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FOOD CONTROL SYSTEM
ASSESSMENT TOOL

DIMENSION D

SCIENCE/KNOWLEDGE BASE AND CONTINUOUS IMPROVEMENT

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ASSESSMENT TOOL

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FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS
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DIMENSION D looks at the necessary features for the system to build its scientific soundness and to keep abreast of new scientific developments and innovations, in order to continuously improve.

SUB-DIMENSION D.1

EVIDENCE/RISK BASE

This sub-dimension explores how CAs anchor their decisions on relevant scientific and technical information, reviews the robustness of information collection processes as a foundation for risk analysis, and assesses the use made of this risk analysis framework to quantify food safety risks.

Competency D.1.1 (Access of CAs to updated scientific and technical information) ensures that CAs base their food control decisions on relevant scientific and technical information. For this to happen, relevant staff should be provided with access to authentic and up-to-date sources of scientific and technical information; active collaborations should be in place with Centres of Excellence or Reference Centres for food safety; and staff should participate in professional associations. Staff should also be facilitated to share new knowledge with work colleagues and work teams, in a collaborative manner.

Competency D.1.2 (Capacity to collect and analyse data for risk analysis purposes) ensures primarily that risk analysis processes are based on robust information collection and quality data. Data collection activities that produce scientifically valid information to support risk analysis can be implemented only in the presence of sufficient infrastructure, technological capacity and expertise. Systems to monitor collection and processing of data should be in place to guarantee quality of data collection and analysis, and CAs should identify and collect data on country-specific hazard and commodity combinations. Multi-sectoral risk analysis should be carried out with a holistic view of the food supply chain that integrates information from the surveillance system and from routine inspection and monitoring. CAs should actively identify data needs for risk assessments while ad hoc research studies should be conducted to attribute food sources to specific diseases and to generate burden of FBD estimates.

Competency D.1.3 (Knowledge and use by CAs of risk analysis framework) evaluates whether CAs appropriately use the risk analysis framework to quantify food safety risks, and use the outputs to plan and cyclically refine their food safety official controls. While competency D.1.2 is essentially about the validity of data that is collected and subsequently used, competency D.1.3 focuses on the processes in place to make use of the data. To begin, food safety and quality policy, food control legislation and related guidance should incorporate principles of risk analysis, within a risk management framework. CAs should demonstrate sound understanding of risk analysis principles and should use risk ranking approaches to target resources for risk management. A repository of risk profiles should exist to inform policy and risk management decision-making and FBOs should be inserted into a risk-based

inspection programme. Qualitative or, if possible, quantitative risk assessments should be conducted to deliver valid risk estimates in support of risk management decision-making process. Risk assessments and risk management measures should be periodically re-assessed. Finally, units conducting risk assessment and risk management should be functionally separated to protect the integrity of risk assessment as a scientific and objective exercise. When assessing this competency it is also important to understand how CAs have actually collaborated to produce an outcome that has a national validity. In other words, it is not sufficient that each CA understands and produces interesting outputs pertaining to the risk analysis framework (be it a risk assessment, or risk management measures, etc.), but that the process and the data used go beyond their immediate purview, if this is appropriate to the risk at stake.

SUB-DIMENSION D.2

CONTINUOUS IMPROVEMENT

This sub-dimension revolves around CAs' capacity to review and improve performance, taking into consideration the most recent scientific and technical knowledge, to ensure the achievement of the relevant outcomes.

Competency D.2.1 (Performance monitoring of CAs and continuous improvement) ensures that CAs implement an array of tools and approaches to regularly review and improve performance. For this to happen, a monitoring plan should be in place and specific outcomes should exist that can be monitored and evaluated to measure performance. The data produced by the performance monitoring plan should be used to improve processes and achievement of outcomes. The CAs responsible for official controls for food safety should, on one hand, perform internal audits of official control processes, and on the other hand, make use of external audits of business processes to improve delivery of public services.

Competency D.2.2 (Mechanism to ensure consideration of newest scientific and technical information for food control) assesses whether the national food control system benefits from the most recent scientific and technical knowledge. In this context, working links should exist between the CAs and academia, universities, technical institutes and other expert groups that support the generation of relevant information for assessing and responding to food safety and fraud issues. Foresight methodologies (such as horizon scanning, simulation modelling, Delphi surveys, etc.) could also help the identification, assessment and control of emerging food safety hazards and frauds, and allow more efficient control of those hazards that are already well understood.





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D.1

EVIDENCE/RISK BASE

COMPETENCY D.1.1 ACCESS OF CAs TO UPDATED SCIENTIFIC AND TECHNICAL INFORMATION

| OVERALL OUTCOME | |
|--|--|
| CAs base their decisions on relevant scientific and technical information. | |
| D.1.1.1 | Relevant staff have access to authentic and up-to-date sources of scientific, technical, monitoring and surveillance information. |
| D.1.1.2 | Staff are supported to share new knowledge with work colleagues and work teams. |
| D.1.1.3 | CAs actively collaborate with one or more Centres of Excellence or Reference Centres for food safety and staff participate in professional associations. |

COMPETENCY D.1.2 CAPACITY TO COLLECT AND ANALYSE DATA FOR RISK ANALYSIS PURPOSES

| OVERALL OUTCOME | |
|---|--|
| Risk analysis is based on robust information collection processes and quality data. | |
| D.1.2.1 | There is sufficient infrastructure and technological capacity to conduct data collection to support risk analysis activities. |
| D.1.2.2 | Sufficient expertise supports the elaboration of sound protocols for data collection and analysis required by the country for risk analysis. |
| D.1.2.3 | CAs monitor data collection and processing, performing data quality controls. |
| D.1.2.4 | CAs identify and collect data on country-specific hazard and commodity combinations. |
| 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.1.2.6 | Data from routine inspection, monitoring and surveillance programmes are used to inform new or current risk analysis activities. |
| D.1.2.7 | The CAs identify data needs for risk assessments and generate the data needed. |
| D.1.2.8 | Targeted research studies are conducted to attribute food sources to specific diseases, understand FBD epidemiology and estimate the burden of FBD on the community. |
| D.1.2.9 | CAs generate burden of FBD estimates that integrate disease incidence and severity data with attribution to food-borne transmission, as the best evidence for risk prioritization. |

COMPETENCY D.1.3 KNOWLEDGE AND USE BY CAs OF RISK ANALYSIS FRAMEWORK (FAO AND WHO, 2006)

| | |
|------------------------|---|
| OVERALL OUTCOME | CAs appropriately use the risk analysis framework to quantify food safety risks, and use the outputs to plan and cyclically refine their food safety official controls. |
| D.1.3.1 | CAs demonstrate sound understanding of risk analysis principles and commitment to the risk management framework in processes and outputs, as appropriate, pertaining to legislation, standard setting, policies, guidance, etc. |
| 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. |
| D.1.3.5 | Risk assessments are being conducted and they deliver scientifically defensible risk estimates (qualitative or semi-quantitative). |
| D.1.3.6 | Quantitative risk assessments are conducted. |
| D.1.3.7 | Advanced techniques are applied to management of food safety risks. |
| D.1.3.8 | Risk assessments and risk management measures are periodically re-assessed and updated as necessary. |
| D.1.3.9 | Units conducting risk assessment and risk management are functionally separated, and CAs and experts involved in risk assessment are not subject to any conflict of interest. |

D.1.1**ACCESS OF CAs TO UPDATED SCIENTIFIC AND TECHNICAL INFORMATION****OVERALL OUTCOME**

CAs base their decisions on relevant scientific and technical information (Ref. para 36(i) of CXG 82-2013).

D.1.1.1

ASSESSMENT CRITERION: Relevant staff have access to authentic and up-to-date sources of scientific, technical, monitoring and surveillance information.

GUIDANCE

Technological change occurs rapidly, not least in food science and food safety. This often results in the implementation of new techniques, methods and technologies. Staff who have responsibilities for official controls over food products, or staff who are key to the scientific processes underpinning food safety and quality controls in the country (whether they belong to the CAs or relevant contracted bodies such as universities or private contractors), can bring these methods into their work only if they are updated with new knowledge. Professionals may be self-motivated to update themselves with new knowledge, but sometimes there may be constraints with regard to permission to access this knowledge through authentic sources that may include: written documents (e.g. newspapers, peer-reviewed journal articles, scientific or technical books) as well as electronic media (e.g. electronic access to scientific and technical validated information). Access to Web browsers is not sufficient.

Equally importantly, this also means that staff have access to information deriving from integrated surveillance and monitoring of the food chain – from FBD surveillance to monitoring of food safety hazards.

POSSIBLE OUTCOME

Decisions related to food control can be based on recent science, which is critically evaluated and also assessed for relevance to the country.

POSSIBLE INDICATORS

- > Evidence (e.g. budgets) that government funding/financial resources are allocated to provide staff with access to scientific information.

- > Interviews or surveys with staff that determine:
 - i. Quantity and quality of media resources for new knowledge that are available to the staff;
 - ii. Whether staff are sufficiently facilitated with access to these media (e.g. staff receive training on how to access electronic resources);
 - iii. Whether key staff have access to science publications, scientific papers or media, via subscriptions provided by government;
 - iv. Whether staff have access to technologies that can facilitate remote learning or collaboration (e.g. remote conferencing facilities);
 - v. Whether staff have access to information derived from food safety monitoring and FBD surveillance;
 - vi. Availability of manuals or guidance for staff providing information about how to access or gain best use from the arrangements;
 - vii. Government investment and attention to continuing learning;
 - viii. Staff awareness that Codex, WHO and FAO websites have scientific and technical resources.

SOURCES OF EVIDENCE

- > Interviews or surveys with staff.
- > Budgets.

SEE ALSO

- A.2.1.3** [An analysis of the cost of the relevant scientific services has been reflected in budget allocations]
- A.2.1.6** [The financial resources required to purchase, renew and maintain essential infrastructure and equipment (office, logistics, transportation, IT, etc.) are financially secured in CAs' budgets]

D.1.1.2

ASSESSMENT CRITERION: Staff are supported to share new knowledge with work colleagues and work teams.

**GUIDANCE**

Team building and communities of practice rely upon enthusiasm and professional motivation arising from individuals who often synthesize new knowledge and who share this with professional colleagues using seminars or workshops. Many benefits can be derived from this type of activity, including the updating of staff on new developments and new knowledge; team building; processing of ideas; identification of new projects; and making new initiatives operational.

POSSIBLE OUTCOME

Staff teams utilize and share new knowledge in a collaborative manner.

POSSIBLE INDICATORS

- > Existence of a CA's policy encouraging staff to bring and share new methods and knowledge.
- > Community of practice promoted through staff sharing of new methods and knowledge.
- > Periodic seminars, targeted workshops or communities of practice in place.

SOURCES OF EVIDENCE

- > Policy documents.
- > Reports of seminars/workshops about knowledge sharing.
- > Interviews with staff.

SEE ALSO

A.3.2.2 [CAs encourage active exchange of knowledge and skills among staff]

D.1.1.3

ASSESSMENT CRITERION: CAs actively collaborate with one or more Centres of Excellence or Reference Centres for food safety and staff participate in professional associations.

GUIDANCE

CAs need to consider “reaching out” to access expertise that they may not possess internally, both at institutional and individual level.

At institutional level, official recognition for high attainment in scientific analysis and the status of “Reference Centre” (which may refer to laboratories) or “Centre of Excellence” (which may refer to academic institutions) requires investment and expertise that some countries do not possess. Despite this, the benefits of the scientific outputs of such centres are frequently needed by all countries engaged with official controls for food safety. The benefits include accurate and reliable analysis of samples – sometimes using assays, techniques and equipment or expertise that are not available in most ordinary food safety laboratories. Information of this type provides CAs with support for science and evidence-based decision-making, including in food

safety crises or emergency situations. CAs should consider concentrating expertise and facilities for certain analyses in nationally accessible reference laboratories. In some countries where such Centres of Excellence or Reference Centres may not be available, collaborations could be envisaged at regional level.

At individual level, this criterion also assesses whether, and the extent to which, relevant staff in CAs are encouraged, when appropriate, to participate in professional associations so that the expertise is maintained and, through exchanges with peers, there is access to complementary knowledge and competences.

POSSIBLE OUTCOME

Links with Centres of Excellence provide the government with reliable scientific information and rationales for decision-making.

POSSIBLE INDICATORS

- > Government can demonstrate active collaboration with Centres of Excellence and/or Reference Centres (e.g. regional food safety laboratories).
- > Evidence of active and ongoing collaboration with (or support from) at least one such centre (e.g. sending samples and/or receiving expertise).

SOURCES OF EVIDENCE

- > Interviews with Reference Centres / Centres of Excellence.
- > Correspondence with the centres.
- > Samples.

SEE ALSO

- D.2.2.1** [There are fruitful working links between the CAs and academia, universities, technical institutes and other expert groups (e.g. scientific committees), with the objective of generating relevant information for assessing and responding to food safety and fraud issues]

D.1.2**CAPACITY TO COLLECT AND ANALYSE DATA
FOR RISK ANALYSIS PURPOSES****OVERALL OUTCOME**

Risk analysis is based on robust information collection processes and quality data

D.1.2.1

ASSESSMENT CRITERION: There is sufficient infrastructure and technological capacity to conduct data collection to support risk analysis activities.

GUIDANCE

The government has to take responsibility for implementing official food controls; when new threats and hazards arise, or are better known, continual improvement in risk reduction is required. CAs must adopt responsibility for research and data generation for risk analysis activities, for creating food safety standards and also for informing official controls. To address this obligation properly, the government must invest in infrastructure such as laboratories and technologies to support data collection (Ref. para 46 of **CXG 82-2013**). Surveys for data collection should be based on statistically valid representative sampling plans. An analysis of capacities of laboratories versus priority food safety issues (or other relevant issues, such as specific frauds) should be undertaken, as well as a review of monitoring programmes and other surveys, and systems to collect, store and analyse data centrally should be in place. This should enable CAs to determine whether data needs are addressed or not, and what should be done about it.

POSSIBLE OUTCOME

Data collection activities can be implemented.

POSSIBLE INDICATORS

- > Sufficient infrastructure and laboratory capacity to expedite data collection and analysis at central level.
- > Facilities dedicated to data collection for risk analysis activities.

- > Lists of technical capacities (technology that is valid, functional and ready for use) and data handling systems that are suitable for risk analysis.
- > CAs' capacity to access and use data prepared or generated by internationally recognized scientific bodies such as JECFA, JMPR, JEMRA, GEMS/Food.
- > Country's capacity to collect data on its own food risks and problems.

SOURCES OF EVIDENCE

- > Interviews with staff.
- > Data collected.
- > Data analysis.

SEE ALSO

- A.2.2.3** [There is an IT system in place for recording, analysing and sharing the data collected during food controls and surveillance of FBDs]
- 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.1.2.3** [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.2.1.2** [The risk ranking processes drive the development of the national food safety and quality monitoring programme]

D.1.2.2

ASSESSMENT CRITERION: Sufficient expertise supports the elaboration of sound protocols for data collection and analysis required by the country for risk analysis.

**GUIDANCE**

A country that has a sufficient number of credible experts covering a sufficiently wide range of food safety disciplines is better equipped to deal with its internal food safety issues quickly and effectively. In particular, data collection protocols require sound expertise for their conception, to support their implementation by field teams, but also for the analysis and interpretation of the results generated, with a view to contributing to risk analysis processes, such as risk assessments, for example. To achieve their objectives, some governments may need to bring

specific expertise from abroad. When possible, countries tend to create their own processes and mechanisms, including nurturing and retaining national experts for addressing food safety research and data collection for risk analysis (Ref. para 46 of CXG 82-2013). This gives more independence, stature and national relevance, as well as being more efficient for the government. This is likely to be achieved through building relevant linkages with universities and academia so that specific research and training programmes are adequately targeted to fill gaps in expertise and knowledge. These connections are best formalized through expert committees supporting CAs in their work – e.g. through service agreements.

POSSIBLE OUTCOME

Data collection activities produce scientifically valid information.

POSSIBLE INDICATORS

- > The significant majority of data collection and analysis needs can be met in terms of expertise.
- > Investments are made to develop sufficient capacity to conduct valid data collection activities.
- > Linkages with universities and academia are in place.

SOURCES OF EVIDENCE

- > Lists of experts, describing their qualifications, experience and roles in conducting data collection activities (technical laboratory staff and general data analysts, including staff from specific risk assessment disciplines such as toxicologists, exposure assessment experts, food consumption experts, etc.)
- > Documentary evidence of government data collection and risk analysis activities and associated lists of experts who were engaged to perform the work.

SEE ALSO

- A.3.1.2** [CAs have clear internal policy guidelines addressing the prerequisite qualifications for the various employees supporting food control activities]
- A.3.2** [Training of personnel]

D.1.2.3**ASSESSMENT CRITERION: CAs monitor data collection and processing, performing data quality controls.****GUIDANCE**

For governments that have the policy and capacity to conduct their own data collection and analysis activities, it is important that the CAs monitor data collection and processing and perform regular data quality controls. This will ensure that high-quality data are available to inform standards and controls to ensure food safety. Appropriate connection to a reliable national metrology system or institute could support the consistent generation of high-quality data. The use of laboratories that maintain the basic form of laboratory management is encouraged. Laboratory accreditations, specifically for the analyses required for data collection, should be achieved.

POSSIBLE OUTCOME

Quality of data collection and analysis is kept high through systems to monitor collection and processing.

POSSIBLE INDICATORS

- > Quality control, demonstrated through:
 - i. Participation in international collaborative testing rounds;
 - ii. The use of reference materials.
- > Approaches to data processing and the statistical significance of conclusions.

SOURCES OF EVIDENCE

- > Documentary evidence of any of the above being formal policy and approach.
- > Documentary evidence of appropriate connection to a reliable national metrology system or institute.

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]
- A.2.3** [Analytical resources]
- D.1.3.6** [Quantitative risk assessments are conducted]

D.1.2.4



ASSESSMENT CRITERION: CAs identify and collect data on country-specific hazard and commodity combinations.

GUIDANCE

Some foods represent high risk due to their propensity to harbour food safety hazards, the frequency of their consumption, or the target consumer groups. Some high-risk foods or hazards may be very specific for the country or the region.

The government is responsible for collecting data about country-specific risks to inform how risks should be safely managed and handled throughout the value chain, and what official controls are therefore appropriate (Ref. para 50, 1st point, of **CXG 82-2013**). To achieve this, valid preliminary data must be collected and used in subsequent risk analysis activities. CAs can conduct their own surveys on food normally found in the country (with the advantage that information gained is directly attributable to the conditions and the foodstuffs found in the country) and complement it with information and data that other stakeholders have produced, including reputable sources such as IOs and Codex Alimentarius. Relevant CAs should consider a sufficiently broad range of risk foods and potential contaminant risks, as well as attribution to food-borne transmission where a range of exposure pathways is possible. It is important that the entire food chain is taken into consideration when determining when and where to collect data to understand the most strategic stages where data should be collected (Ref. para 36 **CXG 82-2013**). These preliminary data collections (surveys) may be necessary either because there are no ongoing monitoring or surveillance plans already in place, or to investigate emerging risks not yet well taken into account by such sampling plans.

POSSIBLE OUTCOME

Data and information about specific risk foods and commodities is generated and utilized in risk analysis activities.

POSSIBLE INDICATORS

- > Hazard data relevant to specific risk foodstuffs, in particular data on prevalence and quantification of hazards.
- > Technical information supporting protocols for surveys or data collection programmes.
- > Identified hazards/commodities that are subjects of surveys or data collection programmes.
- > Human health surveillance data gathered and considered when deciding on focus for surveys or data collection programmes.

SOURCES OF EVIDENCE

- > Documentation supporting surveys or data collection programmes.

SEE ALSO

- B.2.1.2** [The risk ranking processes drive the development of the national food safety and quality monitoring programme]
- D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]

D.1.2.5

ASSESSMENT CRITERION: A surveillance system is in place that integrates information from the entire food chain to enable a better understanding of risk.

**GUIDANCE (WHO, 2013)**

Timely access to information generated by the surveillance system should be ensured for the stakeholders of the national food control system and in particular for the relevant CAs, to allow them to identify the risks or issues that need to be addressed and to determine whether the controls or measures in place are effective (Ref. para 60 of **CXG 82-2013**).

Different approaches may be adopted for integrated food chain surveillance for FBD. Each country will need to structure its integrated food chain surveillance system in a way that takes into account the stakeholders involved and the location of data sources. Nevertheless, regardless of the structure chosen, there are certain elements that are common to every approach. These include:

- i. A team of representatives from each relevant sector, who have detailed knowledge of how the data in their sector are collected. ToRs of the team should include:
 - > Identifying data sources in each sector that are available for integrated food chain surveillance;
 - > Identifying the appropriate pathogens for integrated food chain surveillance;
 - > Determining the animal species and foods to be included.
- ii. Willingness from each sector to be involved in integrated food chain surveillance.
- iii. Clear governance structures for sharing and analysing integrated data (including a coordination mechanism and a communication mechanism).
- iv. Regular communication to discuss all aspects of integrated food chain surveillance.

- v. A clear statement of the surveillance objectives.
- vi. A database to house the data from all the sectors participating in integrated food chain surveillance, with a data dictionary for each data field.
- vii. A data transfer mechanism to extract data from existing surveillance databases and other data sources to send them to the integrated food chain surveillance database, which specifies:
 - > Type of electronic transfer (e.g. automatic feed, manually sent spreadsheets);
 - > Frequency of data transmission;
 - > Data fields to be sent to the database.
- viii. Regular multi-sectoral analysis and interpretation of the integrated data undertaken (which includes a data quality review process and source attribution) and publication in annual reports.

Outputs from the integrated food chain surveillance system should be used routinely in risk analysis to update risk categorization frameworks, inspection and monitoring programmes and plans.

POSSIBLE OUTCOME

Data from the integrated food chain surveillance system is routinely used to carry out multi-sectoral risk analysis that leads to the development of (or changes in) interventions.

POSSIBLE INDICATORS

- > A team of representatives from each of the relevant sectors that collects and shares data.
- > A governance structure that enables the sharing of data.
- > A database to house the integrated food chain surveillance data, with a data dictionary for each data field.
- > A data transfer mechanism to extract data from existing surveillance databases and other data sources to send them to the integrated food chain surveillance database.
- > Data analyses included in a regular surveillance bulletin that is available to all stakeholders.

SOURCES OF EVIDENCE

- > Integrated food chain surveillance database.
- > Data analysis reports.
- > Copies of regular surveillance bulletins.

SEE ALSO

- B.2.2** [Food-borne disease surveillance]
D.1.2.6 [Data from routine inspection, monitoring and surveillance programmes are used to inform risk analysis activities]
D.1.3.2 [CAs use risk ranking approaches to target resources for risk management]
D.1.3.6 [Quantitative risk assessments are conducted]
D.1.3.8 [Risk assessments and risk management measures are periodically re-assessed and updated as necessary]

D.1.2.6

ASSESSMENT CRITERION: Data from routine inspection, monitoring and surveillance programmes are used to inform new or current risk analysis activities.

**GUIDANCE**

Where food safety monitoring (food chain) and surveillance (public health data) programmes are implemented and operational, they will produce information and data that can be useful for reviewing risk assessment investigations or to inform the overall risk analysis activities of the CAs responsible for food control. When these data are not available, data stemming from routine inspection programmes are good places to start with for building a data pool. These data could inform either new risk analysis activities or the review of current risk analysis activities. Data are likely to be produced by a number of different CAs through the sampling plans for which they are responsible and should be shared and jointly considered by other relevant CAs or risk assessment bodies. In a number of instances, this joint review could lead CAs responsible for producing this information to subsequently review aspects of their data collection process to adjust the quality of information produced for better use. A consolidated approach among CAs will ensure that the entire food chain is taken into consideration (Ref. para 36 of **CXG 82-2013**).

POSSIBLE OUTCOME

Risk analysis activities are up-to-date and of good quality and take a holistic view of the food supply and alternative exposure routes.

POSSIBLE INDICATORS

- > Availability of data and processed results of monitoring and surveillance programs (in particular, prevalence and impacts of significant hazards).
- > Evidence that these data are processed to inform risk analysis activities, whether risk assessments or risk management (either for new information or for the review of established information).

SOURCES OF EVIDENCE

- > Data from monitoring and surveillance programmes (produced by a number of different CAs through the sampling plans they are responsible for).
- > Documentation that clearly links the data from surveillance and control programmes with the risk analysis activities.

SEE ALSO

- B.2.1.2** [The risk ranking processes drive the development of the national food safety and quality monitoring programme]
- B.2.1.4** [The national monitoring programme is informed by an FBO risk categorization framework]
- 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.2.2.4** [Capacity to undertake rapid risk assessments of acute public health events exists at the national and subnational levels]
- D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]
- D.1.3.6** [Quantitative risk assessments are conducted]

D.1.2.7



ASSESSMENT CRITERION: The CAs identify data needs for risk assessments and generate the data needed.

GUIDANCE

For a government that has the policy and capacity to conduct its own risk assessment activities, the risk management question, and the subsequent risk assessment commissioning and development process, should inform the specific data requirements. This makes it possible to conduct a valid risk assessment and to ensure appropriate risk management and communication.

POSSIBLE OUTCOME

Risk assessment activities directly address risk management questions and uncertainty or variability in risk estimates and foster further data collection.

POSSIBLE INDICATORS

- > Evidence of data requirements published during the commissioning of a risk assessment.
- > Evidence of data generated to fill the most significant data gaps.

SOURCES OF EVIDENCE

- > Risk assessment documents.

SEE ALSO

- D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]
D.1.3.6 [Quantitative risk assessments are conducted]

D.1.2.8

ASSESSMENT CRITERION: Targeted research studies are conducted to attribute food sources to specific diseases, understand FBD epidemiology and estimate the burden of FBD on the community.



GUIDANCE

There may be occasions when the existing surveillance system cannot answer some important questions in relation to FBD – for example:

- i. What proportion of diarrhoeal illness in a given community is caused by pathogens that might be food-borne?
- ii. We see outbreaks of a particular type of Salmonella, but our surveillance system tells us there are sporadic cases, too. Is the food item responsible for the outbreaks also causing the sporadic cases?
- iii. What proportion of Shiga toxin-producing *E. coli* (STEC) cases reported to the surveillance system are food-borne?
- iv. Do the types of *Campylobacter* found in humans also occur in foods or in animals? What proportion of *Campylobacter* cases reported to the surveillance system may be attributed to chicken meat?

Ad hoc research studies can answer some of these questions. The types of ad hoc studies that countries should be able to undertake include aetiological studies, risk factor studies, burden of disease studies, source attribution studies, pathogen prevalence along the food chain and total diet studies.

In light of a gap in knowledge about FBD that the surveillance and response system cannot address, it may be necessary to conduct an ad hoc study. There are many ways to approach such a study, but the following characteristics should be common to all:

- i. Clear focus (e.g. a specific question to answer) and objectives, reflected in the ToRs for the study to be undertaken.
- ii. Relevant experts involved, who are familiar with research methods, FBD and the context in which the study will be undertaken, under appropriate leadership. Experts should include government staff and academics from the university sector, as a minimum.
- iii. Appropriate methods, related to the study question.
- iv. Appropriate funding and other resources.

- v. Ethical considerations included (e.g. prior approval from a human research ethics committee).
- vi. Clear outcomes achieved, which should be anticipated, so that the relevant experts are involved since the beginning. (For example, is the study likely to lead to a policy change in relation to food safety or regulation? If so, food safety experts will need to be part of the working group to ensure that the outcomes can be used to influence policy change).

For further guidance, refer to the WHO publications (Hald *et al.*, 2016; EFSA, FAO and WHO, 2011; WHO, 2009, 2015).

POSSIBLE OUTCOME

Ad hoc studies are conducted to provide information for risk management outside of acute situations.

POSSIBLE INDICATORS

- > There is a CA that is responsible for initiating and resourcing such ad hoc studies and can implement the findings.
- > There is a mechanism in place for discussing, agreeing, implementing and managing the types of targeted research studies that need to be undertaken in the country.

SOURCES OF EVIDENCE

- > Ad hoc research studies (aetiological studies, risk factor studies, burden of disease studies, source attribution studies, pathogen prevalence along the food chain and total diet studies).

SEE ALSO

- D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]
- D.1.3.6** [Quantitative risk assessments are conducted]

D.1.2.9

ASSESSMENT CRITERION: CAs generate burden of FBD estimates that integrate disease incidence and severity data with attribution to food-borne transmission, as the best evidence for risk prioritization.

**GUIDANCE**

Burden of disease estimates and attribution to food-borne transmission represent the strongest foundation for risk prioritization for food safety resources, but require considerable local data from food monitoring and FBD surveillance. The recent WHO publication on the **Estimate of the Global Burden of Foodborne Disease** can facilitate the development of national estimates by filling data gaps. Nevertheless, local data should always be assembled and reviewed first. The process of conducting (or attempting) a national FBD study can provide information to support national food safety and quality policy development, and stimulate further research to fill data gaps. For example, considering the relative importance of food-borne and water-borne transmission of enteric diseases can inform policy. Any burden of FBD study must consider the entire range of food-borne hazards: microbial, parasitic and chemical.

POSSIBLE OUTCOME

A national burden of FBD study provides estimates for burden-based allocation of resources and develops national capacity in risk prioritization.

POSSIBLE INDICATORS

- > Incidence data on FBD assembled and adjusted for under-reported factors, to estimate community incidence.
- > Hospitalization and mortality data examined for cases caused by FBD.
- > Engagement with the WHO Food-borne Disease Epidemiology Reference Group.

SOURCES OF EVIDENCE

- > Incidence data.
- > Data analysis.
- > Correspondence with the WHO Food-borne Disease Epidemiology Reference Group.

D.1.3**KNOWLEDGE AND USE BY CAs OF RISK
ANALYSIS FRAMEWORK****OVERALL OUTCOME**

CAs appropriately use the risk analysis framework to quantify food safety risks and use the outputs to plan and cyclically refine their food safety official controls.

D.1.3.1

ASSESSMENT CRITERION: CAs demonstrate sound understanding of risk analysis principles and commitment to the risk management framework in processes and outputs, as appropriate, pertaining to legislation, standard setting, policies, guidance, etc.

GUIDANCE

In the context of modern governance of food safety, it is important that CAs integrate risk analysis principles in legislation, but also in their day-to-day operations, adopting a risk management framework (FAO and WHO, 2006) for their decision-making processes and actions. Risk analysis is a conceptual framework to identify and guide implementation of strategic approaches to support achievement of food control policy goals. Risk analysis is about understanding food safety risks and the choices available for effective control of these risks. It is also about the management and communication of risks while achieving maximum public health benefit balanced against cost. This is of particular importance when resources are scarce.

Risk analysis can materialize through different approaches, the simplest being to appropriately base the national risk management decision-making processes on the results of risk assessment carried out at a regional or international level – for example, those carried out by the joint FAO/WHO expert committees (e.g. on food additives and contaminants, by JECFA; on pesticide residues, by JMPR; on microbiological risk assessment, by JEMRA; and other ad hoc expert consultation outputs from the FAO/WHO scientific advice programme). If the country carries out its own risk analysis it is important that risk assessment and risk management take into account relevant production, storage and handling practices used throughout the food chain including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects (Ref. para 25, 33 of **CXG 62-2007**).

Moreover, the risk management process should be transparent, consistent and fully documented. Decisions on risk management should be documented so as to facilitate a wider understanding of the risk management process by all interested parties (Ref. para 35 of **CXG 62-2007**). The scope and purpose of the risk assessment being carried out should be clearly stated (Ref. para 21 of **CXG 62-2007**) and the risk management options should be assessed in terms of the scope and purpose of risk analysis and the level of consumer health protection they achieve (Ref. para 37 of **CXG 62-2007**). Examination of the full range of risk management options should, as far as possible, take into account an assessment of their potential advantages and disadvantages.

Risk communication should be more than the dissemination of information. Its major function should be to ensure that all information and opinions required for effective risk management are incorporated into the decision-making process. It is important that risk communication include a transparent explanation of the risk assessment policy; the assessment of risk, including the uncertainty; the decisions taken and the procedures followed to reach them, including how the uncertainty was dealt with.

It should indicate any constraints, uncertainties, assumptions and their impact on the risk analysis, as well as minority opinions that have been expressed in the course of the risk assessment. This will increase awareness and understanding of the specific issues under consideration during the risk analysis and promote the appropriate involvement of all interested parties (Ref. para 40, 42, 43 of **CXG 62-2007**).

POSSIBLE OUTCOME

Food safety and quality policy, food control legislation and related guidance incorporate principles of risk analysis within a risk management framework.

POSSIBLE INDICATORS

- > All CAs showing a good general knowledge of the risk analysis framework applied to food.
- > Legislation that includes reference to risk analysis.
- > Evidence that the elements of risk analysis are being implemented in practice.
- > A national risk management decision-making process based on the results of risk assessments carried out at regional or international level (e.g. by JECFA, JMPR, JEMRA).
- > Documented decisions on risk management.
- > Documented and clearly stated scope and purpose of past risk assessment.
- > Evidence that risk assessment and risk management take into account relevant production, storage and handling practices used throughout the food chain (including traditional practices, methods of analysis, sampling and inspection and the prevalence of specific adverse health effects).

- > Adaptation of Codex standards to the national context by using national exposure data (food consumption and contamination data).
- > Availability of transparent explanations of:
 - i. The risk assessment policy;
 - ii. The assessment of risk;
 - iii. Constraints, uncertainties, assumptions and their impact on the risk analysis;
 - iv. Decisions taken;
 - v. The procedures followed to reach them, including how the uncertainty was dealt with;
 - vi. Minority opinions that were expressed in the course of the risk assessment.

SOURCES OF EVIDENCE

- > Legislation, policy documents, and manuals for the food safety sectors where the risk analysis framework is outlined and applied.
- > Interviews with CAs.
- > Risk assessment and risk management documents.

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]
 - A.1.3.6** [Legislation includes provisions for setting import requirements]
-

D.1.3.2**ASSESSMENT CRITERION: CAs use risk ranking approaches to target resources for risk management** (FAO, forthcoming).**GUIDANCE**

Within any country, there will be food safety hazards that have historically resulted in a burden upon public health and which are known for that by CAs. Other hazards may be more “silent” in terms of public recognition – due, for example, to lack of data, difficulty in connecting a long-term multi-factorial illness to a single food safety issue, possible cultural bias or other factors. It is important that the government has valid data about the real prevalence and impact of hazards affecting the food chain, and that those data are used to prioritize resource utilization. Situations where government budgets are dedicated to the control of pathogens or hazards based simply upon prior reputations (or ongoing or media-based reputations) should be avoided. Rather, statistical and epidemiological evidence on food safety hazards or hazard/food combinations should be used to prioritize resource allocation. Data to prioritize risks may come from surveys or ad hoc data collection efforts (D.1.2.4) or from routine monitoring and surveillance systems (D.1.2.5). Information from FBD surveillance should also be considered (D.1.2.7 and D.1.2.8). The government should ensure that these food safety hazards (which are demonstrated to be both significant and present) are fully addressed in the planning of official food safety controls of all types and for all sectors. This would allow allocating resources to the management of those risks that have a real impact, contributing to the achievement of the food safety policy objectives.

Risk ranking approaches have been developed, supported by increasingly complex metrics, which can be used by countries at different levels of maturity – in particular, with regard to availability of data. These approaches will be increasingly quantitative and able to capture quality, uncertainty and data gaps in a more or less sophisticated manner.

For the purpose of measuring this assessment criterion, it should be noted that:

- i. Risk ranking here only concerns food safety risks with regard to public health (i.e. approaches incorporating other factors, like food security concerns, economic impact, feasibility of the control measures, etc., are considered under risk prioritization approaches) (see D.1.3.6);
- ii. The assessment should also take into account the appropriateness of the risk ranking approach used with respect to the quality and quantity of data available about risks.

POSSIBLE OUTCOME

Food control activities focus on risks of major significance and contribute to the achievement of the food safety and quality policy overarching objectives.

POSSIBLE INDICATORS

- > Evidence of a ranking process.
- > Results of ranking processes for hazard/food combinations of importance.
- > Food safety hazards identified as significant addressed with active food safety official controls along the food value chains.

SOURCES OF EVIDENCE

- > Reports of relevant scientific investigations of food safety hazards considered to be locally present and significant.
- > Strategic or planning documents addressing identified food safety hazards.

SEE ALSO

- B.1.2.3** [CAs design a coherent risk-based import control programme based on relevant information and responsive to evolving situations]
- B.2.1.2** [The risk ranking processes drive the development of the national food safety and quality monitoring programme]
- B.2.1.4** [The national monitoring programme is informed by an FBO risk categorization framework]
- D.1.2.4** [CAs identify and collect data on country-specific hazard and commodity combinations]
- 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.1.2.6** [Data from routine inspection, monitoring and surveillance programmes are used to inform new or current risk analysis activities]
- D.1.2.7** [The CAs identify data needs for risk assessments and generate the data needed]
- D.1.2.8** [Targeted research studies are conducted to attribute food sources to specific diseases, understand FBD epidemiology and estimate the burden of FBD on the community]
- D.1.3.4** [CAs have collaborated to produce a risk categorization framework of FBOs]
- D.1.3.6** [Quantitative risk assessments are conducted]

D.1.3.3

ASSESSMENT CRITERION: When necessary, CAs use risk profiles to guide and inform the deployment of resources into official controls.

**GUIDANCE**

When CAs are clear about which food product/hazard pairs present significant risks, risk profiles are a useful tool to assist in the planning of official assessment and control activities. Risk profiles (FAO and WHO, 2006) provide a more systematic and formalized basis for bringing together the risk management context and the information needed to describe the problem posed by specific hazard/food combinations. The risk profile can provide an early assessment of risk and potential risk management options, which may be sufficient for action, or outline the data and information required for a more in-depth risk assessment. It should be noted that the level of detail of risk profiles, as well as their structure, vary widely. Some risk profiles are structured similarly to the steps of a risk assessment, while some others are structured around key questions and issues that risk managers need to know.

As the surveillance and response system for FBD is strengthened, countries will be able to use the surveillance data to contribute to risk profiling. It is important that surveillance data from humans can be combined with food monitoring and consumption data and other key information from across the food chain to improve the quality of risk profiles. Effective multi-sectoral collaboration is required if data are to be shared and joint analysis and interoperation undertaken. When ad hoc studies are planned that may contribute to risk profiles, the relevant sectors should be involved in the planning and implementation.

POSSIBLE OUTCOME

A library of risk profiles is created that informs policy and risk management decision-making.

POSSIBLE INDICATORS

- > CAs have performed or commissioned risk profiles relevant to the hazard/food combinations of importance in the country.
- > There is evidence of further risk assessment or risk management actions, taken as a result of risk profile activity.
- > There is evidence of multi-sectoral collaboration to provide data supporting the elaboration of risk profiles.

SOURCES OF EVIDENCE

- > Risk profiles.
- > Correspondence among different CAs/sectors for data sharing, joint analysis and ad hoc studies preparation.

SEE ALSO

- B.1.1.5** [Inspection plans are based on a well-documented risk categorization framework]
B.1.2.3 [CAs design a coherent risk-based import control programme based on relevant information and responsive to evolving situations]

D.1.3.4

**ASSESSMENT CRITERION: CAs have collaborated to produce a risk categorization framework of FBOs.**

GUIDANCE

Risk categorization frameworks are tools that help CAs to classify FBOs and food sectors in terms of their potential risks. They can be used to:

- i. Improve the risk-based planning of domestic inspection (see **B.1.1.5**) or import controls (see **B.1.2.1** and **B.1.2.3**).
- ii. Require specific measures applicable to specific FBOs for export of high-risk products (see **B.1.3.3**).
- iii. Guide the planning of the sampling approach for monitoring programmes (see **B.2.1.4**).

Risk categorization frameworks should be connected to the identification of priority risks, as a result of the risk ranking process (see **D.1.3.2**), and should integrate specific information about FBOs.

A risk categorization framework will take into account elements such as (Ref. para 50 of **CXG 82-2013**):

- i. Food safety hazards associated with different products and the risk to human health posed by the food products;
- ii. Risks of unfair practices in the food trade, such as potential fraud or deception of consumers, associated with different products;
- iii. Statistical data on production, trade and consumption;
- iv. Results of previous controls;
- v. Effectiveness of previous controls, including analytical results;
- vi. Effectiveness and reliability of FBOs' controls;

- vii. Knowledge of operators at various stages of the food chain;
- viii. Typical and atypical use of products, raw materials and by-products;
- ix. Structure of production and supply chains;
- x. Production technologies, processes and practices;
- xi. Relevant product tracing information;
- xii. Epidemiological data on FBD.

POSSIBLE OUTCOME

Registered FBOs are inserted into a risk-based inspection programme.

POSSIBLE INDICATORS

- > Food safety hazards have been identified in relation to specific FBOs' typologies/food sectors and ranked.
- > Different risk categories of FBOs have been defined based on food safety hazard ranking, but also taking into account other factors, such as:
 - i. Risks of unfair practices in the food trade;
 - ii. Statistical data on production, trade and consumption;
 - iii. Results of previous controls;
 - iv. Structure of production and supply chains;
 - v. Production technologies, processes and practices;
 - vi. Epidemiological data on FBD.

SOURCES OF EVIDENCE

- > Documented evidence of ranking processes for FBOs/food sectors of importance.
- > List of FBOs categories connected to priority risks.

SEE ALSO

- B.1.1.5** [Inspection plans are based on a well-documented risk categorization framework]
- B.1.2.1** [Importers are identified through a registration system and importer compliance profiles are established over time]
- B.1.2.3** [CAs design a coherent risk-based import control programme based on relevant information and responsive to evolving situations]
- B.1.3.3** [A specific authorization or licensing scheme is in place for specific FBOs targeting exports]
- B.2.1.4** [The national monitoring programme is informed by an FBO risk categorization framework]
- C.1.2.3** [High-risk FBOs are provided with special communication channels ensuring that CAs' messages are delivered to FBOs]
- D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]

D.1.3.5



ASSESSMENT CRITERION: Risk assessments are being conducted and they deliver scientifically defensible risk estimates (qualitative or semi- quantitative).

GUIDANCE

The risk analysis framework requires specific capacities to deliver scientifically valid risk assessments, whether at a qualitative or semi-quantitative level. The sophistication of the risk assessment is closely related to the pool of data available – the more specific and detailed (e.g. individual data consumption, specific public health data, such as Disability-Adjusted Life Years, DALYs), the higher the quality of the output of the assessment can be. This should not be confused with the quality of data (see D.1.2.3). For the purpose of this criterion, some of the capacities that should be considered during the assessment are: (i) the knowledge and in-depth understanding of the steps recommended by Codex Alimentarius for risk assessments (hazard identification, hazard characterization, exposure assessment and risk characterization); as well as (ii) critical capacity to consider the quality of data used. In addition, when assessing risks, there should be good communication with stakeholders so that the resulting risk estimates can be used subsequently to actively manage risks. The conclusion of the risk assessment, including a risk estimate, if available, should be presented in a readily understandable and useful form to risk managers and made available to other risk assessors and interested parties so they can review the assessment. In some countries risk assessments are conducted by entities other than (public) CAs, as private entities (or academia) can deliver this service to the CAs.

Data gaps, assumptions, constraints and uncertainty in the risk estimates and their impact on the risk assessment should also be explicitly considered at each step in the risk assessment and documented in a transparent manner. They should also be included in the final risk assessment document, so as to inform the data required for further refinement of the risk assessment (Ref. para 26 and 28 of CXG 62-2007). Expression of uncertainty or variability in risk estimates may be qualitative or quantitative, but should be quantified to the extent that is scientifically achievable.

Precaution is also an inherent element of risk analysis. Many sources of uncertainty exist in the process of risk assessment and risk management of food-related hazards to human health. The degree of uncertainty and variability in the available scientific information should be explicitly considered in the risk analysis. The assumptions used for the risk assessment and the risk management options selected should reflect the degree of uncertainty and the characteristics of the hazard (Ref. para 12 of CXG 62-2007).

Note: AC **D.1.3.5** and AC **D.1.3.6** both assess the existence and robustness of risk assessments; **D.1.3.5** focuses on qualitative or semi-quantitative risk assessment, while **D.1.3.6** acknowledges the availability of quantitative risk assessments.

POSSIBLE OUTCOME

Risk assessment outputs are supporting risk management decision-making processes.

POSSIBLE INDICATORS

- > CAs able to demonstrate that risk assessments are occurring.
- > Meaningful outputs reached for each risk assessment component, even if only qualitative or semi-quantitative.
- > Knowledge and in-depth understanding by CAs of the steps recommended by Codex Alimentarius for risk assessment (hazard identification and characterization, exposure assessment and risk characterization).
- > Any documented information on data gaps and the value of filling those gaps, as determined by the impact that the gaps have on the final risk conclusions.
- > Any documented information on the assumptions, constraints and uncertainty in the risk estimates and their impact on the risk assessment.

SOURCES OF EVIDENCE

- > Risk assessment documents.
- > Interviews with the CAs.

SEE ALSO

D.1.2 [Capacity to collect and analyse data for risk analysis purposes]

D.1.3.6**ASSESSMENT CRITERION: Quantitative risk assessments are conducted.****GUIDANCE**

CAs that have developed infrastructures and capacities to collect sufficiently specific data should be able to perform quantitative risk assessments. In so doing, they should take into account the international recommendations (e.g. Codex) and the work must be performed with the requested scientific quality.

Note: AC D.1.3.5 and AC D.1.3.6 both assess the existence and robustness of risk assessments; D.1.3.5 focuses on qualitative or semi-quantitative risk assessment while D.1.3.6 acknowledges the availability of quantitative risk assessments.

POSSIBLE OUTCOME

Scientific quantitative risk assessments are conducted to a high level of quality.

POSSIBLE INDICATORS

- > The government performs its own quantitative food safety risk assessments.
- > Quantitative risk assessment is performed according to internationally recommended standards (e.g. Codex).

SOURCES OF EVIDENCE

- > Risk assessments.

SEE ALSO

- D.1.2.3** [CAs monitor data collection and processing, performing data quality controls]
- D.1.2.6** [Data from routine inspection, monitoring and surveillance programmes are used to inform new or current risk analysis activities]
- D.1.2.7** [The CAs identify data needs for risk assessments and generate the data needed]
- D.1.2.8** [Targeted research studies are conducted to attribute food sources to specific diseases, understand FBD epidemiology and estimate the burden of FBD on the community]
- D.1.3.2** [CAs use risk ranking approaches to target resources for risk management]

D.1.3.7**ASSESSMENT CRITERION: Advanced techniques are applied to management of food safety risks.****GUIDANCE**

Risk management decisions should be based on risk assessment and should be proportionate to the assessed risk, taking into account, where appropriate, other legitimate factors relevant for consumer health protection and for the promotion of fair practices in food trade (in accordance with the “Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principles”¹) as they relate to decisions at the national level. In some cases, risk management decisions will be clear-cut, based on evidence of effective controls in other countries, or on the availability of practical, low-cost or singular risk management options. In some other cases, the situation may be more complex; social circumstances, economic considerations, feasibility of different risk management options and impacts on food security are other factors that provide additional context to the public health consideration, to be incorporated into the concept of risk. In these situations, advanced quantitative analytical tools can be useful in providing frameworks for decision-making that are robust, transparent to stakeholders and repeatable – for example, techniques such as multi-criteria or multi-factor decision analysis, cost-benefit analysis and risk-benefit analysis. This framework can be used when making choices about focusing efforts on specific risks versus others (this would be about risk prioritization, as opposed to risk ranking; see **D.1.3.2**) or to compare different risk management options.

POSSIBLE OUTCOME

Risk management measures are supported by leading-edge analytical processes.

POSSIBLE INDICATORS

- > Documentary evidence of analytical approaches being used in risk management decision-making (process documents, reports, etc.).
- > Use of advanced quantitative analytical tools such as multi-criteria/multi-factor decision analysis, cost-benefit analysis, risk-benefit analysis.
- > Structured and transparent reports of analysis based on advanced quantitative analytical tools.

¹ See: *Statements of Principle Concerning the Role of Science in the Codex Decision Making Process and the Extent to which other Factors are Taken in to Account*, Appendix of Codex Alimentarius Commission Procedural Manual, Fourteenth Edition.

SOURCES OF EVIDENCE

- > Reports of analysis based on advanced quantitative analytical tools (multi-criteria/multi-factor decision analysis, cost-benefit analysis, risk-benefit analysis, etc.).

SEE ALSO

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

D.1.3.8

ASSESSMENT CRITERION: Risk assessments and risk management measures are periodically re-assessed and updated as necessary.

GUIDANCE

Overarching policy objectives for achieving the appropriate level of protection for consumers should have valid and verified scientific foundations. For governments that have successfully adopted risk analysis into their strategy for implementation of official food safety controls, it is necessary to iteratively improve the quality of the risk assessments and their use in risk management, by using appropriate review procedures (Ref. para 20 of **CXG 82-2013**). It should be borne in mind that changes in food safety risk are inevitable and so risk analysis work performed in the past will need to be updated. New data or information (e.g. new data, updated standards, guidelines and other information in accordance with policy objectives) stemming from the implementation of controls can be used to update risk assessments. Risk management measures can likewise be updated on the basis of new information or data affecting the risk and leading to revision of the risk assessment in a continuous process. For example, new data may lead to changes in risk management measures in order to achieve the policy objectives committed to by the government. Hence, the relevance, effectiveness and impacts of risk management decisions and their implementation should be monitored regularly and the decisions and/or their implementation reviewed as necessary (Ref. para 39 of **CXG 62-2007**). The outputs of these revisions should also be used in the development of subsequent annual inspection plans.

POSSIBLE OUTCOME

Risk assessments and risk management measures are periodically re-assessed.

POSSIBLE INDICATORS

- > Established practice of review for risk assessments and risk management in place.
- > Evidence that such reviews have resulted in alterations in risk communication and/or alterations in some aspect of official controls when necessary.

SOURCES OF EVIDENCE

- > Planning documents and reports of reviews of risk assessments and management.

SEE ALSO

- B.1.1.5** [Inspection plans are based on a well-documented risk categorization framework]
- 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]
- D.1.2.5** [Data from routine inspection, monitoring and surveillance programmes are used to inform new or current risk analysis activities]

D.1.3.9

ASSESSMENT CRITERION: Units conducting risk assessment and risk management are functionally separated, and CAs and experts involved in risk assessment are not subject to any conflict of interest.

**GUIDANCE**

Risk assessment is a scientific process, designed to draw conclusions on risk (impact and likelihood of an undesirable event) and to provide specific advice about risk management options (for example, comparing impacts of different measures). Risk assessment is based on the data required to undertake the steps of hazard identification and characterization, exposure assessment and risk characterization, whereas decisions on risk management require additional considerations (e.g. the practicability and cost of risk management measures, as well as stakeholder and other political concerns). It is important that these considerations do not unduly influence the risk assessment process, and that they are discussed and documented separately from the risk assessment. Therefore, to the extent that it is practicable, these two functions should be separate and each function should carry out work independently, although informed by the other. Where resources are limited, and the same personnel are required to carry out both functions, functional separation can be achieved by carrying out tasks independently and documenting the processes as such.

CAs and experts involved in risk assessment should be objective in their scientific work and not be subject to any conflict of interest that may compromise the integrity of the assessment. Information on the identities of these experts, their individual expertise and their professional experience should be publicly available, subject to national considerations. These experts should be selected in a transparent manner on the basis of their expertise and their independence with regard to the interests involved, including disclosure of conflicts of interest in connection with risk assessment (Ref. para 22 of **CXG 62-2007**).

POSSIBLE OUTCOME

The integrity of risk assessment as a scientific and objective exercise is protected.

POSSIBLE INDICATORS

- > Evidence that risk assessment and risk management functions are independent of each other in organizational structure.
- > Evidence of a process setting out the functional separation of risk assessment and risk management tasks.
- > Publicly available information on the identities, expertise and professional experience of the experts involved in risk assessment.

SOURCES OF EVIDENCE

- > Documents/reports on risk management decisions and risk assessment.
- > Documents on the selection process for the experts carrying out the risk assessment.
- > Interviews with relevant CAs.

SEE ALSO

A.3.3.5 [CAs maintain sustainability of programmes and internal stability even in times of political change]



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D.2

CONTINUOUS IMPROVEMENT

COMPETENCY D.2.1 PERFORMANCE MONITORING OF CAs AND CONTINUOUS IMPROVEMENT

| OVERALL OUTCOME | CAs implement an array of tools and approaches to regularly review and improve performance and ensure that relevant outcomes are achieved. |
|-----------------|--|
| D.2.1.1 | Within CAs, there is organizational commitment to monitoring performance. |
| D.2.1.2 | CAs' processes have specific outcomes that can be monitored and evaluated. |
| D.2.1.3 | CAs have created a monitoring plan supporting the measurement of performance. |
| D.2.1.4 | CAs implement a performance monitoring plan and use the data produced to improve processes and achievement of outcomes. |
| D.2.1.5 | The CAs responsible for official controls for food safety have instigated internal audits of official control processes. |
| D.2.1.6 | The CAs responsible for official controls for food safety have written policies to use external audit of business processes to improve public services and these policies are implemented. |

COMPETENCY D.2.2 MECHANISM TO ENSURE CONSIDERATION OF NEWEST SCIENTIFIC AND TECHNICAL INFORMATION FOR FOOD CONTROL

| OVERALL OUTCOME | The national food control system benefits from most recent scientific and technical knowledge to ensure relevance of overall outcomes. |
|-----------------|---|
| D.2.2.1 | There are fruitful working links between the CAs and academia, universities, technical institutes and other expert groups (e.g. scientific committees), with the objective of generating relevant information for assessing and responding to food safety and fraud issues. |
| D.2.2.2 | CAs adopt foresight techniques to support a preventative approach to food control, early identification of emerging and critical issues and implementation of effective policies and decision-making. |

D.2.1**PERFORMANCE MONITORING OF CAs AND
CONTINUOUS IMPROVEMENT**

CAs implement an array of tools and approaches to regularly review and improve performance and ensure that relevant outcomes are achieved (Ref. para 20, 55, 56 and 84 of CXG 82-2013).

OVERALL OUTCOME**D.2.1.1**

ASSESSMENT CRITERION: Within CAs, there is organizational commitment to monitoring performance.

**GUIDANCE**

The policy setting, implementation and other technical components of a national food control system should operate effectively over the course of time and have the capacity to undergo continuous improvement (Ref. para 20 of CXG 82-2013 and para 2 of CXG 91-2017). The monitoring of the system as a whole calls on the CAs to regularly assess their effectiveness and appropriateness in achieving their assigned objectives (Ref. para 55 and 56 of CXG 82-2013 and para 3 of CXG 91-2017), contributing to protecting the health of consumers and ensuring fair practices in food trade. For optimal monitoring, these objectives should be integrated into a coherent policy framework and should be based on a sound policy (A.1.1.1) and reflected in outputs and activities of strategic plans (A.1.1.2) (Ref. para 22 of CXG 91-2017). The commitment of the different CAs to monitoring and reviewing the national food control system should be rooted in a sound understanding of:

- i. How different CAs contribute to the policy objectives of the system;
- ii. The support needed internally for performance monitoring (i.e. the systems and processes that can support data collection and the data quality control functions) (Ref. para 23 of CXG 91-2017);
- iii. The use that can be made of the data collected (need for data analysis to measure performance assessment and reporting systems);
- iv. The resources needed (financial resources, internal competencies in strategic planning, performance management, data analysis, etc.) (Ref. para 24 of CXG 91-2017) (Ref. para 82 of CXG 82-2013).

POSSIBLE OUTCOME

Performance monitoring benefits continuous internal support and is facilitated by adequate resources.

POSSIBLE INDICATORS

- > CAs demonstrate commitment to the monitoring and review function of the national food control system.
- > CAs regularly assess their effectiveness in achieving their assigned objectives.
- > There are reporting systems in place.

SOURCES OF EVIDENCE

- > Documents stating CAs' objectives (policies, strategic plans, etc.).
- > Data analysis to measure performance.
- > Reports on CAs' performance/achievement of objectives.
- > Interviews with CAs.

SEE ALSO

- A.1.1.1** [Clear policy guidance is available for food safety and quality]
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]

D.2.1.2



ASSESSMENT CRITERION: CAs' processes have specific outcomes that can be monitored and evaluated.

GUIDANCE

Measuring outputs resulting from activities performed by CAs is not sufficient and a sound system monitoring and review process should integrate the measurement of outcomes – i.e. the intended effects of outputs (Ref. para 28 to 37 **CXG 91-2017**). Outcomes are useful to support informed decisions, improve targeting of programmes and review their implementation modalities and arrangements, supported by adequate resources. Outcomes should be specific, measurable, attainable, relevant and time-bound (SMART). It is important that relevant stakeholders be engaged to participate in the definition of the outcomes to be achieved. In defining outcomes, their contribution to the policy objectives and desired outcomes at system level should be taken into account.

A logical chain should be observed connecting the different levels of outcomes: the lowest-level outcomes should converge to contribute to the achievement of the intermediate-level outcomes, which in turn contribute to the achievement of highest-level outcomes and can be materialized in an outcome framework. However, other models for connecting outcomes, such as the theory of change, are also valid. The achievement of outcomes should be defined by activities that result in outputs or services.

POSSIBLE OUTCOME

A monitoring plan can be established to measure achievement of specific outcomes.

POSSIBLE INDICATORS

- > CAs define, measure and evaluate the outcomes of their activities.
- > Relevant stakeholders participate in the definition of the outcomes to be achieved.
- > Outcomes are specific, measurable, attainable, relevant and time-bound (SMART).
- > Identified outcomes are connected through a logical chain (or theory of change).

SOURCES OF EVIDENCE

- > Documents listing the identified outcomes.
- > Reports on outcome measurements and evaluation.
- > Interviews with CAs.

D.2.1.3



ASSESSMENT CRITERION: CAs have created a monitoring plan supporting the measurement of performance.

GUIDANCE

Monitoring plans should be established to collect information and data about the outcomes that have been identified to be monitored, in order to measure performance and achievements. Indicators are an anchor to collect such information and should be established for each outcome. They can also be established for outputs or activities (Ref. para 38 to 47 **CXG 91-2017**). Indicators serve as measurement criteria (Ref. para 82 **CXG 82-2013**) and should be un-ambiguous, transparent, easy to interpret and easy to monitor. They should be meaningful from the CAs' perspective, obtainable given the available resources and closely related to the outcomes, including in terms of timing. A monitoring plan should provide an overall framework for the data collection and analysis process for each indicator. Sources of data, frequency of data collection, methods to ensure data quality and analysis, as well as roles and responsibilities for these processes should be defined in the monitoring plan. Baseline data for each indicator should establish a starting point reflecting the current situation. Targets can either be established in terms of defining a tendency (e.g. "increase") from baseline, or expressed in specific terms that should be realized within a specific timeframe (Ref. para 48 to 52 **CXG 91-2017**).

POSSIBLE OUTCOME

The monitoring and review function is rooted in a logical and planned sequence of actions.

POSSIBLE INDICATORS

- > There is a monitoring plan that provides an overall framework for the data collection and analysis process for each indicator.
- > The monitoring plan defines sources of data, frequency of data collection and methods to ensure data quality and analysis, as well as roles and responsibilities for these processes.
- > Indicators have been established for each outcome.
- > Indicators are un-ambiguous, transparent, easy to interpret and easy to monitor.

SOURCES OF EVIDENCE

- > The monitoring plan.
- > Documents defining the indicators for each outcome.

D.2.1.4

ASSESSMENT CRITERION: CAs implement a performance monitoring plan and use the data produced to improve processes and achievement of outcomes.

**GUIDANCE**

CAs should collect data to support evidence around indicators defined for each outcome. The monitoring plan defines roles and responsibilities. Results should be presented in an understandable format for use by different audiences (Ref. para 55 of **CXG 91-2017**). This would support policy setting or iterative revisions of policy (Ref. para 50, 5th point, of **CXG 82-2013**). Different strategic activities can be performed such as (Ref. para 56 of **CXG 91-2017**):

- i. Holding regular performance review meetings to assess appropriateness of activities, relevance of outcomes and associated indicators (Ref. para 90 of **CXG 82-2013**);
- ii. Integrating performance data in the process of resource prioritization and budgeting;
- iii. Identifying best practices, gaps and other opportunities (Ref. para 86 **CXG 82-2013**) to trigger revision and update of documentation, procedures and guidance (Ref. para 91 and 92 of **CXG 82-2013**);
- iv. Reviewing the outcome framework.

POSSIBLE OUTCOME

CAs collect and use the data they need to improve the national food control system.

POSSIBLE INDICATORS

- > CAs monitor performance based on established outcomes through the collection of data and evidence.
- > CAs conduct performance review meetings to assess appropriateness of activities, relevance of outcomes and associated indicators.
- > CAs integrate performance data in the process of resource prioritization and budgeting.
- > CAs identify best practices, gaps and other opportunities based on the performance results as a feedback loop and opportunity to learn.

SOURCES OF EVIDENCE

- > Performance reports.
- > Performance review meeting reports.
- > Changes to the inspection plans/monitoring programmes.

D.2.1.5

ASSESSMENT CRITERION: The CAs responsible for official controls for food safety have instigated internal audits of official control processes.

GUIDANCE

A reliable method to assess efficiency and effectiveness of an organization that holds mandates for public service, such as the network of CAs in a government, is to conduct internal audits. This means that an experienced and senior auditor, who is employed within the organization and who understands the business process (i.e. official controls for food safety), will audit the sections of the government's work that the audit plan indicates and will provide a report with notes of good and poor performance and suggestions for improvements.

POSSIBLE OUTCOME

Internal audit of key official food control activities supports delivery of high- quality services.

POSSIBLE INDICATORS

- > Recent formal internal audit reports (including the notes of the successful elements, and those elements which have deficiencies or could be improved).
- > The recommendations made.

SOURCES OF EVIDENCE

- > Internal audit reports.
- > Written recommendations.

D.2.1.6

ASSESSMENT CRITERION: The CAs responsible for official controls for food safety have written policies to use external audit of business processes to improve public services and these policies are implemented.

**GUIDANCE**

Organizations can arrange and manage themselves and can assess their own efficiency and effectiveness. However, people are subjective in judgments. A reliable method to assess internal efficiency and effectiveness is to conduct an independent external audit. This means that an experienced auditor, who is not employed within the organization or CAs (but who understands the business processes and official controls for food safety), will come to audit the components of the government's work that the government or heads of CAs identify for audit. An audit can be performed to support a process of certification with regard to a given standard (e.g. ISO 17020: General criteria for the operation of various types of bodies performing inspection; ISO 17025: General requirements for the competence of testing and calibration laboratories).

POSSIBLE OUTCOME

External audits of business processes highlight issues that can be managed to ensure improved delivery of public services.

POSSIBLE INDICATORS

- > Written policy document that explains the policy and the extent to which external audit is to be used (i.e. which sections of the government or CAs will be audited for their performance in supporting food safety controls).
- > Formal evidence of external audit reports to relevant standards (e.g. ISO 17020, 17025, 9001) that point out instances of poor performance, or which recommend improvements.

SOURCES OF EVIDENCE

- > Written policy to use external audit of business processes.
- > External audit reports.

SEE ALSO

A.2.3.7 [Designated food control laboratories are accredited ISO 17025 (testing laboratories) and ISO 15189 (clinical laboratories) by internationally recognized bodies]

D.2.2**MECHANISM TO ENSURE CONSIDERATION
OF NEWEST SCIENTIFIC AND TECHNICAL
INFORMATION FOR FOOD CONTROL****OVERALL OUTCOME**

The national food control system benefits from the most current scientific and technical knowledge to ensure continuous relevance of its overall outcomes (Ref. para 26 of CXG 82-2013).

D.2.2.1

ASSESSMENT CRITERION: There are fruitful working links between the CAs and academia, universities, technical institutes and other expert groups (e.g. scientific committees), with the objective of generating relevant information for assessing and responding to food safety and fraud issues.

GUIDANCE

Scientific knowledge about food and food safety hazards and fraud and the best methods to control these is always advancing, largely due to academic and research activities conducted by universities and technical institutes. Governments need to be aware of current knowledge and new developments and results derived from research and must be able to access “pure” science, as well as “applied science and technology”, in order to implement the best and most scientifically and technologically advanced systems of food control and surveillance. The advantages that arise are beneficial for both CAs and academia; thus such links are complementary and mutually supportive (Ref. para 15 and 50, 3rd point, of CXG 82-2013).

POSSIBLE OUTCOME

Synergies, complementarities and support mechanisms arise from links with universities, technical institutes and other expert groups.

POSSIBLE INDICATORS

- > CAs having developed formal working relationships with the food safety research sector.
- > Evidence of exchanges of data for a food safety purpose.
- > Training courses for CA staff provided by university.

SOURCES OF EVIDENCE

- > Project proposal documents.
- > Research contracts.
- > Data exchange documents.
- > Training course documentation.

SEE ALSO

- D.1.1.3** [CAs actively collaborate with one or more Centres of Excellence or Reference Centres for food safety and staff participate in professional associations]
-

D.2.2.2



ASSESSMENT CRITERION: CAs adopt foresight techniques to support a preventative approach to food control, early identification of emerging and critical issues and implementation of effective policies and decision-making.

GUIDANCE

Foresight can be described as a systematic, participatory and multidisciplinary approach to exploring medium to long-term futures and drivers for change. This is both a process and an approach requiring broad thinking and resulting in the generation of multiple scenarios and ideas. These can then be further developed and serve as the basis for shaping policy and taking relevant action. Foresight is about providing space to various stakeholders and experts to develop anticipatory and participatory knowledge. It is used to identify multiple future scenarios and explore future changes quantitatively and qualitatively, by anticipating and analysing possible developments and challenges.

Foresight is increasingly employed to improve policy preparedness and prevention-based policy approaches. The main aim of foresight in food control is to anticipate emerging and critical risks that are the long-term outcomes of a range of operational and environmental factors that could occur in the future.

Foresight can also be used to support processes for strategic planning, formulating a vision for the future, improving decision-making and evaluation, effecting organizational transformation, influencing public attitudes, generating policy options, mapping policy effects in advance, forming coalitions across stakeholder groups, etc.

Foresight in food control can support the identification of emerging and critical food safety issues or fraud – in terms of risks as well as opportunities. Applying foresight can support the implementation of adequate and effective policy and decision-making. As a multidisciplinary approach, it can also help to engage various stakeholders in a wide range of activities, promoting prevention-oriented and pro-active risk-based policy approaches considering food systems as a whole. This holistic approach is crucial to achieve coherence in risk governance, which is often guided by various sector-based policies or CAs.

Different methods can be used, singly or in combination, to explore potential futures and trends; the selection of methods will be related to the desired outcome. Horizon scanning is a specific foresight method and refers to approaches that scan or review various data sources to identify issues that may have impact in the medium to long-term future. It is based mainly on desk research, involving a variety of sources (online and offline databases and journals, Internet, research communities, international, governmental and non-governmental organizations, companies, etc.). Other approaches include situation modelling, futures thinking, etc.).

POSSIBLE OUTCOME

Prevention-based policy approaches are promoted and supported by relevant information and analyses.

POSSIBLE INDICATORS

- > Documentation that shows application of foresight methodologies (e.g. horizon scanning, simulation modelling) to:
 - > identify gaps within an organization's knowledge base;
 - > test policy assumptions;
 - > develop a research plan;
 - > inform future monitoring practices;
 - > assess the vulnerability of a food system;
 - > identify and understand emerging hazards;
 - > etc.
- > Evidence that a mix of different data sources (e.g. scientific evidence, observations, experience, global trends, expert insights) is being collected and used to support decisions and that different disciplines are considered.
- > Evidence that findings and results are translated into staff development and training events to keep staff updated and pro-active.

SOURCES OF EVIDENCE

- > Documentation of foresight methodologies (data collection, analysis, related developments, etc.).

SEE ALSO

- A.2.1.9** [Staff preparation for, and attendance at, selected international scientific and policy-makers' meetings and conferences relevant for food safety and quality is financially secured in the CAs' budgets]
- A.3.2.3** [CAs supply or facilitate periodic update training events for staff with responsibilities in food control]
- B.2.3.3** [A functional central coordination mechanism includes all relevant CAs to address food safety emergencies]
- C.2.2.1** [The country is an active member of Codex and other relevant IOs with mandates in food safety and quality]



DIMENSION D

SCIENCE/KNOWLEDGE BASE AND CONTINUOUS IMPROVEMENT

Dimension D reviews the necessary features for the system to build scientific soundness, incorporate risk analysis principles and keep abreast of new scientific developments and innovations to continuously improve. It explores how CAs anchor their decisions on relevant scientific and technical information, reviews the robustness of information collection processes as a foundation for risk analysis, and assesses the use made of this risk analysis framework to handle food safety risks. It also revolves around competent authorities' capacity to review and improve performance, taking into consideration the most recent scientific and technical knowledge, to ensure the achievement of relevant outcomes.

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