

International Comparability Assessment Tool (ICAT)

BACKGROUND

The International Comparability Assessment Tool is an objective framework for determining the robustness of trading partners' overall food safety systems. The ICAT is based on the Manufactured Food Regulatory Program Standard (MFRPS), which is an assessment tool for U.S. States, though significant modifications have been made in order to provide an assessment that is less prescriptive and more appropriate for international use.

FORMAT

The ICAT is composed of ten sections, with each section corresponding to a specific food safety program standard. Standards include: Regulatory Foundation; Training Program; Inspection Program; Program Assessment and Inspection Audit Program; Food-related Illness and Outbreaks; Compliance and Enforcement Program; Industry and Community Relations; Program Resources; International Communication and Harmonization; and Laboratory Support.

Each ICAT section includes a narrative which describes the purpose and requirements of the standard as well as the program elements necessary to satisfy the basic requirements. Following each narrative is a self-assessment worksheet, to be completed by trading partners' Competent Food Safety Authorities.

The self-assessment worksheets are organized in tabular form, with column one listing the food safety program elements that satisfy the standard, and column two listing descriptions and links to U.S. programs and measures that satisfy the element. Columns three to five provide space for the Competent Food Safety Authority to outline comparable measures that they have in place, provide links to references (if available) and explain how measures may differ from those of the U.S.

GENERAL DIRECTIONS FOR COMPLETING THE ICAT

1. Please read each narrative prior to completing the accompanying self-assessment worksheet.
2. Column 2, "United States Reference", provides information and links to material that are applicable to the element listed in column one. Please use these references to guide the level of detail in your answers.
3. Please include all relevant information describing elements of your food safety system in column 3 as well as links to that information (if available) in column 4. If links are not available, please attach relevant documentation and make a note in column 4 of the number of pages that are attached.
4. Because we are seeking a full picture of your food safety system, please include all relevant information, including information that describes any provisions that may differ from the U.S. references listed in column 2.
5. In column 5, please provide information to highlight differences between your system and that of the U.S for each of the elements, based on your answers and the references provided in column 2.

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STANDARD No. 1 - Regulatory Foundation

Purpose of the Standard- The Regulatory Foundation standard describes the laws, regulations, rules, ordinances, or other regulatory requirements that govern the operation of a food plant or manufacturing establishment which are used by competent food safety authorities to define and ensure compliance with food safety regulations.

Basic Requirement of this Standard - The competent food safety authority has the legal authority and regulatory provisions to perform inspections and investigations, gather evidence, collect and analyze samples, and take enforcement actions to protect the public health by ensuring the safety and security of the food supply. .

Program Elements to Satisfy the Basic Requirements:

- **Legal Authority** - describes the set of laws and regulations which provide the competent food safety authority with the legal authority and regulatory provisions to protect the public health by ensuring the safety and security of the food supply, including performing inspections and investigations, gathering evidence, collecting samples, and taking enforcement actions.
- **Enforcement Mechanisms** - describes how the competent food safety authority ensures that the regulatory provisions specified under “Legal Authority” are met. (i.e., How are food safety regulations enforced?)
- **Additional Enforcement Mechanisms (if applicable)** - relates to any additional enforcement mechanisms that may be in place. For example, in the absence of an official law or regulation related to a particular food safety concern or product, how is the regulatory authority achieved to ensure food safety in that area?
- **Documentation** - relates to the competent food safety authority’s maintenance of records pertaining to Legal Authority and Enforcement of food safety regulations.

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STANDARD No. 2 - Training Program

Purpose of the Standard- The Training Program standard defines the essential elements of a competent food safety authority's training program for food safety inspectors.

Basic Requirement of this Standard - The competent food safety authority has a training plan in place that ensures all inspectors receive the training required to adequately perform their work assignments. The plan provides for basic and advanced food inspection training as well as continued training for professional development.

Program Elements to Satisfy the Basic Requirements:

- **Training Program** – describes in detail the training available to food safety inspectors, from newly hired inspectors through professional inspectors with advanced credentials. Program descriptions should include coursework as well as joint inspections and/or field training.
- **Training Requirements** – describes the training requirements for inspectors at all professional levels.
- **Documentation** - relates to the competent food safety authority's maintenance of records pertaining to the training of food safety inspectors, including relevant coursework materials and to the documentation of training completed by individual inspectors.

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STANDARD No. 3 - Inspection Program

Purpose of the Standard – The Inspection Program Standard describes the key elements of an effective food safety inspection program.

Basic Requirement of this Standard - The competent food safety authority has an inspection program that reduces the occurrence of food borne illness, injury, or allergic reaction by:

- Focusing inspection resources on high risk plants, products, and processes. The criteria for classification of risk for food processors includes: type of processing, type of food, volume of product manufactured/distributed, target population, and compliance history.
- Obtaining immediate corrections and long-term improvements by manufactured food processors.
- Responding efficiently to prevent unsafe products from reaching consumers or to remove unsafe food from the human food system.

Program Elements to Satisfy the Basic Requirements

- **Risk-based inspection program:**
 - The competent food safety authority maintains an accurate inventory of its food plants.
 - The inventory is categorized by the degree of risk associated with the likelihood that a food safety incident will occur.
 - Inspections are prioritized, frequencies assigned, and resources allocated based on risk categories assigned to a food plant or product, the manufacturing processes, and the inspection history of the food plant.
- **Inspection protocol** - written policies and procedures in place for inspecting food and food facilities and ensures inspector compliance.
- **Food recalls** - system in place that includes written procedures regarding communication, removal of recalled products from the marketplace and maintaining records pertaining to recalls
- **Consumer complaints** - system in place for receiving, tracking, evaluating, answering, closing, and maintaining records of consumer complaints
- **Food industry inspection complaints** - written procedures in place for receiving, evaluating, answering, and maintaining records of industry complaints about inspections
- **Documentation** - relates to the competent food safety authority's maintenance of the following records:
 - An official establishment inventory of food plants
 - Written procedures and rationale used for grouping establishments based on food safety risk, including the inspection frequency based on risk

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STANDARD No. 3 - Inspection Program (continued)

- Inspection policies and procedures including guidelines for performing inspections that require immediate corrective action and re-inspection
- Written procedures for food recalls, consumer complaints, and industry complaints about inspections
- Records for the three previous years, including inspection reports, reports of food recalls and follow-up activities, consumer complaints, and industry complaints

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STANDARD No. 4 - Program Assessment and Inspection Audit Program

Purpose of the Standard - The Program Assessment and Inspection Audit Program Standard describes the basic quality assurance reviews necessary to: (1) evaluate the effectiveness of the food safety and inspection program, (2) recognize trends in inspectional coverage, and (3) identify best practices used to achieve quality inspections and sample collections and to protect the public health by ensuring a safe food supply.

Basic Requirement of this Standard - The competent food safety authority conducts periodic self-assessments and quality assurance reviews of the food safety and inspection program that are designed to identify the strengths and weaknesses of the program. The results of the self-assessments are used to determine areas or functions of the food safety program that need improvement, to develop improvement plans and to establish timelines for implementing improvements.

Program Elements to Satisfy the Basic Requirements:

- **Inspection and Sample Collection** - The competent food safety authority conducts well-defined, systematic evaluation activities of its inspection and sample collection systems to ensure that activities and information are accurate, complete, and comply with written procedures and policies.
- **Field Operation Evaluations:**
 - Evaluations include assessments of field operations (on-site performance, evaluation of inspections and sample collections) as well as a performance review of the written reports of inspections and sample collections.
 - Evaluations are performed on a regular basis.
 - Inspections selected for evaluation should include high-risk food firms such as seafood facilities, juice processors, and low-acid canned food operations.
- **Reviews:**
 - Evaluation results are used to develop or update improvement plans.
 - Periodic reviews of evaluation reports are conducted to ensure that reports are being carried out as outlined by competent food safety authority protocols.
- **Documentation** - The competent food safety authority maintains the following records:
 - Written documents describing the program assessment and inspection audit programs.
 - Records of previous assessments and audits, including any resulting improvement plans and/or corrective action plans.

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STANDARD No. 5 - Food-related Illness and Outbreaks

Purpose of the Standard - The Food-related Illness and Outbreaks Standard applies to the surveillance, investigation, response, and subsequent review of alleged food-related incidents and emergencies that may result in illness, injury, and outbreaks. The standard also applies to the collection, analysis, and dissemination of information that may prevent illness and outbreak recurrence.

Basic Requirement of this Standard – The competent food safety authority has a system for surveillance, investigation, response, documentation, analysis, communication and follow-up of alleged food-related illnesses, injuries, and unintentional or deliberate food contamination.

Program Elements to Satisfy the Basic Requirements: - The competent food safety authority establishes systems for:

- **Surveillance and Investigation:**
 - Use epidemiological information supplied by local, regional and/or national authorities to detect incidents or outbreaks of food borne illness or injury
 - Investigate reports of illness, injury, and suspected outbreaks
- **Review and Response:**
 - Correlate and analyze data
 - Conduct trace-back and trace-forward investigations of food implicated in an illness, injury, or outbreak
 - Disseminate public information
- **Documentation** – relates to the competent food safety authority's maintenance of the following records:
 - A written description of standard procedures regarding:
 - Response to illness, injury or outbreak
 - Release of information to the public
 - Access to epidemiology support that is available to the program
 - A complaint log or database with documented timeframes for responding to complaints
 - Investigation reports and summaries

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STANDARD No. 6 - Compliance and Enforcement Program

Purpose of the Standard - The Compliance and Enforcement Program Standard describes the competent food safety authority's strategies, procedures and actions to enforce food safety laws and regulations to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program.

Basic Requirement of this Standard – The competent food safety authority has a compliance and enforcement program that provides procedures to ensure that policies are supported by sound judgment, adequate evidence, and appropriate documentation.

Program Elements to Satisfy the Basic Requirements:

- **Compliance and Enforcement Program Elements:**
 - contains written enforcement strategies
 - tracks critical and chronic violations and violators
 - uses a risk-based system to determine when a directed investigation follow-up, or re-inspection is needed
 - establishes a timeline for progressive actions
 - has a system to communicate verbal and written policy and guidance to managerial and non-managerial staff
 - Includes special program elements for specific food safety systems, such as Hazards and Critical Control Points (HACCP), Good Agricultural Practice (GAP), Good Manufacturing Practices (GMP) etc.
- **Periodic Review** - The competent food safety authority conducts periodic review of enforcement actions to assess areas in need of improvement or corrective action, and updates policies and practices based on findings.
- **Documentation** – relates to written procedures that describe the compliance and enforcement program and records of periodic review and follow-up activity.

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STANDARD No. 7 - Industry and Community Relations

Purpose of the Standard - The Industry and Community Relations Standard describes the elements of industry and community outreach activities developed and accomplished by the competent food safety authority.

Basic Requirement of this Standard - The competent food safety authority participates in activities that foster communication and information exchange among regulators, industry, academia, and consumer representatives and uses outreach and educational activities to inform the varied populations about food safety-related issues.

Program Elements to Satisfy the Basic Requirements:

- **Outreach Activities:**
 - The competent food safety authority interacts with industry and consumers by sponsoring or actively participating in meetings, outreach events and educational events related to food safety, which may include food safety investigation strategies, regulatory requirements, or other topics.
 - Representatives from affected food industries, consumers, academia, and related food safety authorities are invited to these meetings.
 - Outreach efforts are tailored to target populations and may include dissemination of information in hard copy or electronic format.
- **Documentation** - The competent food safety authority maintains records of industry and community relations events, including meeting summaries, agendas, or other records documenting interaction with food industries and consumers.

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STANDARD No. 8 - Program Resources

Purpose of the Standard -The Program Resources Standard describes the elements for assessing the adequacy of the resources (staff, equipment, and funding) available to support a food safety regulatory program.

Basic Requirement of this Standard - Resources (including staff, equipment, and funding) are available to support a comprehensive food safety program.

Program Elements to Satisfy the Basic Requirements:

- **Staffing** - Adequate staffing is available to provide the following:
 - General Administration and Management support (including direction, support, and oversight needed to achieve food safety program management goals)
 - Coordination, implementation and tracking of: Training Program, Inspection and Inspection Audit Program, Tracking and Addressing Food-related Illness and Outbreaks, Compliance and Enforcement Program, Industry and Community Relations Program and Program Assessment.
- **Equipment** – Adequate equipment is available to provide the following:
 - Program administration and recordkeeping (computers, software, and equipment necessary to maintain and secure)
 - Communication systems and equipment (equipment needed for routine and emergency communications)
 - Inspections (inspectors with equipment needed to conduct quality inspections)
- **Program funding** - Adequate funding is in place to cover the following:
 - Salary and benefits
 - Training costs
 - Travel-related expenses
 - Equipment and supplies, including laboratory expenses
 - Industry and community outreach expenses
 - Legal services fees
 - Overhead costs
- **Documentation** - The competent food safety authority maintains the records listed here:
 - Self-assessment documentation
 - Documentation showing number and functions of staff, including any calculations used to determine an adequate number of staff
 - Inventory of assigned and available inspection equipment

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STANDARD No. 9 - International Communication and Harmonization

Purpose of the Standard - The International Communication and Harmonization standard describes interaction between the competent food safety authority and the international community.

Basic Requirement of the Standard - The competent food safety authority has mechanisms in place to interact with the international community regarding international food safety standards as well as communication mechanisms to enact during food safety events of international concern.

Program Elements to Satisfy the Basic Requirements

- **International harmonization:**
 - Participation in Codex Alimentarius or other international food safety organizations
 - Participation in the World Trade Organization (WTO) Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) committees
 - Notification of food safety measures to the WTO
- **International communication** - The competent food safety authority has written policies describing:
 - Protocols for implementing International Notification and Reporting
 - Requirements through the International Food Safety Authorities Network (INFOSAN) International Health Regulations (IHR (2005))
 - Communication of food safety issues and concerns with trading partners
 - Participation in bilateral exchange with trading partners related to food safety regulations and their enforcement.
 - Communication and collaboration with international authorities in cases where food(s) implicated in incidents or outbreaks of food borne illness may be circulating in international trade

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STANDARD No. 10 - Laboratory Support

Purpose of the Standard - The Laboratory Support Standard describes the elements of laboratory support for a food safety regulatory program.

Basic Requirement of this Standard - The competent food safety authority has access to the laboratory services needed to support program functions and documents its laboratory capabilities including agreements with external laboratories, if applicable.

Program Elements to Satisfy the Basic Requirements:

- **Laboratory Services** - The competent food safety authority has access to a laboratory that is capable of analyzing a variety of samples including food, environmental, and clinical samples.
- **Documentation:**
 - The competent food safety authority maintains a record of services for routine and non-routine analyses such as biological hazard determinations.
 - The competent food safety authority has a contract or written agreement with its servicing laboratories, if applicable.
 - The competent food safety authority utilizes laboratories that are accredited or certified or that have a written quality assurance program (QAP). The QAP will require:
 - Calibration, verification, and maintenance of equipment
 - Documentation of analytical results
 - Control and maintenance of documents
 - Sample accountability
 - Sample integrity and chain of custody
 - Qualifications and training of analysts
 - Audit procedures such as scheduled performance reviews of staff and checks