by food safety management systems implemented by FBOs, and overseen by routine inspection and controls performed by CAs. However, some hazard/commodity pairs might present a higher risk and deserve to be monitored as a matter of priority by designing specific data collection programmes. This priority setting process should relate to the risk analysis processes being implemented at central level by the food control system. The risks to be analysed would be chemical (including, for example, environmental contamination) and biological. Information stemming from FBD epidemiological situation analyses should also be taken into account in this priority setting process. In other cases, intelligence from various sources can also drive the set-up of programmes aimed at detecting and measuring trends related to specific frauds; these can have an impact on the safety or key quality features of food products (e.g. fraud in relation to food fortification programmes).

These control programmes could target both processes and products. A decision will need to be made as to whether to focus the monitoring resources onto specifically selected food safety hazard(s) or quality features at selected stages of the food chain, or to focus on food types.

Based on the appropriate selection of risks to be monitored, it should be decided if such monitoring plans should be aimed at, for example:

- > **Assessing the prevalence of a contaminant in a given population** (i.e. a food product or a family of food products), thereby supporting the assessment of consumers' exposure to the hazard. In that case, sampling is done on a

representative basis, and is unbiased and random. Total Diet studies are an example of comprehensive large-scale chemical monitoring programmes. These programmes would eventually help to identify possible risk management measures.

- > **Specifically detecting non-compliance.** In this case, sampling would be targeted according to specific criteria (for example, on a certain type of food identified as likely to present a higher level of risk). These plans help increase the capacity to detect and manage non-conformities, and are a risk management tool. They support the assessment of effectiveness of risk management measures.

A number of well-targeted monitoring plans would contribute to the national monitoring programme.

Note: With regard to B.2.1.1, this AC, B.2.1.2, is fully risk-based and has specific national relevance.

POSSIBLE OUTCOME

The monitoring programme has a risk-based rationale.

POSSIBLE INDICATORS

- > The monitoring programme is anchored in a risk-based rationale (priorities are set based on risk level).
- > Hazard/commodity pairs are identified that might present higher risk.
- > Information stemming from FBD epidemiological situation analyses are taken into account.

SOURCES OF EVIDENCE

- > Documentary evidence of the risk analysis processes for the identification of risks.
- > Records of chemical and biological risks analysed.
- > Documentary evidence of the risk priority setting process and selection of risks to be monitored.

SEE ALSO

- B.2.2** [Food-borne disease surveillance]
- C.1.2.3** [High-risk FBOs are provided with special communication channels ensuring that CAs' messages are delivered to FBOs]
- C.1.2.5** [CAs inform FBOs on the results of monitoring and routine inspection reports to incentivize positive collaboration with government and enhance compliance]
- D.1.2.5** [A surveillance system is in place that integrates information from the entire food chain to enable a better understanding of risk]
- D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]
- D.1.3.3** [When necessary, CAs use risk profiles to guide and inform the deployment of resources into official controls]
- D.1.3.4** [CAs have collaborated to produce a risk categorization framework of FBOs]

B.2.1.3

ASSESSMENT CRITERION: All relevant CAs have collaborated to facilitate the planning, ongoing implementation, operation and analysis of the national monitoring programme.

**GUIDANCE**

All involved CAs (at central and deconcentrated/decentralized level) and other relevant stakeholders (analytical services, FBOs' representatives if appropriate, etc.) should be brought together so that the national monitoring programme, which may be composed of a number of specific plans, is implemented in a coordinated, collaborative and efficient manner in order to achieve the necessary outputs and outcomes. The coordination among CAs should be within the “farm to fork” approach of the risk under consideration and should identify the most appropriate steps of the chain for sampling (according to the risk management measure under verification or investigation).

POSSIBLE OUTCOME

The national monitoring programme is operational.

POSSIBLE INDICATORS

- > CAs working together on the implementation of the monitoring programme.
- > Evidence of communication among CAs and relevant stakeholders.
- > Programme operating as planned, in a coordinated way.
- > Evidence of coordination in the implementation of the monitoring plans or programme.
- > Identification of the most appropriate steps of the chain for sampling.

SOURCES OF EVIDENCE

- > Records of communication/collaboration among CAs and relevant stakeholders (e.g. analytical services).
- > Documented identification of the most appropriate steps of the chain for sampling.
- > Interviews with CAs, analytical services.

SEE ALSO

- C.2.1.1** [The CAs support the development of bilateral or regional trading relationships with an open and pro-active communication approach on food safety and quality regulations, as well as on control measures and documentation requirements]

B.2.1.4**ASSESSMENT CRITERION: The national monitoring programme is informed by an FBO risk categorization framework.****GUIDANCE**

A well-developed FBO risk categorization framework (see **D.1.3.4**) can contribute to refining the conception of a national monitoring programme, through specific monitoring plans. Ranking FBOs using a risk-based logic would inform identification and targeting of those premises that should be included in the sampling protocol, in particular for monitoring plans aiming at specifically detecting non-compliance (non-random sampling).

In cases where a well-developed FBO risk categorization framework is not available, specific criteria could be taken into account to inform planning of the monitoring plans, such as:

- i. Product characteristics (some products are more prone to specific contaminations than others; some are consumed directly without possibility to mitigate the risk, etc.).
- ii. Control characteristics (which could in turn be internal controls for FBOs when considering domestically produced commodities and official controls for imported goods).
- iii. FBO history.
- iv. Other appropriate characteristics depending on context.

These criteria should be used to qualify the FBOs and decide on their inclusion in the sampling protocol. The plan should indicate how many samples of which type will be taken from target premises, also considering staff time.

POSSIBLE OUTCOME

Premises and products are identified and prioritized for sampling.

POSSIBLE INDICATORS

- > Criteria for risk categorization are developed and available for consultation (e.g. product characteristics, control characteristics, firm history).
- > A clear list of premises for sampling has been derived and confirmed.
- > The selection is risk-based and rational.
- > The monitoring plan indicates how many samples of which type will be taken from target premises.

SOURCES OF EVIDENCE

- > Record of criteria for risk categorization.
- > List of premises for sampling.
- > Results from the sampling plan.

SEE ALSO

D.1.3.2 [CAs use risk ranking approaches to target resources for risk management]

D.1.3.4 [CAs have collaborated to produce a risk categorization framework of FBOs]

B.2.1.5

ASSESSMENT CRITERION: The national monitoring programme takes into consideration available human, financial and analytical resources.



GUIDANCE

The implementation of a basic national sampling protocol for monitoring purposes will require significant resources, which will have to be sourced and made available. Necessary resources include sufficient physical infrastructure, equipment and consumables, and human resources for the appropriate operation of the laboratory component.

For planning purposes, it is necessary to:

- i. Review current availability of laboratory capacity and balance it against numbers and samples that need to be processed, while considering timing (including seasonality), types of tests requested and logistical constraints.
- ii. Calculate how much staff time is available for sampling activities. Total staff time must be distributed against all of the endorsed staff activities. If greater time for sampling will be required, the requirement must be created to either acquire more staff or alter the ratio of allocation.

Below is an example of how to calculate available staff time. Note that each CA needs to use figures appropriate to its administration.

EXAMPLE ONLY		
STAFF NUMBERS	STAFF HOURS X STAFF WEEKS	TOTAL STAFF HOURS
200 full-time food safety inspection staff	40 hours per week x 45 weeks per annum	$200 \times 45 \times 40 = 360\,000$ hours p.a.
Activity	Allocation % of total staff time available	Calculation (hours p.a.)
(all) Inspection	55%	$360\,000 \times 0.55 = 198\,000$
(all) Administration and reporting	25%	$360\,000 \times 0.25 = 90\,000$
(all) Travelling to sites	10%	$360\,000 \times 0.10 = 36\,000$
(all) (Other activities)	5%	$360\,000 \times 0.05 = 18\,000$
(all) Sampling	5%	$360\,000 \times 0.05 = 18\,000$
18 000 officer-hours are available for (all) sampling activities on food production sites, including submission of samples.		

The purpose is to ensure that the national monitoring programme is implementable, considering other planned work outputs and the resources available.

POSSIBLE OUTCOME

The implementation of the national monitoring programme is not hampered by lack of resources.

POSSIBLE INDICATORS

- > Laboratory capacity has been reviewed and balanced against numbers and samples needing to be processed.
- > The CA has made a calculation of the inspectors' time that can be dedicated to sampling for monitoring purposes.
- > The actual time available is sufficient and realistic to implement the proposed monitoring policy.
- > Analytical results are provided, as requested in the plan.
- > Laboratory capacity is not given as a reason for which the sampling plan has failed to deliver its intended outputs.

SOURCES OF EVIDENCE

- > Documentary evidence on the assessment of:
 - i. Laboratory capacity (taking into consideration types of tests requested and logistical constraints).
 - ii. Availability of staff time for sampling activities.

SEE ALSO

- A.2.1.4** [The financial resources required to hire, pay and retain sufficient and skilled staff are secured and accounted for in financial planning and budgeting]
- A.2.1.7** [Funding for the sampling activities related to monitoring of priority food safety risks, as well as human health surveillance relevant to FBDs, is financially secured in the CAs' budgets]
- A.2.2.5** [Suitable sampling equipment, space and facilities (such as temperature-controlled storage and infrastructure for transportation of samples to laboratories) are provided for monitoring or surveillance activities]
- A.2.3.1** [CAs and laboratories work jointly to plan the analytical workload for servicing routine inspections, sampling programmes for monitoring of priority food safety risks, FBD surveillance and other scientific related activities]
- A.2.3.2** [The laboratory capacities meet the country's strategic analytical needs with appropriate geographical coverage across the country, including for import and export]
- A.2.3.3** [The national system of laboratories has sufficient technical capabilities to address priority hazards and quality parameters for food analysis, and the analysis of clinical samples for detection of FBDs]
- B.1.1.14** [Authoritative and clear guidance on sampling techniques is available to inspectors and samples taken during inspections are appropriate]

B.2.1.6

ASSESSMENT CRITERION: The outputs of the national monitoring programme are used to review/inform food control policies and strategies and to propose suitable interventions/measures.

**GUIDANCE**

Results produced by the sampling protocols underpinning the national monitoring programme should be:

- i. Of scientific value (i.e. they generate knowledge). For example, they compare detected average levels of specific contaminants to maximum limits allowed; they improve understanding of consumers' exposure; etc.
- ii. Of sufficient quantity and appropriate quality to inform review of official food control policies and strategies (refine risk management strategy; establish new measures; refine criteria for subsequent sampling programmes; etc.) (Ref. para 83 of CAC/GL 82-2013). This should also lead to review of and/or proposed suitable measures (controls and/or other approaches such as specific training or communication programmes) aiming at reducing contamination levels.
- iii. Of sufficient quality to produce admissible evidence. While the primary aim of monitoring plans is not routine control of food products, in cases of important non-compliance, urgent action should be undertaken (i.e. the organization of recalls or withdrawals of products or other relevant control measures). Therefore, the results of the monitoring programme should also be appropriate for enforcement work.

Over time, a successful monitoring programme should support:

- i. An improved standardization of implementation practices among CAs, through successful coordination and joint planning work.
- ii. A better vision of performance of food controls across the food chain, through the analysis of data. Joint data management should be established for this purpose (Ref. para 50, 5th point, of CAC/GL 82-2013).
- iii. A review and update of sampling and inspection plans, as well as other measures.

POSSIBLE OUTCOME

Review of official food safety and quality policies and CAs' food control strategies is facilitated.

POSSIBLE INDICATORS

- > Data are produced by the sampling protocol that are:
 - i. Of scientific value.
 - ii. Appropriate for enforcement work (i.e. they produce admissible evidence).
 - iii. Of sufficient quantity and quality to inform review of official food control policy and strategy.
- > These data are analysed and used to inform/review food control policies and strategies.

SOURCES OF EVIDENCE

- > Sampling data.
- > Analysis of sampling data.
- > Documentation on conclusions of data analysis generated by monitoring.
- > Food control policies and strategies that incorporate the evidence from monitoring programmes.
- > Changes in sampling plans over time.

SEE ALSO

- D.1.2.6** [Data from routine inspection, monitoring and surveillance programmes are used to inform new or current risk analysis activities]
 - D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]
 - D.1.3.8** [Risk assessments and risk management measures are periodically re-assessed and updated as necessary]
-

B.2.1.7

ASSESSMENT CRITERION: A mechanism to rapidly inform the other CAs responsible for FBD surveillance and response is in place when a monitoring plan detects a potential risk to human health in the food chain.

**GUIDANCE**

A communication mechanism should be in place allowing CAs responsible for implementing specific food hazard monitoring plans to rapidly inform the CA responsible for surveillance of FBD as well as CAs responsible for response on the food chain, to ensure that information can be exchanged and necessary action can be taken. This can include, among other actions: contributing to the initiation or revision of a risk assessment; establishing long-term communication strategies with consumers if the monitoring programme reveals a particular risk for a specific category of consumers (e.g. in a given area of the country).

POSSIBLE OUTCOME

Public health activities are informed by information stemming from the food hazard monitoring programmes.

POSSIBLE INDICATORS

- > Existence of a communication mechanism with focal points designated.
- > Operational and logistical arrangements including ToRs, contact lists, addresses, email, etc.
- > Examples of actions taken by CAs integrating FBD information from monitoring plans.

SOURCES OF EVIDENCE

- > Records of such communications and actions.

B.2.2**FOOD-BORNE DISEASE SURVEILLANCE
(WHO, 2017)****OVERALL OUTCOME**

The national surveillance system ensures an effective detection of FBD and contributes to the management of food safety events, including outbreaks and emergencies.

B.2.2.1

ASSESSMENT CRITERION: There is a fully functional Indicator-Based Surveillance (IBS) system in place that can successfully monitor trends and detect food-borne disease (FBD) outbreaks.

GUIDANCE

IBS is the regular systematic collection, monitoring, analysis and interpretation of structured data related to a case or syndrome definition (WHO, 2014). Data about illness in individuals (either syndromes or laboratory results) are recorded systematically, analysed, interpreted and disseminated. Thresholds are often applied to the data to detect outbreaks and the data can be used to monitor trends and evaluate interventions. Almost all countries have a functioning IBS system and they range in complexity from basic syndromic surveillance systems to laboratory-based systems. To have an indicator-based surveillance system that can monitor trends in disease syndromes and identify outbreaks of FBDs, countries will need to have in place the following:

- i. A surveillance system for notifiable diseases that collects syndromic data from the local level, and collates and analyses them regularly at the national level (with an efficient reporting system from local to central level).
- ii. Inclusion in the surveillance system of diseases and syndromes that may indicate FBD (e.g. diarrhoea).
- iii. (A database to store the surveillance data.
- iv. Capacity to analyse surveillance data on a regular basis (e.g. every week or every two weeks) to monitor trends and detect outbreaks.
- v. Regular publication of surveillance bulletins, showing the trends in syndromic data that may indicate FBD.
- vi. A protocol that documents how the surveillance system will function.

Laboratories and health care workers should be provided with guidance about conditions that are notifiable and their case definitions, with clear instruction for reporting and specific notification forms to notify cases.

The notifiable disease surveillance system database should be accessible at any time and it should be easy to enter data and to extract data for analysis. It should include mechanisms and thresholds for detecting signals requiring action and it should record all of the information required under the minimum data requirements. For further guidance, refer to the WHO publications (WHO, 1999, 2006b).

POSSIBLE OUTCOME

All priority FBDs are under surveillance and action is taken based on the output from the IBS system.

POSSIBLE INDICATORS

- > Case definitions for each of the notifiable FBDs.
- > A clear mechanism for reporting (e.g. fax number, telephone notification, Web-based system).
- > Laboratories and health care workers who are aware of their obligations to report positive test results to the surveillance system.
- > The notifiable disease surveillance system database that is effective (accessible at any time, easy to enter and extract data for analysis, with mechanisms for detecting signals requiring action).

SOURCES OF EVIDENCE

- > Interviews with health care workers.
- > Written procedures.
- > Guidance on the conditions that are notifiable and their case definitions.
- > Notification forms.
- > The notifiable disease surveillance system database.

SEE ALSO

A.1.3.12 [Legislation includes provisions for surveillance of priority FBDs, guided by the food safety and quality policy]

B.2.2.2



ASSESSMENT CRITERION: There is a fully functional Event-Based Surveillance (EBS) system in place that is capable of detecting food-borne events.

GUIDANCE

The IHR expands usual infectious disease notification to include surveillance of public health events from various origins (e.g. nuclear, chemical or unknown), and prompts Member States to develop the capacities of their surveillance systems to detect, assess, notify and respond to all acute health events or health risks that may constitute a threat to human health. When it comes to the timely detection of outbreaks and important public health events, IBS systems often fail. Furthermore, such systems are not suited to the detection of rare but high-impact outbreaks (e.g. acute chemical intoxication) or emerging and unknown diseases. Therefore, countries have had to develop EBS systems that rely on the immediate reporting of events and are designed to detect:

- i. Events before human cases occur or before an event is detected and/or reported through conventional IBS;
- ii. Rare and new events that are not specifically included in IBS;
- iii. Events that occur in populations that do not access health care through formal channels.

EBS is defined as the organized collection, monitoring, assessment and interpretation of mainly unstructured ad hoc information regarding health events or risks, which may represent an acute risk to human health. Such information includes monitoring of absenteeism in schools or in workplaces, sales of medicine and paramedical products such as insect repellent, activities on Internet or social networks and information in newspapers, TV, radio and other public media, etc.

Many countries now have an EBS system in operation and strengthening the sensitivity of the system when it comes to food-borne events is a critical step towards effective FBD surveillance. Food-borne events are any events related to the occurrence of disease in humans caused by contaminated food or that have the potential to expose humans to known or suspected hazards through food. To have an EBS system capable of detecting food-borne events, countries will need to:

- i. Designate a national focal point to receive reports about events and develop an event report form to systematically capture information about an event;
- ii. Develop an event database to store information about reported events;
- iii. Ensure that health care workers and sanitary/food inspectors have been trained to report food-borne events to the EBS system.

For further guidance, refer to the WHO publications (WHO, 2008b, 2014).

POSSIBLE OUTCOME

Food-borne events that result from a range of food-borne hazards are detected by the EBS system and rapid action is taken to prevent cases in humans or to limit further spread.

POSSIBLE INDICATORS

- > Existence of an EBS surveillance system that receives reports from the local level which are collated within 24 hours at the national level for rapid risk assessment.
- > Health care workers and sanitary/food inspectors who have been trained on reporting food-borne events to EBS.
- > Existence of a dedicated focal point/unit at the national level which analyses and, if necessary, disseminates information from the EBS.

SOURCES OF EVIDENCE

- > Reports from the local level.
- > National level report, based on collated local reports, for rapid risk assessment.
- > Training material.
- > Training reports and certificates.
- > Interviews with sanitary/food inspectors.

B.2.2.3

ASSESSMENT CRITERION: There is an IBS system that includes laboratory analysis to assign aetiology for suspected FBDs (particularly diarrhoeal disease), investigate hazards in foods linked to cases and outbreaks, understand trends in FBD and increase the sensitivity and specificity of outbreak detection.

**GUIDANCE**

When countries are developing their national surveillance systems, IBS is mainly focused on syndromes that are reported through the notifiable disease surveillance system. Over time, as laboratory capacity increases, it is possible to confirm some of the aetiological agents responsible for FBD. There will be a transition from a notifiable disease surveillance system based on clinical syndromes to one based on laboratory-confirmed diseases. Strengthening the role of the laboratory provides an opportunity to collect and analyse data from individual cases rather than aggregated surveillance data. Capturing specific information for each case, such as age, sex and place of residence, will allow analysis of surveillance data that are more detailed.

In addition, further characterization of pathogens can provide important information about possible sources of contamination, linkages between cases and antimicrobial resistance patterns.

There should be protocols in place for collecting clinical specimens for all priority FBD that include information on which/when/how specimens will be collected (e.g. faeces, blood samples, etc. collected from every 20th patient meeting the case definition of diarrhoea). How specimens will be stored before transporting to the laboratory and where the specimens need to be transported should also be reported.

Protocols for testing clinical specimens for all priority FBD should also be in place and these would include: a description of how laboratory testing is organized (e.g. identifying what samples from which reporting sites go to which laboratories); procedures for obtaining food samples for analysis as potential vehicles (e.g. obtaining leftover food from cases); instruction for the further characterization of priority food-borne pathogens (e.g. subtyping); instructions for antimicrobial susceptibility testing of food-borne pathogens and how this links to the broader antimicrobial surveillance system.

CAs should have a database to house the laboratory-based surveillance data, with a data dictionary. Data reporting protocols for all priority FBD should include: what data will be sent to the surveillance system, how often and by whom, and what actions will be taken based on the information sent to the surveillance system.

Antimicrobial susceptibility testing for relevant FBD should be included as a routine part of the surveillance system and should not have too many changes to the data fields within the database over time to enable trends to be monitored.

Elements that support the surveillance process are: data dictionary; surveillance system log; disease-specific surveillance log. Data analysis should be undertaken regularly and should be included in a regular surveillance bulletin that is available to all stakeholders.

Surveillance protocols must include the list of notifiable diseases and for each disease there should be: a case definition; reason for surveillance; data analyses requirement; and public health action requirement (e.g. one case triggers a response or response is launched when there is a cluster).

For further guidance, refer to the WHO publications (WHO and CDC 2003, 2008).

POSSIBLE OUTCOME

Laboratory data coming from the IBS system is routinely used to assign aetiology for disease syndromes, link transmission vehicles with cases and support outbreak detection and risk profiling.

POSSIBLE INDICATORS

- > A formal process for selecting priority FBD for surveillance.
- > Laboratory-based surveillance for priority FBD.
- > Evidence that priority FBD cases captured within the surveillance system are laboratory- confirmed and further characterized.
- > Defined responsibilities for requesting, collecting and transporting clinical samples.
- > Protocols for collecting clinical specimens for all priority FBD.
- > Protocols for testing clinical specimens for all priority FBD.
- > Data reporting protocols for all priority FBD.
- > Antimicrobial susceptibility testing for relevant FBD.
- > Elements that support the surveillance process (data dictionary, surveillance system log, disease-specific surveillance log).
- > Data analyses included in a regular surveillance bulletin that is available to all stakeholders.
- > Surveillance system that includes appropriate analysis plans for monitoring trends, with thresholds for cluster detection.
- > Surveillance protocols that include the list of notifiable diseases.
- > For each disease, existence of:
 - i. Case definition;
 - ii. Reason for surveillance;
 - iii. Data analyses requirement;
 - iv. Public health action requirement (e.g. one case triggers a response or response is launched when there is a cluster).

SOURCES OF EVIDENCE

- > Protocols for collecting/testing clinical specimens for all priority FBD.
- > Data reporting protocols for all priority FBD.
- > Data dictionary.
- > ToRs.

B.2.2.4



ASSESSMENT CRITERION: Capacity to undertake rapid risk assessments of acute public health events exists at the national and subnational levels.

Note: It should be noted that the term rapid “risk assessment” used in the context of public health emergencies is distinct from the process of “risk assessment” applied to food safety including emergencies (FAO and WHO, 2011) (see B.2.3.7) Refer to Glossary for more details.

GUIDANCE

Rapid risk assessment of acute public health events includes: (i) gathering information; (ii) assessing risk; and (iii) assigning a level of risk to further spread of food-borne events, such as outbreaks. To do this, countries need enough designated and trained staff who can rapidly assess acute public health events and protocols that cover how to deal with suspected food-borne events. Once a food-borne event or potential outbreak has been detected through EBS or IBS, health and food safety staff need to assess the credibility of the report and determine if the event presents a potential risk to public health that requires further action. Rapid risk assessment is important: it documents the available evidence related to the event, assigns a level of risk, and supports decision-making on actions to mitigate the impact of the event on public health. Guidance on conducting rapid risk assessments for public health emergencies has been published by WHO (2012) and the European Centre for Disease Prevention and Control (2011). For further guidance, refer to the WHO publications (WHO, 2012).

POSSIBLE OUTCOME

All suspected food-borne events are assessed within 24 hours and appropriate action is taken.

POSSIBLE INDICATORS

- > There is a team (trained staff) at the national level who can rapidly assess acute public health events.
- > All suspected FBD events are assessed within 24 hours of the initial report.
- > The assessment process is adapted to assess suspected FBD events.
- > Where regional resources are needed, trained teams are available at subnational level.
- > There are staff designated at the subnational level who are responsible for carrying out rapid risk assessments.
- > Training for staff at the subnational level has taken place.
- > The training includes examples of food-borne events that have occurred.

- > A mechanism is in place to offer technical support and advice from the national level to the subnational level as required.
- > Laboratory data are routinely used in the rapid risk assessment process.

SOURCES OF EVIDENCE

- > List of team members.
- > Assessment reports.
- > Training reports.
- > List of contact laboratories.

SEE ALSO

- B.2.3.7** [When appropriate, the risk analysis framework is used to structure the response to food safety emergencies]
- D.1.2.6** [Data from routine inspection, monitoring and surveillance programmes are used to inform new or current risk analysis activities]

B.2.2.5

ASSESSMENT CRITERION: Capacity for multidisciplinary and inter-sectoral subnational outbreak response exists and analytical epidemiology is being applied during outbreak investigations.

**GUIDANCE**

The primary aim of all FBD outbreak investigations is to identify the source, in order to allow timely intervention to stop further cases from occurring. WHO has published guidance on investigating FBD outbreaks (FAO, 2015; WHO, 2008c, 2016). The outbreak investigation is generally carried out by an outbreak response team (ORT). In investigating a suspected FBD outbreak, it is important to collect epidemiological and laboratory evidence about both the illness and any possible food sources. An appropriate number of trained staff at the national and subnational level should be in place to ensure that analytical epidemiology can be carried out during food-borne outbreaks. To perform analytical epidemiological studies during food-borne outbreak investigations, CAs need to be able to:

- i. Generate hypotheses about specific food sources on the basis of food history questionnaires;
- ii. Choose the correct study design (cohort study vs case control study);
- iii. Design or adapt questionnaires to test hypotheses about the food source (e.g. include specific food items thought to be responsible for the illness);

- iv. Administer the questionnaires;
- v. Create a database to store responses from the questionnaires;
- vi. Enter data into the database;
- vii. Manage and clean the data in the database;
- viii. Extract the data from the database;
- ix. Analyse the data using univariate and multivariate analyses;
- x. Evaluate the effect of bias and confounding on the results of the analysis;
- xi. Communicate the findings from the analysis.

A response protocol should document each step the ORT should take when investigating a suspected FBD outbreak. During each event/outbreak response, the ORT should undertake the following:

- i. Interview people affected with the disease using a standardized questionnaire;
- ii. Develop and apply a case definition;
- iii. Describe the number of cases using a line list;
- iv. Provide some descriptive comments about the syndrome and possible source of the illness;
- v. Collect appropriate clinical specimens from symptomatic cases;
- vi. Collect appropriate samples of suspected food vehicles;
- vii. (Log priority information about each event/outbreak in a database.

There should be at least one epidemiologist in the country who can conduct analytical studies.

For further guidance, refer to the WHO publications (WHO, 2008a).

POSSIBLE OUTCOME

The majority of suspected food-borne outbreak investigations include analytical epidemiology and identification of the most likely source of the outbreak.

POSSIBLE INDICATORS

- > There are outbreak response teams (ORTs).
- > Appropriate people have been nominated to take part in the ORT (e.g. representatives from food safety and laboratories, animal health staff).
- > ORT staff have been trained to undertake outbreak investigations of FBD and to collect the appropriate clinical specimens.
- > There is a response protocol, which documents each step the ORT should take when investigating a suspected FBD outbreak (including sample collection and transportation).

- > Clinical specimens are being regularly collected in FBD outbreak investigations.
- > ORTs have the capacity to collect and transport appropriate specimens to a laboratory to identify aetiological agents.
- > If laboratory capacity does not exist in the country, referral pathways for specimens to be tested at regional laboratories have been documented.
- > There is at least one epidemiologist in the country who can conduct analytical studies.
- > A response capacity capable of carrying out analytic epidemiology during outbreak investigations exists at the national and subnational levels.

SOURCES OF EVIDENCE

- > Training reports.
- > Clinical specimens.
- > Response protocol.
- > Updated list of laboratories that can perform the necessary testing.
- > Questionnaires for priority food-borne pathogens.

SEE ALSO

B.2.3 [Management of food safety emergencies]

B.2.2.6

ASSESSMENT CRITERION: Multi-sectoral collaboration facilitates rapid information exchange and support with laboratory testing during FBD outbreak investigation.

**GUIDANCE**

Food-borne outbreak investigations are generally multidisciplinary and multi-sectoral. At a minimum, there should be rapid exchange of information describing the possible food source, plus any information that would enable authorities involved in food control to conduct a trace-back in order to determine exactly where control measures need to be targeted. Ideally, CAs responsible for food control and animal health will be involved as early as possible in an investigation as members of the ORT. This facilitates the information exchange and also improves the effectiveness of the ORT, as the mandate to implement possible control measures is often with food control and animal health authorities.

There is also a critical role for laboratories that cover sample analysis along the food chain. With the greater precision provided by new technologies (for example, whole genome sequencing) further characterization of the pathogens in samples from human, animal, food and environment is becoming a routine and key component of effective surveillance and response systems. The capacity to share detailed laboratory information from across the food chain during an outbreak investigation speeds up the identification of the source of contamination and allows for targeted and faster control measures. This not only reduces the impact on human health but also reduces the economic cost of food-borne outbreaks.

POSSIBLE OUTCOME

Outbreak investigation results are contributing towards identification of specific control measures.

POSSIBLE INDICATORS

- > The surveillance and response staff know where the focal points are for food safety, animal health and the key laboratories that would be required to test clinical and/or food samples collected during an event.
- > There is an effective (formal or informal) mechanism for rapid information exchange during suspected FBD outbreak investigations among all the stakeholders/relevant sectors.

SOURCES OF EVIDENCE

- > Interviews with surveillance and response staff.
- > Documentary evidence of information exchange.

SEE ALSO

B.2.3.3 [A functional central coordination mechanism includes all relevant CAs to address food safety emergencies]

B.2.3

MANAGEMENT OF FOOD SAFETY EMERGENCIES

A coordinated management system scans, identifies and responds to food safety emergencies, and communicates effectively with all stakeholders (national and international).

OVERALL OUTCOME**B.2.3.1**

ASSESSMENT CRITERION: A suitable national food safety emergency plan has been developed in a participatory way and food safety emergencies have been defined to serve as a trigger for escalating appropriate response.

**GUIDANCE**

In CAC/GL 19-1995, Codex Alimentarius defines a food safety emergency as “a situation, whether accidental or intentional, that is identified by a competent authority as constituting a serious and as yet uncontrolled food-borne risk to public health that requires urgent action”. The definition of a food safety emergency at country level will also depend on the national food control system in place and its capacities; what might be well handled as a routine incident in one country constitutes a food safety emergency in another country.

To address a food safety emergency it is important that key CAs and other important stakeholders, including the decision-makers, leaders and working teams, share and understand response procedures. These should be documented in a plan, which should:

- i. Refer to the threshold to trigger an emergency response. Each country needs to describe an emergency in terms of its own control system, defining also the threshold for response. Elements such as number of people affected, severity of illness, distribution and volumes of food, source of contamination, international trade implications, level of coordination among CAs and access to “exceptional resources” required to implement risk management measures will need to be taken into account.
- ii. Refer to a central coordination mechanism – for example, a multi-agency coordination group.
- iii. Ensure that roles and responsibilities of all stakeholders are clearly defined.
- iv. Refer to established procedures in place to manage operations and communications.

Key partners need to be involved in preparing the plan and subsequently they need to be well identified as responsive and easily accessible. These would generally involve services such as: public health surveillance services; food inspection services; veterinary services; official laboratory services; customs and quarantine; agriculture services; legal services (as well as law enforcement); food science and technology; media and communications; other relevant sectors (e.g. tourism, national security department, environmental services).

The food safety emergency response plan should refer to relevant regulations or national legislation that provides the legal basis for its implementation. In addition, where other national and international emergency plans exist – for instance, those relating to the control of FBD outbreaks or outbreaks of animal diseases – the response plan should be linked to these to ensure an integrated response (Ref. para 61 of CAC/GL 82-2013).

POSSIBLE OUTCOME

All CAs involved in food safety emergency response are aware of their roles and declaration of food safety emergencies is expeditious when necessary.

POSSIBLE INDICATORS

- > A plan that documents response procedure to address food safety emergencies is available and:
 - i. Includes definition of trigger;
 - ii. Refers to central coordination;
 - iii. establishes clear roles and responsibilities;
 - iv. Establishes procedures for communications.
- > Evidence that the plan was developed in a participatory way.
- > Evidence that all key partners and involved stakeholders are properly aware of their roles and of the response procedures required of them in the event of a food safety crisis/emergency.
- > Key CAs and other important stakeholders (including the decision-makers, leaders and working teams) are all fully briefed on response procedures.

SOURCES OF EVIDENCE

- > Documentary evidence of the food safety emergency plan.
- > Documentation showing a definition of a national food safety emergency.
- > Interviews with key partners/stakeholders regarding knowledge of their roles and of response procedures.

SEE ALSO

B.1.1.15 [CAs have appropriate controls in place to ensure that FBOs have effective traceability systems]

B.2.3.2

ASSESSMENT CRITERION: Mechanisms to gather and analyse information are in place to allow incident identification.



GUIDANCE

Mechanisms to rapidly share information should be developed by a central management team. Information from a variety of sources (e.g. international notification, CAs, food industry, trading partners, laboratory reports, FBD surveillance, hospital admission records) should be gathered and channelled under the mandate of the relevant CAs for collective evaluation and validation. This would increase the capacity to timely detect food safety incidents.

Ideally, this should be part of a national integrated food chain surveillance system, which collects and collates information from along the food chain.

To ensure efficient incident identification, links between the symptomatic FBD surveillance system and the food monitoring system should be in place. Data on symptoms and effects of chronic exposure to food-borne contamination should be available and regularly updated, complemented by relevant links to the veterinary public health sector. There should be regular reviews to ensure that the system allows effective incident identification and triggers a relevant response (Ref. para 87 of *CAC/GL 82-2013*).

At the international level, IHR and INFOSAN provide mechanisms for notification and communication exchange, and each country should have a contact/focal point properly identified and in close contact with the national food safety emergency coordination team (Ref. para 68 of *CAC/GL 82-2013*). Some countries have set up national or regional information-sharing networks. Different types of Early Warning/Rapid Alert systems for food safety exist, ranging from reactive systems that identify hazards in food products to public health surveillance that identifies food-borne illness in people to predictive systems that use risk-based approaches to forecast new food safety threats.

POSSIBLE OUTCOME

Early reaction and international support in the control of emergencies are facilitated.

POSSIBLE INDICATORS

- > National mechanisms in place ensuring gathering and sharing of relevant information for collective evaluation (e.g. national or regional information-sharing networks).
- > Active contact/focal points for INFOSAN, IHR, or relevant regional networks.
- > Evidence of reception and dissemination of information received from the network.
- > Evidence of communication to the network in appropriate cases.
- > Early Warning/Rapid Alert systems for food safety.
- > Reviews of system's effectiveness.

SOURCES OF EVIDENCE

- > Records of information exchange and communication with relevant international, regional and national networks.

SEE ALSO

B.1.1.15 [CAs have appropriate controls in place to ensure that FBOs have effective traceability systems]

B.2.3.3

ASSESSMENT CRITERION: A functional central coordination mechanism includes all relevant CAs to address food safety emergencies.

GUIDANCE

The response to food safety emergencies is likely to involve a number of CAs (e.g. public health services, food inspection services, veterinary services, official laboratory services, customs and quarantine, agriculture services) but also other relevant sectors (e.g. tourism, national security department, environmental services). Therefore, a coordination mechanism (i.e. a multi-agency coordination group formed of senior staff delegated to act on behalf of their respective agencies) should be set up to enable easy and quick communication between central level (identification, triggering of response plan) and local level (implementation of response). All partners of the coordination team need to have clear roles and responsibilities, be aware of these and be reachable. The individuals can be permanent or ad hoc (set up for a specific event), but the mechanism needs to be in place to allow such coordination. CAs might decide to have an additional internal coordination group

and relate to their correspondent in the overall coordination mechanism. In addition to public authorities, management of emergencies can require specific experts and a range of different skill sets. Creating a range of food safety emergency scenarios serves to outline which experts, competencies, or specialist groupings are required and to establish useful contacts ahead of the actual emergency.

POSSIBLE OUTCOME

A coordination mechanism allows an efficient response from all relevant CAs.

POSSIBLE INDICATORS

- > A coordination mechanism is in place (e.g. a multi-agency coordination team):
 - i. With clear ToRs centred on facilitating communication between central and local levels.
 - ii. Involving CAs from public health, food inspection, veterinary services, official laboratory, customs and quarantine, agriculture, etc.
 - iii. Involving other relevant sectors such as tourism, national security department, environmental services, etc.
- > Clear roles and responsibilities are assigned to all partners of the coordination team.
- > Coordination team partners are reachable.
- > CAs have considered a range of possible scenarios and food safety emergencies and events with different contexts.
- > Examples can be seen of how the coordination mechanism worked in the past during a food safety emergency.

SOURCES OF EVIDENCE

- > Updated list of partners' contacts.
- > Documented and updated lists of possible external resources (experts, competencies or specialist groupings).
- > Documentation, reports or records of the establishment, implementation and ongoing work of the coordination mechanisms.
- > Documentary evidence of how the coordination mechanism worked in the past during a food safety emergency.

SEE ALSO

B.2.2.6 [Multi-sectoral collaboration facilitates rapid information exchange and support with laboratory testing during FBD outbreak investigation]

B.2.3.4

ASSESSMENT CRITERION: Functional arrangements are in place for communication and implementation of response in the event of a food safety emergency.

GUIDANCE

The principles and practices of communication supporting risk management response for a food safety emergency need to be clarified, agreed and formally adopted by each of the CAs. A range of preparatory or contingency arrangements should be in place to ensure that information flows from the key response implementation partners involved in the investigation towards the central coordination mechanism. In turn, based on the review of information received, the central coordination mechanism should be able to quickly communicate the necessary course of action (risk management response expected from local teams, for example, or provision of updates).

POSSIBLE OUTCOME

Risk management responses are implemented in a timely manner.

POSSIBLE INDICATORS

- > Key stakeholders are aware of the principles and practices of communication and control systems in the event of a food safety crisis or emergency.
- > Each CA or stakeholder has a focal point for communication and control, going:
 - i. “Upstream” (towards the command level);
 - ii. “Downstream” (towards the implementation level).

SOURCES OF EVIDENCE

- > Documented principles and practices of communication supporting risk management response.
- > Interviews with key CAs and stakeholders.

SEE ALSO

B.1.1.15 [CAs have appropriate controls in place to ensure that FBOs have effective traceability systems]

B.2.3.5

ASSESSMENT CRITERION: Strategies and guidance for communicating with partners, stakeholders, general public and international organizations are in place.

**GUIDANCE**

Effective communications are essential and need to be well prepared in advance of the food safety emergency. The aim is to provide accurate, timely and relevant information to a range of very different audiences, with different needs, and to ensure a common understanding of the problem. Besides communication among CAs (and with the central coordination team, to ensure implementation of response and flow of technical information) as seen in criterion **B.1.3.4**, communications should also target:

- i. Inter-agency communications, including with local and foreign governments, as well as IOs (i.e. WHO, in particular with respect to IHR requirements and INFOSAN contact/focal points);
- ii. Industry;
- iii. General public through the media.

One basic tool is a list of all necessary contact details readily available and updated. Other useful tools that should be prepared in advance are: templates for notifications of incidents; model press releases; recall and withdrawal notices; prepared questions and answers; etc. Means of dissemination include websites, TV, radio, press and specific material adapted to the literacy level of the population so that information is transferred in a way that makes it accessible to all, including populations in rural or remote areas. Advice should contain practical information on what to do if somebody has consumed the affected product; on what has been and is being done to contain affected product; and on contact details for more factual information and specific advice.

A trained spokesperson, recognized to have authority on the topic, should also be available.

POSSIBLE OUTCOME

Communications are made strategically.

POSSIBLE INDICATORS

- > List of all necessary contact details readily available and updated (local and foreign governments, IOs, industry).
- > Designated and competent spokesperson.
- > Readily available means of dissemination for the general public (websites, TV, radio, press, specific material, etc.)
- > Activities aimed at preparing effective communications for food safety emergency responses that have occurred periodically as part of standard operating procedures.
- > Investments that have provided tangible improvements in the government's preparedness for food safety emergency responses.

SOURCES OF EVIDENCE

- > List of all necessary contact details (local and foreign governments, IOs, industry).
- > Templates for notifications of incidents.
- > Model press releases.
- > Recall and withdrawal notices.
- > Prepared questions and answers.

B.2.3.6

ASSESSMENT CRITERION: Food safety emergency response plans are pre-tested and reviewed after an emergency has occurred.



GUIDANCE

Iterative improvement is a key principle of modern management and governance. Improvement of food safety emergency response plans should be done before and after an emergency has occurred to delineate matters that need to be solved or improved. Before an emergency, mock exercises should be implemented to pre-test all considerations in the plan and improve them in the light of findings gathered at this occasion. After an emergency, the real-life experience will offer useful feedback. In both cases, review should consider: the appropriateness of response activities; the different means of communications; the regulatory procedures available to inspectors to take the necessary course of action (e.g. prevent production and distribution of food products); the capacity of analytical services; the effectiveness of withdrawal or recalls implemented; and the global capacity of inspection services and laboratories to report to the central coordination mechanism (Ref. para 86 of CAC/GL 82-2013). Lessons should be drawn not only with regard to improving the plan but also if there are serious gaps with regard to resources (staff, analytical, etc.) or capacities (additional needs for training).

POSSIBLE OUTCOME

Food safety emergency response mechanisms are improved over time.

POSSIBLE INDICATORS

- > Periodic mock exercises to pre-test the response emergency plan.
- > Record of feedback from past emergency reviews, considering:
 - i. Appropriateness of response activities;
 - ii. Effectiveness of withdrawal or recalls implemented;
 - iii. Regulatory procedures available to inspectors to take action (e.g. prevent production and distribution of food products);
 - iv. Capacity of analytical services;
 - v. Global capacity of inspection services and laboratories to report to the central coordination mechanism;
 - vi. Means of communication;
 - vii. Sufficient resources (staff, analytical, etc.) and capacities (additional needs for training?)
- > Investment providing tangible and valid improvements in the government's preparedness for food safety emergency responses.

SOURCES OF EVIDENCE

- > Reports on mock exercises to pre-test the response emergency plan.
- > Records of feedback from past emergency reviews.

B.2.3.7



ASSESSMENT CRITERION: When appropriate, the risk analysis framework is used to structure the response to food safety emergencies.

GUIDANCE (FAO AND WHO, 2011)

Management of food safety emergencies always calls for a multidisciplinary approach. A multi-agency coordination group (see B.2.3.3) helps to mobilize the response to food safety emergencies. The risk analysis framework, on the other hand, offers a useful tool for structuring the overall response and increasing the gains for food safety (Ref. para 44 of CAC/GL 82-2013). In their routine activities, CAs are probably involved in one or more components of the risk analysis framework. However, in times of emergency, when time is short to gather sufficient information, pressure may lead to considering that this approach is difficult to implement. In these cases, preparedness is key. This means that supporting tools can be prepared in advance for the different steps of the risk analysis framework so that the risk analysis framework still applies in its sequence, with some tweaking related to the specific context of a food safety emergency. Supporting tools for preparedness could involve:

- i. For **preliminary risk management activities** (identification of the food safety event through preliminary investigation, activation of the emergency response and formulation of targeted questions to risk assessors):
 - > Templates for data gathering;
 - > Situation report templates and decision trees;
 - > Reference materials for use during emergencies.
- ii. For **risk assessment**:
 - > Databases of surrogate data (for example, toxicological data on similar chemical substances);
 - > Food consumption database or easy access to international food consumption databases;
 - > Established partnerships with external experts/advisory groups;
 - > Compilation of reference values published by regulatory agencies.

As it is likely that there will be limitations and uncertainties in the risk assessment step, it is important to ensure that there is prior awareness about its existence and causes of uncertainties.

iii. For **risk management**:

- > Identification of pre-developed risk categories and their related risk management options;
- > Templates, checklists and decision trees supporting implementation approaches.

Communicating with FBOs on the risk categorization framework and associated risk management option is a useful way to allow FBOs to align emergency management protocols with arrangements by CAs for increased effectiveness.

iv. For **risk communication**:

- > Communication tools in relation to the pre-identified risk management options;
- > Pre-identification (in collaboration with professional associations) of the FBOs' contact points and discussion of the arrangements that will operate in case of an emergency.
- > The communication with the general public should not underestimate the gravity of the situation and indicate as clearly as possible: what is known about the food safety emergency; the food products involved; the nature of risks, and whether they are known; the levels of exposure that could be harmful; what the public should do; links to further information.

POSSIBLE OUTCOME

Response to food safety emergencies benefits from the risk analysis framework that maximizes impact and targets resources to what is most needed.

POSSIBLE INDICATORS

- > Existence of tools that would support rapid initial assessment and decision-making (templates for data gathering, situation report templates, decision trees, reference materials for use during emergencies, etc.)
- > Pre-developed risk categories and their related risk management options identified.
- > Communication tools and supporting aids prepared in advance in relation to the pre-identified risk management options.
- > FBOs informed on the CAs' risk categorization framework and associated risk management options (for alignment of their emergency management protocols with CAs' arrangements).
- > Existence of databases of surrogate data (e.g. toxicological data on similar chemical substances).
- > Existence of food consumption databases and/or easy access to international food consumption databases.
- > Established partnerships with external experts/advisory groups.

- > Communication to general public that clearly reports: food products involved; nature of risks; levels of exposure that could be harmful; recommended behaviour; links to further information.

SOURCES OF EVIDENCE

- > Preliminary investigation reports.
- > List of identified risk management options.
- > Assessment tools (templates for data gathering, situation report templates, decision trees, reference materials for use during emergencies, etc.)
- > Communication tools.
- > List of FBOs' contact points.
- > Databases of food consumption and of surrogate data.
- > Interviews with FBOs.
- > Records of communication to general public.

SEE ALSO

- B.2.2.4** [Capacity to undertake rapid risk assessments of acute public health events exists at the national and subnational levels]
 - B.2.3.3** [A functional central coordination mechanism includes all relevant CAs to address food safety emergencies]
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DIMENSION B

CONTROL FUNCTIONS

Dimension B focuses on the processes and the outputs of the control activities inherent to a national food control system. It reviews the control functions exercised by CAs over Food Business Operators (FBOs), be it at domestic, import or export level, to guarantee food safety and quality for national consumers along the food chain and fair trade practices. It also maps the control functions and mechanisms at the overall food supply level, necessary to identify, monitor, predict and handle food safety hazards and emerging risks and to deal with food emergencies. The main mechanisms that should be in place include data collection programmes on food products (also referred to as *monitoring programmes*), data collection programmes on food-borne diseases (also referred to as *surveillance programmes*), as well as programmes aiming at managing food safety emergencies.

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