International Comparability Assessment Tool (ICAT)

BACKGROUND

The International Comparability Assessment Tool is an objective framework for determining the robustness of potential participating country's (competent food safety authority/ies or equivalent) (shall only be referred to as participating country throughout the document) overall food safety systems. The ICAT was originally based on the Manufactured Food Regulatory Program Standard (MFRPS) in 2008, which is a voluntary program that aligns domestic U.S. FDA to U.S. states food safety systems. Modifications have been made in order to provide a comparability assessment tool that is more suitable for international use.

FORMAT

The ICAT is divided into three sections: Narrative; Standards (ICAT self-assessment worksheets) containing the Elements; and the U.S. Reference Guide.

A narrative is provided for each ICAT standard (included in this document) which outlines the purpose and requirements of the standard as well as the program elements necessary to satisfy its basic requirements.

Ten standards make up the response section of the ICAT, with each standard corresponding to a specific food safety program. The standards are as follows: Legal and Regulatory Foundation; Training Program; Inspection Program; Program Assessment and Audit Program; Food-related Illness and Outbreaks; Compliance and Enforcement Program; Industry and Community Relations; Program Resources; International Communication and Harmonization; and Laboratory Support.

The standards are designed into the ICAT self-assessment worksheets containing "Comparability Element" that satisfy the specific requirements listed under each standard. Descriptions and links to U.S. programs and measures to satisfy the comparability element are listed under "United States Reference" for each element. Space is provided for the participating country to outline their comparable measures under "Comparable Element Response." Explanation(s) of how measures differ from those of the U.S must be provided under "Differences with United States Reference." The corresponding ICAT self-assessment worksheets will assist the potential participating country of the Systems Recognition Program compile necessary information to satisfy each element; however, all information will be submitted to FDA for review electronically.

The U.S. Reference Guide (included in this document) provides direction to the type of information that should be submitted in the ICAT self-assessment worksheets to support the participating country's responses to each element.

GENERAL DIRECTIONS FOR COMPLETING THE ICAT

1. Read each narrative prior to completing the accompanying ICAT self-assessment worksheet.
2. "United States Reference" and "Reference Guide Information (tool tips in the online " provide information and links to materials that are applicable to the element listed in the "Comparability Element". Use these references to guide the level of detail in your answers.

3. Include all relevant information describing elements of your food safety system as well as links* to that information (if available) in the space provided for the “Comparable Element Response” and “Differences with United States Reference” respectively. Attach relevant documentation and make a note in the text area of the name of the attached document.
4. Because we are seeking a comprehensive picture of your food safety system, include all relevant information, including information and links* that describes any provisions that may differ from the U.S. references listed in “United States Reference” area.
5. In the “Differences with United States Reference,” 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 ”United States Reference” area.

***** All URLs/links/web-addresses provided in the text space of “Comparable Element Response” and/or “Differences with United States Reference” must begin with http:// with a blank space immediately following the URL/link (for example: http://www.google.com).

Standard Narrative Information
ICAT Standards (Self-assessment Worksheets)
US Reference Guide

STANDARD NARRATIVE INFORMATION

[TOP]

STANDARD 1 – Legal and 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 safety control system which are used by participating country to define and ensure compliance with food safety regulations.

Basic Requirement of this Standard – To demonstrate that the participating country 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 which provide the participating country with the legal authority to protect the public health by ensuring the safety and security of the food supply, by performing such actions as: inspections and investigations, gathering evidence, collecting samples, and enforcement.
- **Regulatory Foundation** – Describe the set of regulations that provide the provisions.
- **Documentation** – Food safety laws and regulations are documented, maintained, and accessible

Standard 1 – Worksheet Standard 1 – Reference Guide

STANDARD 2 - Training Program

Purpose of the Standard- The Training Program Standard defines the essential elements of a participating country's training program for food safety personnel (e.g., investigators, inspectors, auditors, compliance officers) and technical support staff (e.g. laboratory personnel.)

Basic Requirement of this Standard - To determine that a training plan is in place and implemented to ensure all food safety personnel and technical support staff receives the training required to adequately perform their work assignments. The plan provides for basic and advanced 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 personnel and technical support staff, from newly hired employees through established professionals with advanced credentials. Program descriptions should include coursework as well as joint inspections and/or field training.
- **Training Requirements** – Describes employee training requirements for all food safety personnel and technical support staff.
- **Documentation** - Records are maintained pertaining to the training of food safety personnel and technical support staff, including relevant coursework materials and to the documentation of training completed by individual employees.

Standard 2 – Worksheet Standard 2 – Reference Guide

STANDARD 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 - To ensure the inspection program reduces the risk of food borne illness, or injury by:

- Maintaining basic surveillance of the entire food safety system, from production to manufacturing and transportation are in place and implemented;
- 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, and compliance history;
- Obtaining immediate corrections and long-term improvements by manufactured food processors; and
- Responding efficiently to prevent unsafe food from entering commerce or removing potentially unsafe food from commerce.

Program Elements to Satisfy the Basic Requirements:

- **Risk-Based Inspection Program includes:**
  - Maintaining an accurate inventory of food plants;
  - Categorizing the inventory by the degree of risk associated with the likelihood that a food safety incident will occur; and
  - Prioritizing inspections based upon 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** - System(s)/program(s) for maintaining the following types of 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;
  - 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; and
  - Record retention for the three previous years, including inspection reports, reports of food recalls and follow-up activities, consumer complaints, and industry complaints.

Standard 3 – Worksheet Standard 3 - Reference Guide

STANDARD 4 - Program Assessment and Audit Program

Purpose of the Standard - The Program Assessment and 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 - 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 are conducted. 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. This also includes responding to the results of audits or assessment conducted by outside governmental agencies.

Program Elements to Satisfy the Basic Requirements:

- **Inspection and Sample Collection** - Well-defined, systematic evaluation activities of the inspection and sample collection systems are conducted 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.
- **Reviews:**
  - Evaluation results are used to develop or update policies, programs, procedures, and/ or improvement plans.
  - Periodic reviews of evaluation reports are conducted to ensure that reports are being carried out as outlined by the participating country's protocols.
- **Documentation** - The following records are maintained:
  - Written procedures and protocols describing the program assessment and audit programs; and
  - Records of previous assessments and audits, including any resulting improvement plans and/or corrective action plans.

Standard 4 – Worksheet Standard 4 – Reference Guide

STANDARD 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 – A system(s) for surveillance, investigation, response, documentation, analysis, communication and follow-up of alleged food-related illnesses, injuries, and unintentional or deliberate food contamination is in place and implemented.

Program Elements to Satisfy the Basic Requirements:

- **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.
  - System for reporting and tracking illnesses and 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.
  - Utilization of information for program enhancement
- **Documentation** – Relates to the participating country's maintenance of the following records:
  - A written description of standard procedures/ policies regarding:
    - Response to illness, injury or outbreak.
    - Release of information to the public.
    - Access to epidemiology support that is available to the program;
  - Written procedures/ policies for processing complaints within timeframes based on public health impact; and
  - Investigation reports and summaries.

Standard 5 – Worksheet Standard 5 – Reference Guide

STANDARD 6 - Compliance and Enforcement Program

Purpose of the Standard - The Compliance and Enforcement Program Standard describes the participating country'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 – A compliance and enforcement program is in place and implemented to provide procedures and processes that ensure 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 system for resource allocation and inspectional focus;
  - Establishes a timeline for progressive actions;
  - Has a system to communicate verbal and written policy and guidance to managerial and non-managerial staff;
  - Establishes a mechanism for preventing unsafe food from entering commerce or removing potentially unsafe food from commerce; and
  - Establishes written requirements for food safety programs.
- **Review** - Review of enforcement actions to assess areas in need of improvement or corrective action, and updates policies and practices based on findings.
- **Documentation** – Written procedures that describe the:
  - Regulatory, compliance, and enforcement program and procedures;
  - Records of review and follow-up activity; and
  - Record of notifications.

Standard 6 – Worksheet Standard 6 – Reference Guide

STANDARD 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 participating country.

Basic Requirement of this Standard – Active participation to foster communication and information exchange among regulators, industry, academia, and consumer representatives that use outreach and educational activities to inform the varied populations about food safety-related issues are instituted.

Program Elements to Satisfy the Basic Requirements:

- **Outreach Activities:**
  - Include sponsoring or actively participating in meetings, outreach events and educational events related to food safety with industry and consumers. These 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:**
  - Records are maintained of industry and community relations events, including meeting summaries, agendas, or other records documenting interaction with food industries and consumers.

Standard 7 – Worksheet Standard 7 – Reference Guide

STANDARD 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/available to provide the following:
  - General administration and management support (including direction, support, and oversight needed to achieve food safety program management goals); and
  - Coordination, implementation and tracking of: Training Program, Inspection and 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);
  - Communication systems and equipment needed for routine and emergency communications;
  - Inspections and audits (equipment necessary to conduct quality inspections and audits); and
  - Laboratory support (equipment necessary to conduct appropriate product testing)
- **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; and
  - Overhead costs.
- **Documentation** - The following records are maintained:
  - Documentation showing the number and functions of staff, including any calculations used to determine an adequate number of staff;
  - Inventory of assigned and available inspection/laboratory equipment;
  - Funding and allocation of resources; and
  - Resource audits.

Standard 8 – Worksheet Standard 8 – Reference Guide

STANDARD 9 - International Communication and Harmonization

Purpose of the Standard - The International Communication and Harmonization standard describes interaction between the participating country and the international community.

Basic Requirement of the Standard - Mechanisms are 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 Communication** - There are 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; and
  - Communication and collaboration with international authorities in cases where food(s) implicated in incidents or outbreaks of foodborne illness may be circulating in international trade.
- **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.
  - Participation in technical exchange and capacity building activities related to food safety.

Standard 9 – Worksheet Standard 9 – Reference Guide

STANDARD 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 - Accessibility to laboratory services is in place and implemented to support the program function and document its laboratory capabilities including written agreements with external laboratories, if applicable.

Program Elements to Satisfy the Basic Requirements:

- **Laboratory Services** - Laboratory(ies) capable of analyzing a variety of samples including food, and environmental samples are available and accessible.
- **Documentation:**
  - Records of services for routine and non-routine analyses such as biological or chemical hazard determinations are maintained;
  - Contract(s) and/or written agreement(s) with servicing laboratories are current and available, if applicable; and
  - Laboratories are accredited, certified, or have a written quality assurance program (QAP) that is utilized. Program requirements include such elements as:
    - 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 instrument checks.

Standard 10 - Worksheet Standard 10 – Reference Guide

ICAT STANDARDS
ICAT Self-assessment Worksheets

[TOP]

Standard 1 – Legal and Regulatory Foundation

Competent Authority

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
1.1	Competent Food Safety Authority and scope of Jurisdiction over Food Supply	United States Food and Drug Administration has jurisdiction over all foods except meat, poultry and certain egg products		
1.2	Statutory or legal definitions for "food" and "food additive"	Federal Food Drug and Cosmetic Act: • Sec 201 (§321) – o Definition (f) – "Food"; o Definition (s) – "Food Additive"		

Standard 1 – Narrative Standard 1 – Reference Guide

Legal Authorities

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
1.3	Authority to delegate responsibility to local and regional governmental organizations and/or rely on the work of recognized or accredited third parties.	Federal Food Drug and Cosmetic Act: • Section 702 (§372) – Examinations and investigations – provides authority for FDA to establish federal-state cooperative partnerships and to commission state investigators as well as officials from other federal agencies.		

1.4	Authority to verify adequacy of delegated work	Federal Food Drug and Cosmetic Act: • Section 702 (§372) – Examinations and investigations - provides authority for FDA to establish federal-state cooperative partnerships and to commission state investigators as well as officials from other federal agencies. Authority provided by sub-national authority through memorandum of understanding (MOU), partnership agreement or contract		
1.5	Authority to implement requirements for ethical standards for employees	Ethics in Government Act of 1978 The Criminal Statutes support FDA's Ethics requirements The Compilation of Federal Ethics Laws has been prepared by the Office of Government Ethics (OGE) and outlined the provisions signed into law Executive Order 12674 supports standards of ethical conduct for FDA employees (as modified by Executive Order 12731). Major subjects covered by these standards include: • Gifts • Conflicting financial interests • Impartiality in performing official duties		

		• Outside employment and other outside activities • Misuse of position		
1.6	Authority to take appropriate actions to prevent the spread of food borne illness Authority to prohibit: "introducing into commerce adulterated food", "adulteration of food", "receipt of adulterated food", "refusing records access", "refusal to permit entry or inspection" Authority to recall or remove adulterated food from commerce	Title 42 U.S.C. Public Health Service Act and Title 42 USC §243 (General Grant of Authority for Cooperation – General Powers and Duties) Federal Food Drug and Cosmetic Act: • Sec. 301 (§331)– Prohibited acts (a), (b), (c), (e), (f), and (v) • Sec. 304 (§334) – Seizure • Sec 420 (§350i) – Protection against intentional Adulteration • Sec 423 (§350l) – Mandatory Recall Authority		
1.7	Authority to conduct inspections of any establishment, including farms, where food is manufactured, processed, packed or held for introduction into commerce	Federal Food Drug and Cosmetic Act: • Sec. 704 (§374) – Inspection • Sec. 706 (§376) – Examination of sea food on request of packer; marking food with results; fees; penalties		
1.8	Authority to access records of foods entering into commerce	Federal Food Drug and Cosmetic Act: • Sec. 703 (§373) – Records of Interstate Shipment • Sec. 414 (§350c) – Maintenance and Inspection of Records: Food Safety Modernization Act: • Sec 101 – Inspections of records		

1.9	Authority to control and regulate new animal drugs as they relate to residues in FDA regulated human foods	Federal Food Drug and Cosmetic Act: • Sec. 504 (§354) – Veterinary Feed Directive Drugs • Sec. 512* (§360b) – New Animal Drugs (NAD) • Sec. 571 (§360ccc) – Conditional approval of NAD for minor use and minor species • Sec. 573 (§360ccc-2) – Designated NAD for minor use and minor species * The reference to Sec. 512 of the FD&C Act refers specifically to veterinary drugs intended for use in feed for food animals.		
1.10	Authority to ban or approve food additives (either by developing standards in-house or by adopting other national or international standards)	Federal Food Drug and Cosmetic Act: • Sec. 409 (§348) – Food Additives		
1.11	Authority to require labeling of allergens of human foods	Food Allergen Labeling and Consumer Protection Act of 2004 (Public Law 108-282, Title II) (FALCPA)		
1.12	Authority to promulgate regulations to enforce statutory requirements	Federal Food Drug and Cosmetic Act: • Sec. 701 (§371) – Regulations and Hearings		
1.13	Authority to maintain a list of food facilities	Federal Food Drug and Cosmetic Act: • Sec. 415 (§350d) – Registration of Food Facilities		
1.14	Authority to assess penalties for violation of food safety laws	Federal Food Drug and Cosmetic Act: • Sec. 303 (§333) – Penalties		

1.15	Authority to require standards for preventive controls	Federal Food Drug and Cosmetic Act: • Sec 418 (§350g) – Hazard analysis and risk-based preventive controls		
1.16	Authority to require standards for produce safety	Federal Food Drug and Cosmetic Act: • Sec 419 (§350h) – Standards for Produce Safety		
1.17	Authority to require standards for sanitary transportation of human food	Federal Food Drug and Cosmetic Act: • Sec 416 (§350e) – Sanitary transportation practices		

Standard 1 – Narrative Standard 1 – Reference Guide

Regulations

	Comparability Element	**United States Reference**	**Comparable Element (Include brief description, with reference or citation)**	**Differences with United States Reference**
1.18	Specific regulatory requirements for use of food additives	21 Code of Federal Regulations Part : • 170 – Food Additives		
1.19	Specific regulatory requirements for the use of new animal drugs as they relate to residues in FDA regulated foods	21 Code of Federal Regulations Part : • 510 – 558 – Animal Drugs, Feeds, and Related Products		
1.20	Specific regulatory requirements for good manufacturing practices for foods for special dietary use	21 Code of Federal Regulations Part : • 105 – Foods for Special Dietary Use		
1.21	Specific requirements for preventive controls systems	21 Code of Federal Regulations Part : • 1.900 – Sanitary Transportation of Human and Animal Food		

		• 108 - Emergency Permit Control • 110 - Current Good Manufacturing Practices in Manufacturing, Packing, or Holding Human Food • 112 – Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption • 113 – Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers • 114 - Acidified Food • 117 – Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Human Food • 120 – Hazard Analysis and Critical Control Point (HACCP) System • 123 – Fish and Fishery Products • 1240 – Control of Communicable Diseases		
1.22	Specific requirements to prevent intentional adulteration	21 Code of Federal Regulations Part : • 121 – Mitigation Strategies to Protect against Intentional Adulteration		
1.23	Specific requirement to meet ethical conduct	5 Code of Federal Regulations Part : • 2638 – Executive Branch Ethics Program		
1.24	Specific requirements for Food facility registration	21 Code of Federal Regulations Part : • 1 subpart H – Registration of Food Facilities		

Standard 2 – Training

Available Training for Food Safety Personnel and Technical Support Staff

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
2.1	Job descriptions and duties for food safety personnel and technical support staff	Description of job duties: • Consumer safety officer • General Description of FDA Jobs Classification & Qualifications of employees – • Consumer Safety Series 0696 Field Management Directives # - 76 (FMD)– State Contracts – Evaluation of Inspectional Performance ORA laboratory requirements for labs to maintain Job descriptions: Office of Regulatory Affairs (ORA) Laboratory Manual section 5.2.4: Job Descriptions		
2.2	Staff requirements in place regarding ethics and conflict of interest standards, for direct staff and contractors, as appropriate	Food and Drug Administration's Ethics Program is structured to provide advice and assistance to current and former employees in order to help ensure that decisions they make, and actions they take, are not, nor appear to be, tainted by any question of conflict of interest. The ethics laws and regulations were established to promote and strengthen the public's confidence in the integrity		

		of the Federal government. The Ethics and Integrity Staff strives to maintain a positive public perception in the way FDA conducts its business activities. The Food and Drug Administration's (FDA) filers (i.e., employees who are required to file either a confidential or public financial disclosure report) may not hold financial interests in companies which are significantly regulated by the FDA. The Hatch Act: Political Activity and the Federal Employee – identifies political activities permitted by Federal employees The U.S. Office of Government Ethics outlined specific topics by which an employee must follow. Additional information is available to support FDA's commitment to ensure all employees are trained regarding conflict of interest and ethics: https://intranet.hhs.gov/ethics/laws_and_regulations/index.html		
2.3	Minimum training requirements and additional opportunities for food safety personnel and technical support staff at all levels of competency	Office of Training Education & Development (OTED) – Location for basic training and training requirements to meet minimum program requirements can be found on our intranet page (http://inside.fda.gov:9003/EmployeeResources/Training/ORAU/default.htm). This link is accessible only by FDA		

		personnel. A snapshot of the screen has been provided in the following document as well as available on site  Standard training includes: • Web-based Courses - Discussion Questions and Exercises (Should be completed within 3 months of employment); • On-the-Job Training associated with each web based course (Should be completed within 9 months of employment); • Classroom Courses (Should be completed within 9 months of employment); AND • Satisfactory completion of an Audit (Should be completed within 11 months of employment) ORAU General Information – FDA's training center is available for all employees. (http://inside.fda.gov:9003/EmployeeResources/Training/ORAUGeneralInformation/default.htm) This link is accessible only by FDA personnel. A snapshot of the screen has been provided in the following document as well as available on site 		

		Training available for local authorities: • State Training • Training Curriculum for State, Local & Tribal Regulators Staff development & training policy • Mentoring – an agency wide program to enhance career and interpersonal development of FDA employees by creating mutually beneficial professional relationships through a formally structured Agency wide mentoring program. This link is accessible only by FDA personnel. A snapshot of the screen has been provided in the following document as well as available on site. ORA Quality Manual – location for criteria for employee selection FDA's Food Compliance Programs for commodity specific inspections lists minimum training requirements		

Standard 2 – Narrative Standard 2 – Reference Guide

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
2.4	Documentation of food safety personnel and technical support staff training and organizational responsibility	Patholore documents Office of Regulatory Affair's completed training courses and webinars (http://inside.fda.gov:9003/employeeresources/training/oraugeneralinformation/ucm404648.htm). This link is accessible only by FDA personnel. A snapshot of the screen has been provided in the following document as well as available on site. Include Level 1 audit requirements and outlines responsibility of training programs: (http://inside.fda.gov:9003/EmployeeResources/Training/ORAU/default.htm) This link is accessible only by FDA personnel. A snapshot of the screen has been provided in the following document as well as available on site. FDA Staff Manual Guides, Volume I addresses organizational responsibility for training at all levels from HQ through to the District		

		ORA Laboratory requirement for labs to maintain training records: Office of Regulatory Affairs (ORA) Laboratory Manual section 5.2.2.1 Goals for Education, Training and Skills.		

Standard 2 – Narrative Standard 2 – Reference Guide

Standard 3 - Inspection Program

Inventory of Food Facilities

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
3.1	Describe the process for maintaining a food facility inventory	Registration of Food Facilities		

Standard 3 – Narrative Standard 3 – Reference Guide

Inspection Program / Documentation of Regulatory Requirements

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
3.2	Describe the structure of your inspection program	FDA basic information: • Setting of inspectional priorities • Each year FDA generates an Annual Field Workplan, which projects resources and output (foreign, import and domestic) deemed necessary to carry out FDA's mission during the fiscal year. Workplans include projected resource requirements for compliance programs, investigational/inspection work, analytical and district resources, and laboratories. Workplan goals are revised where appropriate, to accommodate emergencies and		

		other unforeseen changes in program priorities Investigations Operations Manual (IOM) is the primary procedural document describing FDA's procedures for field investigators and state inspectors performing inspections ORA Field Work Plans – is designed to provide field managers with foreign, import, and domestic resources and output projections deemed necessary to carry out FDA's mission during a fiscal year. (http://inside.fda.gov:9003/ORA/Offices/OPOP/SPOP/DPE/ucm522769.htm)This link is accessible only by FDA personnel. A snapshot of the screen has been provided in the following document as well as available on site.  ORA Annual Field Workplan 101 ORA Quality Manual – Chapter 5 "Work Process, Controls, and Execution" identifies how ORA plans, assigns and completes work activities Staff Manual Guides are our agency's directives that document organizations and functions; delegations of authority; and administrative and program		

		policies, responsibilities and procedures Regulatory Procedures Manual: reference manual providing personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters Federal, State, or Local Inspections – Programs that advance the national Food Safety System. Site leads to resources and links to assist with accomplishing work		
3.3	Describe commodity-specific inspection requirements and/or standard operating procedures and/or guidance documents for field staff performing inspections of all commodities including certain high risk products (where relevant)	Compliance Program Manual – Commodity-specific compliance programs. Programs provide instructions to FDA personnel for conducting activities to evaluate industry's compliance with the Federal Food, Drug and Cosmetic Act. Specific programs include the following: • Cheese and Cheese Products - Domestic and Import • Chemotherapeutics in Seafood • Domestic Acidified & Low-Acid Canned Food • Domestic Fish and Fishery Products Inspection • Domestic Food Safety • Intentional Adulterant Program for human food		

		• Juice HACCP Inspection • Milk Safety • Mycotoxins in Food - Domestic and Import • Pesticides and Industrial Chemicals in Food - Domestic and Import • Preventive Control Program for human food • Produce Control Program (Farms) • Sanitary Transportation Program for human food • Inspection of Egg Farms for Monitoring Compliance with Egg Safety Rule • Toxic Elements in Food and Foodware, and • Radionuclides in Food - Domestic and Import Certain Equivalence Programs are handled on a case by case bases under SRA such as: • Molluscan Shellfish • Grade A dairy and Grade A dairy Products		
3.4	Procedures for food recalls, consumer complaints, and food industry complaints and how they apply to an inspection	Examples of information gathering: • Reportable Food Registry for Industry • Recall Activities • Consumer Complaint Coordinators • Recall Procedures		

		• Investigations (Investigations Operations Manual (IOM))		

Standard 3 – Narrative Standard 3 – Reference Guide

Standard 4 – Program Assessment and Audit Program

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
4.1	Self-assessment and/ or audit programs in place to ensure that activities conducted by the participating country and information collected and generated by the food safety authority are accurate, complete and comply with written procedures/ policies	QMS policies and procedures are utilized for the work accomplished for ORA audits by food safety inspectional staff. (http://inside.fda.gov:9003/ProgramsInitiatives/FieldOperations/QMS/ucm049662.htm) An example procedure and table of contents for other procedures are attached Investigations Operations Manual - Contains inspectional procedures that investigators audited against FDA has programs in place to assess investigators and auditors competencies to include laboratory staff State audit program FMD #76 – Procedure for the oversight of contract inspections Headquarters audit of field compliance work to ensure consistency with regulations		

		FDA conducts assessments of state human food regulatory programs using the Manufactured Food Regulatory Program Standards (MFRPS) Compliance program Summaries: are general reviews of most compliance programs. Juice HACCP Program summary is attached as an example. This link is accessible only by FDA personnel. A snapshot of the screen has been provided in the following document as well as available on site Example of Quality Management System's internal system audit procedure		

Standard 4 – Narrative Standard 4 – Reference Guide

Standard 5 –Food-related Illness and Outbreaks

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
5.1	Use of epidemiological information (supplied by local, regional, or national authorities) to detect incidents or outbreaks of foodborne illness or injury Investigation of reports, data correlation and analysis to determine the extent of foodborne incidents or outbreaks	FDA's Coordinated Outbreak Response and Evaluation (CORE) Network was created in 2011 to manage outbreak response, surveillance, and post-response activities related to incidents involving multiple illnesses linked to FDA-regulated human and animal food and cosmetic products. National programs utilized include: • FoodNet, a national network for foodborne disease surveillance and epidemiological study • PulseNet - a network of laboratories that coordinate data related to food safety issues: • Food Emergency Response Network (FERN) – a network which integrates food testing laboratories at the local, state and federal level, to detect, identify, respond to and recover from food-related emergencies or outbreaks. Objectives include detection, prevention, preparedness, response and recovery. • Electronic Laboratory Exchange Network (e-LEXNET) - electronic database system developed with FERN to facilitate		

		the rapid sharing of test results and other information among FERN members. (Available only to registered users)		
5.2	Conduct trace-back and trace-forward investigations of food implicated in an illness, injury or outbreak	FDA regulations regarding establishment and maintenance of records: • Reportable Food Registry • FDA CORE Network coordinates trace-back investigations during food safety events and emergencies		
5.3	Outreach program to communicate and disseminate foodborne illness information to the public	The following websites/links are available to disseminate information regarding FDA regulated products: • Food Safety – information regarding food recalls and other timely information, including "Ask the Experts" and "Report a Problem" with food. • Social media – such as Twitter, Facebook, YouTube, and Blogs • Consumer Updates • Foodborne Illness & Contaminants • Outbreaks: Investigation, Response & Evaluation • Resources & Related Links • Outbreak Investigations • How Government Responds to Food Illness Outbreaks		

5.4	Maintenance of written documents describing: • Response to illness, injury or outbreak; • Release of information to the public; • Access to epidemiological support available to the program; • Complaint log or database with documented timeframes for responding to complaints; • Investigation reports and summaries; and • Program enhancement resulting from event.	Reportable Food Registry – portals for industry and consumers to report food safety issues directly to the FDA. Annual reports are accessible online. Investigations Operations Manual – Chapter 8 - Investigations Coordinated Outbreak Response and Evaluation • Outbreaks: Investigation, Response & Evaluation • Environmental Assessments CFSAN Adverse Event Reporting System (CAERS) is a database that contains information on adverse event and product complaint reports submitted to FDA. This database supports CFSAN's safety surveillance program. The database is available online.		

Standard 5 – Narrative Standard 5 – Reference Guide

Standard 6 –Compliance and Enforcement

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
6.1	Structure of regulatory program for food safety-related enforcement activities (Note: this element does not relate to compliance programs)	The Regulatory Procedures Manual (RPM) provide an overview of the organizational structure of the offices involved in compliance related functions within FDA Field Management Directive #86 – Establishment Inspection Report Conclusions and Decisions		
6.2	Procedures in place to manage progressive enforcement actions, manage and track critical and chronic violations and violators and respond appropriately	The Regulatory Procedures Manual (Chapter 6) is a reference manual for FDA personnel, providing FDA personnel with information on internal procedures to be used in processing domestic and import regulatory and enforcement matters. The text also covers emergency procedures, import operations and actions and other procedures. FDA conducts progressive enforcement actions from advisory through judiciary actions. Food Compliance Program outlines regulatory enforcement actions.		

6.3	Procedures to communicate compliance and enforcement policy and guidance to managerial and non-managerial staff	Communication between headquarters and field offices is facilitated through the Manual of Compliance Policy Guides. The Manual of Compliance Policy Guides provides a convenient and organized system for statements of FDA compliance policy, including those statements which contain regulatory action guidance information. Examples of sources from which the Manual of Compliance Policy Guides are prepared include: a. statements or correspondence by headquarters offices or centers reflecting new policy or changes in compliance policy including Office of the Commissioner memoranda, center memoranda and other informational issuances, agency correspondence with trade groups and regulated industries, and advisory opinions; b. precedent court decisions; c. multicenter agreements regarding jurisdiction over FDA regulated products; d. preambles to proposed or final regulations or other Federal Register documents; and e. individual regulatory actions. Field Alerts and Field bulletins are used to communicate information from headquarters to the field (internal documents)		

		• Alerts utilized ORA wide • Bulletins utilized for commodity/program specific areas ORA Monthly Calls conducted at various levels including: • Director of Investigators Branch (DIB); • Director of Compliance Branch (DCB); and • District Director (DD Example agenda attached Monthly Program wide meetings are conducted. Example presentations attached: Webinars for training and exchange of information occur. Topics include: • new assignments • training updates A snapshot of the screen has been provided in the following document as well as available on site		

6.4	Written procedures that describe compliance and enforcement programs and records of periodic review and follow-up activity	Field Management Directives (FMD) Draft Guidance for Industry: Questions and Answers Regarding Mandatory Food Recalls – to provide guidance to industry on the implementation of the mandatory food recall provisions. Guidance for Industry: Questions and Answers Regarding the Reportable Food Registry as Established by the Food and Drug Administration Amendments Act of 2007 – To provide guidance regarding the Reportable Food Registry requirements. Regulatory Procedures Manual: Contains and describes compliance and enforcement activities. Food Compliance Programs: • Description of enforcement actions for program area • Collaboration between headquarters and field staff from audit conducted by HQ regarding Direct Reference.		

Standard 7 –Industry and Community Relations

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
7.1	Activities and communication tools used by the participating country to interact with industry and consumers; Documentation of activities	FoodSafety.gov serves as a gateway for information on all aspects of food safety, from safe handling of food by consumers to recall information and information from U.S. government agencies with food safety authority. FDA and other U.S. government agencies contribute to this regularly updated website. FDA provides specific information in the following areas: • Industry • Consumers • Federal, State, Local and Tribal Officials To assist in its mission to protect and promote the public health, FDA uses numerous committees and panels to obtain independent expert advice on scientific, technical, and policy matters: Advisory Committees In addition, FDA Field Public Affairs Specialists (PASs) are key links between the Agency and our constituents throughout the United States and Puerto Rico. They serve as FDA's community-based educators.		

Standard 7 – Narrative Standard 7 – Reference Guide

Standard 8 –Program Resources

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
8.1	Funding allocation for food safety programs and activities (e.g. are programs and activities centrally funded or funded through fee for service activities?)	Example of performance budget overview: • Budget overviews (summaries) • Budget proposals • Field workplans – allocating resources • Available staff and offices • Planning and oversight • Available funding for buildings and supplies (General Services Administration: https://www.gsa.gov/about-us/organization/public-buildings-service)		

Standard 8 – Narrative Standard 8 – Reference Guide

Standard 9 - International Communication and Harmonization

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
9.1	Participation in international food safety organizations and consideration of international food safety standards	Examples include: • Active member of Codex Alimentarius • The US Codex Office is under the USDA • Federal Code citation regarding review of Codex Alimentarius Food Standards (21 CFR Part 130.6)		
9.2	Participation in WTO Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Committees and notification of food safety measures to the WTO	Active participation in WTO SPS and TBT committees Notification of food safety measures to the WTO US SPS Enquiry Point US TBT Inquiry Point: National Institute of Standards and Technology		
9.3	Communication with INFOSAN or comparable mechanism	FDA Harmonization and Multilateral Relations and communication information: International Programs		
9.4	Communication of food safety issues and concerns with trading partners	Direct communication with trading partners through US Embassies, including • USDA Foreign Agricultural Service Foreign Service Officers		

		• FDA Officials posted overseas • Office of International Programs		
9.5	Participation in technical assistance, capacity building and partnership activities related to food safety.	FDA CFSAN – International Outreach and Technical Assistance Additional information includes: • International Arrangements • Bilateral and Multilateral activities Other US food safety bilateral exchange, including capacity building partnerships and technical exchange through interagency partnerships: USDA Foreign Agricultural Service		

Standard 9 – Narrative Standard 9 – Reference Guide

Standard 10 – Laboratory Support

	Comparability Element	United States Reference	Comparable Element (Include brief description, with reference or citation)	Differences with United States Reference
10.1	Describe the organizational structure and capabilities for laboratory food testing, including government and/or private/ contracted labs that test food for possible regulatory action or for research. Include laboratory capabilities such as microbiological and chemical analyses.	The FDA Office of Regulatory Affairs (ORA) operates permanent laboratory facilities across the United States and Puerto Rico. For more information see: Office of Regulatory Science		
10.2	Identify and describe the program utilized by the laboratories such as Quality Assurance Program (QAP) or Quality Management Systems (QMS) for government and private/ contracted laboratories. Identify and describe the type of accreditation or certification for the government and private contracted laboratories utilized for product testing.	Office of Regulatory Affairs (ORA) Laboratory Manual of Quality Policies, - section 3.0 "Quality Policy Statement" states: "ORA laboratories are committed to laboratory accreditation according to the requirements of ISO/IEC 17025." Office of Regulatory Science Additional information: Guidance for Industry - Submission Of Laboratory Packages By Accredited Laboratories		

10.3	Provide the requirements regarding the use of standard laboratory methodologies (for analysis including microbiological as well as chemical residue or contaminant analysis)	FDA conducts testing using standard methods including but not limited to the following: • Compliance Programs, • Field Assignments, • Official Compendia methods, such as o AOAC International, o Bacteriological Analytical Manual (BAM), o Pesticide Analytical Manual (PAM) , o United States Pharmacopeia–National Formulary (USP–NF), o Other US FDA and standard methods FDA ORA laboratories operate per ISO/IEC 17025 regarding selection of laboratory methods. The FDA ORA Laboratory Manual (Section 5.4) states that standard methods are preferred, as well as requirements for laboratory developed methods, non-standard methods, and validation/verification of methods following FDA Guidelines, ISO 16140:2016 or AOAC's Appendix J as appropriate.		
10.4	Identify and describe management of records/ documentation of services for routine and non-routine analyses such as biological or chemical hazard determinations	FDA ORA laboratories operate per ISO/IEC 17025 (section 4.13 Control of records). The Office of Regulatory Affairs (ORA) Laboratory Manual, (section 4.13) also contains similar language describing the Control of Records.		

U.S. REFERENCE GUIDE

[TOP]

Standard 1 – Legal and Regulatory Foundation

Competent Authority

	Comparability Element	Reference Guide Info
1.1	**Competent Food Safety Authority and scope of Jurisdiction over Food Supply**	Indicate which government agency or ministry has authority to enact and implement food safety regulations and programs. • Specify and identify the scope of each agency's role when more than one agency is responsible for ensuring food safety. • Explain which foods are regulated by which entities when food safety authority is shared between agencies or ministries.
1.2	Statutory or legal definitions for "food", and "food additive"	Provide your statutory or legal definitions for "food", and "food additive" Provide specific link(s) and/ or document(s) that identify the definitions

Standard 1 – Narrative Standard 1 – Worksheet

Legal Authorities

	Comparability Element	Reference Guide Info
1.3	Authority to delegate responsibility to local and regional governmental organizations and/or rely on the work of recognized or accredited third parties.	Provide specific link(s)* and/or document(s) that identify the authority.
1.4	Authority to verify adequacy of delegated work	Provide specific link(s)* and/or document(s) that identify the authority (e.g. authority to recall of food products, and to take action other appropriate actions.)
1.5	Authority to implement requirements for ethical standards for employees	Provide specific link(s)* and/or document(s) that identify the authority in place to require ethics.
1.6	Authority to take appropriate actions to	Provide specific link(s)* and/or document(s) that identify the authority.

	prevent the spread of food borne illness Authority to prohibit: “introducing into commerce adulterated food”, “adulteration of food”, “receipt of adulterated food”, “refusing records access”, “refusal to permit entry or inspection” Authority to recall or remove adulterated food from commerce	
1.7	Authority to conduct inspections of any establishment, including farms, where food is manufactured, processed, packed or held for introduction into commerce	Provide specific link(s)* and/or document(s) that identify the authority.
1.8	Authority to access records of foods entering into commerce	Provide specific link(s)* and/or document(s) that identify the authority.
1.9	Authority to control and regulate new animal drugs as they relate to residues in FDA regulated human foods.	Provide specific link(s)* and/or document(s) that identify the authority.
1.10	Authority to ban or approve food additives (either by developing standards in-house or by adopting other national or international standards)	Provide specific link(s)* and/or document(s) that identify the authority.
1.11	Authority to require labeling of allergens of human foods	Provide specific link(s)* and/or document(s) that identify the authority.
1.12	Authority to promulgate regulations to enforce statutory requirements	Provide specific link(s)* and/or document(s) that identify the authority.
1.13	Authority to maintain a list of food facilities	Provide specific link(s)* and/or document(s) that identify the authority.

1.14	Authority to assess penalties for violation of food safety laws	Provide specific link(s)* and/or document(s) that identify the authority.
1.15	Authority to require preventive controls	Provide specific link(s)* and/or document(s) that identify the authority.
1.16	Authority to require standards for produce safety	Provide specific link(s)* and/or document(s) that identify the authority
1.17	Authority to require standards for sanitary transportation of human food	Provide specific link(s)* and/or document(s) that identify the authority

Standard 1 – Narrative Standard 1 - Worksheet

Regulations

	Comparability Element	**Reference Guide Info**
1.18	Specific regulatory requirements for use of food additives	Provide specific link(s)* and/or document(s) that identify the relevant regulations.
1.19	Specific regulatory requirements for the use of new animal drugs as they relate to residues in FDA regulation human foods	Provide specific link(s)* and/or document(s) that identify the relevant regulations.
1.20	Specific regulatory requirements for good manufacturing practices for foods for special dietary use	Provide specific link(s)* and/or document(s) that identify the relevant regulations regarding good manufacturing practices for foods for special dietary use (e.g. foods for populations that have specific dietary needs). See 21 CFR Part 105 for detail.
1.21	Specific requirements for preventative controls systems	Provide specific link(s)* and/or document(s) that identify the relevant regulations, including specific requirements for preventative controls systems
1.22	Specific requirements to prevent intentional adulteration	Provide specific link(s)* and/or document(s) that identify the relevant regulations

1.23	Specific requirements to meet employee ethical conduct	Provide specific link(s)* and/or document(s) that identify the relevant regulations
1.24	Specific requirements for Food Facility Registration	Provide specific link(s)* and/or document(s) that identify the relevant regulations

Standard 1- Narrative Standard 1 – Worksheet

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Standard 2 – Training

Available Training for Food Safety Personnel and Technical Support Staff

	Comparability Element	Reference Guide Info
2.1	Job descriptions and duties for food safety personnel and technical support staff	Provide specific link(s)* and/or descriptive document(s) outlining job descriptions and duties for food safety personnel (e.g., investigators, inspectors, auditors, compliance officers) and technical support staff (e.g. laboratory personnel), including those for personnel conducting audits, audit reviews, audit decision making process and laboratory analysis.
2.2	Staff requirements regarding ethics and conflict of interest standards, for direct staff and contractors, as appropriate.	Provide specific link(s)* and/or document(s) to relevant programs in place to ensure: • Employees, and/ or contractors understand the ethical requirements required of them; • Documentation of relevant staff ethics training; and • Include specific information regarding training of individuals responsible for conducting inspections.
2.3	Minimum training requirements and additional opportunities for food safety personnel and technical support staff at all levels of competency	Provide specific link(s)* and/or descriptive document(s) listing or summarizing required courses for newly hired staff as well as courses for career development and advancement. Training could be onsite or off site, and conducted as national or regional/local training. Submit additional minimum educational and/or training requirements via specific link(s)* and/or document(s) for hires who will be conducting audits, review of audits, and supporting roles (e.g. laboratory) such as: • Training requirements for contracted auditors; • Description of courses and requirements for meeting minimum obligations; and • Staff training timelines Information provided should include who is responsible for training and maintenance of training.

Standard 2 – Narrative Standard 2 – Worksheet

Structured Curriculum for Food Safety Personnel and Technical Support Staff Training: Documentation Requirements for Training

	Comparability Element	**Reference Guide Info**
2.4	Documentation of food safety personnel and technical support staff training and organizational responsibility	Provide specific link(s)* and/or document(s) regarding the system/program/process used to track and maintain records for individual staff training. Include information related to training documentation for contracted auditors, auditing entities, and/or laboratories.

Standard 2 – Narrative Standard 2 – Worksheet

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Standard 3 - Inspection Program

Inventory of Food Facilities

	Comparability Element	Reference Guide Info
3.1	Describe the process for maintaining a food facility inventory.	Provide specific link(s)* and/or document(s) describing the requirements for maintaining a food facility inventory as well as the link(s)* to the list.

Standard 3 – Narrative Standard 3 - Worksheet

Inspection Program / Documentation of Regulatory Requirements

	Comparability Element	Reference Guide Info
3.2	Describe the structure of your inspection program.	Provide specific link(s)* and/or document(s) that describe the structure and procedures for the inspection program including, For example: • Describe the structure of the field offices and where they are located • Describe the reporting structure of the field office • Describe the process for scheduling facilities for inspection • Identify the frequency of inspections • Identify who inspects the facilities • Describe the components of a facility inspection (include inspection process and sampling) • Describe documentation of the inspection results • Identify who evaluates the results of the inspection • Describe follow-up actions taken as a result of inspection or sample findings • Describe the structure of delegated or contracted work
3.3	Describe commodity-specific inspection requirements and/or standard operating procedures and/or guidance documents for field staff performing inspections of all commodities including certain high risk products (where relevant.)	Provide specific links* and/or documents regarding each commodity-specific preventive controls programs and associated requirements with regards to inspectional requirements, as applicable (for example, requirements for HACCP, Preventive control, LACF/AF, etc.)

3.4	Procedures for food recalls, consumer complaints, and food industry complaints and how they apply to an inspection.	Provide specific links* and/or documents regarding procedures for collecting information and responding to food recalls, consumer complaints and food industry complaints. Explain how this information is used in setting inspectional priorities, if applicable.

Standard 3 – Narrative Standard 3 – Worksheet

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Standard 4 – Program Assessment and Audit Program

	Comparability Element	Reference Guide Info
4.1	Self-assessment and/ or audit programs in place to ensure that activities conducted by the participating country and information collected and generated by the food safety authority are accurate, complete and comply with written procedures/ policies.	Provide specific link(s)* and/or document(s) describing the structure and procedures of internal audits for: • Inspections • Inspection reports • Sample Collections • Compliance reviews • Documenting audit results • Reviewing audit reports • Program improvements based on results Include information regarding the frequency of inspector audits, documentation requirements and any consequences if audit frequency is not met.

Standard 4 – Narrative Standard 4 – Worksheet

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Standard 5 – Food-related Illness and Outbreaks

	Comparability Element	Reference Guide Info
5.1	Use of epidemiological information (supplied by local, regional, or national authorities) to detect incidents or outbreaks of foodborne illness or injury Investigation of reports, data correlation and analysis to determine the extent of foodborne incidents or outbreaks	Provide specific link(s)* and/or procedures for identification of and response to incidents of outbreaks of foodborne illness or injury. Provide information regarding data gathering, data use in identifying food safety incidents and response determinations
5.2	Conduct trace-back and trace-forward investigations of food implicated in an illness, injury or outbreak	Provide specific link(s)* and/or procedures for conducting trace-back and trace-forward investigations of food that is implicated in an illness, injury or outbreak and removing potentially unsafe foods from commerce.
5.3	Outreach program to communicate and disseminate foodborne illness information to the public	Provide specific link(s)* and/or procedures/ policies regarding communication and outreach to the public in response to food safety incidents or emergencies. Provide system(s) used to communicate the information.
5.4	Maintenance of written documents describing: • Response to illness, injury or outbreak; • Release of information to the public; • Access to epidemiological support available to the program; • Complaint log or database with documented timeframes for responding to complaints; • Investigation reports and summaries: AND • Program enhancement resulting from event.	Provide specific link(s)* and/or document(s) of examples related to responses to foodborne illness, injuries, or complaints. Include information pertaining to each step of foodborne illness detection, investigation and response.

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Standard 6 – Compliance and Enforcement

	Comparability Element	Reference Guide Info
6.1	Structure of regulatory program for food safety-related enforcement activities (Note: this element does not relate to compliance programs.)	Provide specific link(s)* and/or document(s) describing your regulatory program for ensuring compliance with food safety regulations. For example: • Describe your organizational structure. • Describe your regulatory strategy. • Describe the working relationship between local authorities and the national competent authority (e.g. How is information exchanged? How is responsibility delegated? How are issues conveyed between local and national entities?)
6.2	Procedures in place to manage progressive enforcement actions, manage and track critical and chronic violations and violators and respond appropriately	Provide specific link(s)* and/or document(s) describing: • Procedures and systems to manage and track violations and violators. • Application of the information in your compliance and enforcement program • Procedures for administrative and criminal actions.
6.3	Procedures to communicate compliance and enforcement policy and guidance to managerial and non-managerial staff	Provide specific link(s)* and/or documents describing the dissemination of information/ communications to all regulatory staff (e.g. information may include policy, guidance, regulatory actions, etc.)
6.4	Written procedures that describe compliance and enforcement programs and records of periodic review and follow-up activity	Provide specific link(s)* and/or document(s) regarding written procedures: • Describing compliance and enforcement programs and records of periodic review and follow-up activity • Procedures for conducting periodic review of enforcement actions to assess areas in need of improvement or corrective actions. • Describe the process for communicating any deficiencies and/or violations to firms, including corrective actions that need to be made.

Standard 6 – Narrative Standard 6 – Worksheet

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Standard 7 – Industry and Community Relations

	Comparability Element	Reference Guide Info
7.1	Activities and communication tools used by the participating country to interact with industry and consumers; Documentation of activities	Provide specific link(s)* and/or document(s) describing the activities and communication tools utilized for interaction and exchanges between industry, consumers and government authorities (including the national competent authority and/or local authorities). Provide specific link(s)* and/or document(s) for examples of activities.

Standard 7 – Narrative Standard 7 – Worksheet

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Standard 8 –Program Resources

	Comparability Element	Reference Guide Info
8.1	Funding allocation for food safety programs and activities (e.g. are programs and activities centrally funded or funded through fee for service activities?)	Provide specific link(s)* and/or document(s) regarding: • The budget process, • Resource allocations, and • Development and distribution of funding, including funding for national and local authorities, where relevant. Provide specific link(s)* and/or document(s) regarding funding mechanism for any contracted or third party activities.

Standard 8 – Narrative Standard 8 - Worksheet

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Standard 9 - International Communication and Harmonization

	Comparability Element	Reference Guide Info
9.1	Participation in international food safety organizations and consideration of international food safety standards	Provide specific link(s)* and/or document(s) describing and/or list your involvement in international food safety organizations that promote food safety standards
9.2	Participation in WTO Sanitary and Phytosanitary (SPS) and Technical Barriers to Trade (TBT) Committees and notification of food safety measures to the WTO	Describe or list (provide specific link(s)* and/or document(s)) the involvement in international committees that deal with food related trade barriers.
9.3	Communication with INFOSAN or comparable mechanism	Provide specific link(s)* and/or document(s) describing how your agency communicates food safety emergency information through mechanisms such as INFOSAN. Specify all mechanisms used.
9.4	Communication of food safety issues and concerns with trading partners	Provide specific link(s)* and/or document(s) describing the mechanisms used for communication with trading partners regarding food safety issues and concerns.
9.5	Participation in technical assistance, capacity building and partnership activities related to food safety.	Provide specific link(s)* and/or document(s) to describe any food safety-related outreach and technical exchange activities in which your organization participates, providing examples of activities.

Standard 9 – Narrative Standard 9 – Worksheet

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Standard 10 – Laboratory Support

	Comparability Element	Reference Guide Info
10.1	Describe the organizational structure and capabilities for laboratory food testing, including government and/or private/ contracted labs that test food for possible regulatory action or research purposes. Including laboratory capabilities such as microbiological and chemical analyses.	Describe organizational placement of laboratories in the overall regulatory organization. Include government and contracted laboratories, as applicable. Provide link(s)* and/or document(s) to support the description. Provide a list of laboratories via link(s)* and/or document(s) that perform testing for regulatory purposes (including government and/or contract labs). Include information on the responsibility of laboratories (e.g. geographical, test methodology, foods or other specialties.) Describe the process for contracted laboratory work (e.g. frequency of contracted work, circumstances for utilizing contracted labs, the amount (i.e. percentage) of work contracted verses performed by government labs). Provide link(s)* and/or documentation to support the description
10.2	Identify and describe the program utilized by the laboratories such as Quality Assurance Program (QAP) or Quality Management Systems (QMS) for government and private/ contracted laboratories. Identify and describe the type of accreditation or certification for the government and private contracted laboratories utilized for product testing.	Provide specific link(s)* and/or document(s) regarding the type of program utilized by the laboratories (i.e., Implementation of a quality management systems (QMS) or quality assurance programs (QAP)). Provide specific link(s)* and/or document(s) regarding the type of program/accreditation the laboratories adhere to such as standards or schemes, certification type, scope of accreditation or certification.
10.3	Provide the requirements regarding the use of standard laboratory methodologies (for analysis including microbiological, chemical residue and/or contaminant analysis).	Provide specific link(s)* and/or document(s) regarding analytical method selection and implementation.

10.4	Identify and describe the management of records/documentation of services for routine and non-routine analyses such as biological and/or chemical hazard determinations.	Provide specific link(s)* and/or document(s) describing laboratory records management program. The response should include the following: • The types of records generated. • Record storage procedures (e.g. location of records, on-site or off site, regional or central offices, etc.) • Record Retention procedures/process • Procedures for record collection by regional or local laboratories shared with the participating country

Standard 10 – Narrative Standard 10 – Worksheet

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