

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 modifications have been made in order to provide an assessment that is more suitable 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.

STANDARD 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 safety control system 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.

STANDARD 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 personnel.

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 investigators, laboratory personnel, risk assessment professionals and others, 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 the training requirements for employees at all professional levels.
- **Documentation** - Relates to the competent food safety authority's maintenance of records pertaining to the training of staff, including relevant coursework materials and to the documentation of training completed by individual employees.

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

- Maintaining basic surveillance of the entire food safety system, from production to manufacturing and transportation
- 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.

- 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 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.

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 – 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.

STANDARD 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.

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 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.

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 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.)
 - Communication systems and equipment needed for routine and emergency communications.
 - Inspections (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 the number and functions of staff, including any calculations used to determine an adequate number of staff.
 - Inventory of assigned and available inspection equipment.

STANDARD 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 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 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.

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 - The competent food safety authority has access to the laboratory services needed to support program functions and documents its laboratory capabilities including written 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 instrument checks.

Self-Assessment Worksheet for Standard 1 – Regulatory Foundation

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

Food Safety Infrastructure and Legislation

The laws, regulations, rules, ordinances or provisions in a comparable food safety system do not have to be identical if it can be demonstrated that the same effect is achieved.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹	Differences with United States Reference
Competent Food Safety Authority	United States Food and Drug Administration			
Scope of jurisdiction over food supply	All foods except meat, poultry, egg products and catfish			
Authority to take appropriate actions to prevent the spread of communicable disease	Title 42 U.S.C. Public Health Service Act http://www.fda.gov/RegulatoryInformation/Legislation/ucm148717.htm http://www.fda.gov/RegulatoryInformation/Legislation/ucm149277.htm			

¹ Provide internet link or electronic copy if available. Otherwise provide hard copy with submission

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element¹	Differences with United States Reference
Authority to approve new animal drugs	Federal Food, Drug and Cosmetic Act (FFDCA) Sec. 108			
Authority to delegate responsibility to sub-national governmental organizations	Federal/State cooperative programs, partnerships & inspection contracts http://www.fda.gov/Food/FoodSafety/FoodborneIllness/InteragencyCoordination/FederalStateFoodPrograms/default.htm http://www.fda.gov/ForFederalStateandLocalOfficials/PartnershipsContracts/default.htm			
Authority to verify adequacy of delegated work	Authority provided by sub-national authority through memorandum of understanding (MOU), partnership agreement or contract			
Statutory or legal definitions for “food”, “food additive” and “dietary supplement”	FFDCA ² Sec. 201 - Definitions (f), (s) and (ff)			

² The Federal Food, Drug, and Cosmetic Act [21 U.S.C. §§ 301 et seq]
<http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCA/default.htm>

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹	Differences with United States Reference
Statutory or legal ban on “introducing into commerce adulterated food”, “adulteration of food”, “receipt of adulterated food”, “refusing records access”, “refusal to permit entry or inspection”, “introducing into commerce unsafe dietary supplements”	FFDCA Sec. 301 - Prohibited acts (a), (b), (c), (e), (f), and (v)			
Ability to assess penalties for violation of food safety laws	FFDCA Sec. 303 ³			
Ability to prevent adulterated food from entering into commerce	FFDCA Sec. 304 ⁴			
Standards of identity for foods	FFDCA Sec. 401			
Definition of adulterated food	FFDCA Sec. 402 (a)			

³ Penalties may vary from Federal statute.

⁴ Seizure authority is not required under this standard. The competent food safety authority having jurisdiction should have legal authority to stop adulterated and misbranded products from moving in commerce, for example, detention, stop-sale orders, and embargoes.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element¹	Differences with United States Reference
Authority to require emergency permits when necessary	FFDCA Sec. 404			
Authority to approve food additives	FFDCA Sec. 409			
Authority to control new dietary ingredients	FFDCA Sec. 413			
Authority to promulgate regulations to enforce statutory requirements	FFDCA Sec. 701			
Authority to access records of foods entering into commerce	FFDCA Sec. 703 & 415			
Authority to conduct inspections of any establishment, including farms, where food is manufactured, processed, packed or held for introduction into commerce	FFDCA Sec. 414, 704 & 706			
Authority to establish reportable food registry	FFDCA Sec. 1005			

b. Implementing Laws, Regulations, Rules, Ordinances and Provisions

Implementation should have the full force and effect of underlying legislation.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element	Differences with United States Reference
Authority to recall or remove adulterated food from commerce	21 CFR ⁵ Part 7.40			
Specific regulatory requirements for good manufacturing practices for foods for special dietary use	21 CFR Part 105			
Specific regulatory requirements for good manufacturing practices for foods	21 CFR Part 110			
Specific regulatory requirements for good manufacturing practices for dietary supplements	21 CFR Part 111			
Specific requirements for the prior approval of processes used during the manufacture of commercially sterile foods	21 CFR Parts 108, 113 & 114			

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⁵ Code of Federal Regulations

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element	Differences with United States Reference
Specific requirements for preventative controls systems	21 CFR Parts 110, 120 & 123			
Specific requirements or procedures for approval of new food additives	21 CFR Part 170			
Specific requirements or procedures for the approval of new animal drugs	21 CFR Part 500			

c. Procedures and Guidelines

Guidance documents for inspection staff.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element	Differences with United States Reference
Administrative procedures for food safety regulatory activities	Staff Manual Guides http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/default.htm			

Self-Assessment Worksheet for Standard 2 - Training Program

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

Food Inspection Training Programs

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ⁶	Differences with United States Reference
Organizational responsibility for employee training and maintenance of records	Overview of organization duties and background information: http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm121831.htm			
Job descriptions and duties for personnel	Description of job duties for consumer safety officers: http://www.opm.gov/fedclass/gso696.pdf General Description of FDA Jobs http://www.fda.gov/AboutFDA/WorkingatFDA/CareerDescriptions/default.htm			
Minimum education or other qualification requirements for personnel	Basic education requirements for federal job positions: http://www.opm.gov/qualifications/standards/group-stds/GS-PROF.asp			

⁶ Provide internet link or electronic copy if available. Otherwise provide hard copy with submission.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element⁶	Differences with United States Reference
Available training for personnel at all levels of competency	Example of available training classes: http://www.fda.gov/Training/ForStateLocalTribalRegulators/ucm119027.htm Staff development & training policy: http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm201320.htm			
Minimum training requirements for staff	See Appendix 2B for example			

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Appendix 2B: Sample Training Curriculum for Standard 2 - Training Program

Investigator New Hire Curriculum

OVERVIEW

A standard training curriculum will be followed by every new Investigator/Analyst. The curriculum is the corner stone of ORA's New Hire Training plan. The main objective of the training plan is to assure that newly hired employees possess the knowledge, skills, and abilities necessary to protect public health. The curriculum is designed to minimize the time required for newly hired employees to become productive in assuring that products regulated by the agency are safe and effective. The standard training curriculum includes -

1. Successful completion of all necessary *web-based: courses, modules, and units.*
2. Successful completion of required *classroom courses.*
3. Passing an *audit* after completing all required web-modules and classroom courses.

TIMEFRAMES

<i>Web-based Courses, Discussion Questions and Exercises</i>	<i>Should be completed within 3 months of employment.</i>
<i>On-the-Job Training associated with each web based course</i>	<i>Should be completed within 9 months of employment.</i>
<i>Classroom Courses</i>	<i>Should be completed within 9 months of employment.</i>
<i>Audit</i>	<i>Should be completed within 11 months of employment.</i>

READINGS/ASSIGNMENTS

Prerequisite Reading for FACTS Classroom Course

- [FACTS Investigation Activities Miscellaneous Accomplishment Time](#) (Version 2.0 Revised July 24, 2002)
- [FACTS Investigation Activities Overview](#) (Version 2.0 Revised July 24, 2002)

Reading

- [FDA Data Codes and the OEI](#)
- [FDA Laboratory Orientation](#)
- [Field References](#)
- [Photography](#)
- [Orientation to Quality Management in ORA](#)

On-the-Job Readings for Investigators

- [FACTS Investigation Activities Establishment Inspection Record \(OP12\)](#) (Version 2.0 Revised July 24, 2002)
- [FACTS Investigation Activities Domestic Investigations \(OP 13\)](#) (Version 2.0 Revised July 24, 2002)
- [FACTS Investigation Activities Domestic Sample Collection Report \(OP 31\)](#) (Version 2.0 Revised July 24, 2002)
- [FACTS Investigation Activities Field Examinations \(OP 53\)](#) (Version 2.0 Revised July 24, 2002)
- [OASIS Introduction](#) (Version 2.0 Revised July 24, 2002)
- [OASIS Self Guided Lesson: Printing Assignments/Notices of FDA Action](#) (Version 2.0 Revised July 24, 2002)
- [OASIS Self Guided Lesson: Adding work/Unaccomplishing Work](#) (Version 2.0 Revised July 24, 2002)
- [OASIS Self Guided Lesson - Import Sample - Reporting Reconditioning](#) (Version 2.0 Revised July 24, 2002)
- [OASIS Self-Guided Lesson - Import Sample - Reporting Destruction](#) (Version 2.0 Revised July 24, 2002)
- [OASIS Self Guided Lesson: Import Field/Label Examination](#) (Version 2.0 Revised July 24, 2002)
- [OASIS Self-Guided Lesson - Import Samples Collection Report \(OP 33\)](#) (Version 2.0 Revised July 24, 2002)
- [Turbo EIR Field Agent Overview and Assignments](#) (Version 3.0 Revised May 2, 2007)
- [Turbo EIR Field Agent Establishment Inspection Reports](#) (Version 3.0 Revised May 2, 2007)
- [Turbo EIR Field Agent FDA-483](#) (Version 3.0 Revised May 2, 2007)

Discussion Questions for Investigators

- [A Tour of the FDA](#)
- [Orientation to ORA and FDA Fieldwork](#)
- [Expected Conduct of FDA Personnel](#)
- [Personal Safety](#)
- [Food and Drug Law - FDA Jurisdictions](#)
- [Food and Drug Law - Prohibited Acts](#)
- [Food and Drug Law - Criminal Acts/Violations](#)
- [Food and Drug Law - Judicial Actions](#)
- [Food and Drug Law - Imports and Exports](#)
- [Import Operations](#)
- [FDA Data Codes and the OEI](#)
- [FDA Forms for Investigators](#)
- [Affidavits](#)
- [FDA Establishment Inspection \(EI\)](#)
- [Sample Collection](#)
- [Field Examinations](#)
- [FDA 483s: Inspectional Observations](#)
- [Field References](#)
- [Quality Management in ORA](#)
- [Evidence and Proof](#)

- [Interviewing Techniques](#)
- [FDA Regulated Product Labeling](#)
- [Food Labeling](#)
- [FDA Establishment Inspection Report Writing](#)
- [Photography](#)
- [Food Microbiological Control - 1: Overview of Microbiology](#)
- [Food Microbiological Control - 5: Controlling Growth Factors](#)
- [Food Microbiological Control - 6: Control by Refrigeration](#)
- [Food Microbiological Control - 10: Aseptic Sampling](#)
- [Food Microbiological Control - 11: Good Manufacturing Practices \(GMPs\)](#)
- [Food Microbiological Control - 12: Cleaning & Sanitizing](#)
- [Recalls of FDA Regulated Products](#)
- [Special Investigations](#)
- [Destruction & Reconditioning](#)
- [FDA Lab Orientation](#)
- [Courtroom Testimony](#)

Exercises for Investigators

- [A Tour of the FDA](#)
- [Orientation to ORA and FDA Fieldwork](#)
- [Expected Conduct of FDA Personnel](#)
- [Food and Drug Law: FDA Jurisdictions](#)
- [Import Operations](#)
- [FDA Data Codes and the OEI](#)
- [FDA Forms for Investigators](#)
- [Affidavits](#)
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- [Food Microbiological Control 5: Controlling Growth Factors](#)
- [Food Microbiological Control - 6: Control by Refrigeration and Freezing](#)
- [Food Microbiological Control - 10: Aseptic Sampling](#)
- [Food Microbiological Control 11: Good Manufacturing Practices \(GMPs\)](#)
- [Food Microbiological Control 12: Cleaning & Sanitizing](#)
- [Recalls of FDA Regulated Products](#)
- [Special Investigations](#)
- [Destruction & Reconditioning](#)
- [FDA Laboratory Orientation](#)
- [Courtroom Testimony](#)

On-the-Job Training for Investigators

- [Food and Drug Law: FDA Jurisdictions](#)
- [Import Operations](#)
- [FDA Forms for Investigators](#)
- [Affidavits](#)
- [FDA Establishment Inspection \(EI\)](#)
- [Sample Collection](#)
- [Field Examinations](#)
- [FDA 483s: Inspectional Observations](#)
- [Reference Materials](#)
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- [FDA Lab Orientation](#)

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Self-Assessment Worksheet for Standard 3 - Inspection Program

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

The Laws, Regulations, Rules, Ordinances and Provisions in a comparable food safety system do not have to be identical if it can be demonstrated that the same effect is achieved.

Food Safety Comparability Element	United States Reference ^{7 8}	Comparable Element	Reference or Citation for Comparable Element ⁹	Differences with United States Reference
<p>A Program element(s) to provide an accurate inventory of food plants to be included in the risk based inspection program</p>	<p>http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm Bioterrorism Act of 2002 Legislation</p> <p>http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM122900</p> <p>http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm</p>			

⁷ These references will be updated from time to time. Use the most current version for each of these references.

⁸ Several of the FDA references in the following self assessment worksheet are directly related to FDA Compliance Programs which are used by the FDA to provide inspection criteria and requirements based on the degree of risk associated with the likelihood that a food safety incident will occur in a particular category of food or from a particular category of contaminant. Inspection activities for these categories of foods and contaminants are prioritized and frequencies for those activities are assigned in annual work obligations that are based on the history and degree of risk.

⁹ Provide internet link or electronic copy if available. Otherwise provide hard copy with submission.

Food Safety Comparability Element	United States Reference ^{7 8}	Comparable Element	Reference or Citation for Comparable Element ⁹	Differences with United States Reference
<p>Program element(s) to provide a risk-based inspection program and inspection protocol and documentation</p>	<p>Cheese and Cheese Products - Domestic and Import (FY 99/00/01) (7303.037)</p> <p>Chemotherapeutics in Seafood (FY 09/10/11) (7304.018)</p> <p>Dietary Supplements - Domestic and Import (7321.008) (Implementation Date: 03/26/2010)</p> <p>Domestic Acidified & Low-Acid Canned Food (FY 03/04/05) (7303.803A)</p> <p>Domestic Fish and Fishery Products Inspection (FY 08/09/10) (7303.842)</p> <p>Includes Pen & Ink changes as of 02/06/09 to Part III, IV, V, VI. Includes Pen & Ink changes as of 08/12/09 to Part II.</p>			

Food Safety Comparability Element	United States Reference ^{7 8}	Comparable Element	Reference or Citation for Comparable Element ⁹	Differences with United States Reference
<p>Program element(s) to provide a risk-based inspection program and inspection protocol and documentation (Continued)</p>	<p>Domestic Food Safety (FY 07/08) (7303.803)</p> <p>Import Acidified & Low-Acid Canned Food (FY 06/07/08) (7303.003)</p> <p>Import Foods - General (FY 06/07/08) (7303.819)</p> <p>Import Food and Color Additives (FY 09/10/11) (7309.006)</p> <p>Import Seafood Products (FY 07/08/09) (7303.844) Includes Pen & Ink changes as of 02/05/08 to Part IV, Section C.</p> <p>Infant Formula - Domestic and Import (FY 06/07/08) (7321.006)</p> <p>Juice HACCP Inspection (FY 07/08/09) (7303.847)</p>			

Food Safety Comparability Element	United States Reference ^{7 8}	Comparable Element	Reference or Citation for Comparable Element ⁹	Differences with United States Reference
<p>Program element(s) to provide a risk-based inspection program and inspection protocol and documentation (Continued)</p>	<p>Medical Foods - Domestic and Import (FY 06/07/08) (7321.002)</p> <p>Milk Safety (FY 09/10/11) (7318.003)</p> <p>Molluscan Shellfish (FY 09/10/11) (7318.004)</p> <p>Mycotoxins in Food - Domestic and Import (FY 07/08) (7307.001)</p>			
<p>Program element(s) to provide a risk-based inspection program and inspection protocol and documentation (Continued)</p>	<p>Pesticides and Industrial Chemicals in Food - Domestic and Import (FY 06/07/08) (7304.004A)</p> <p>Toxic Elements in Food and Foodware, and Radionuclides in Food - Domestic and Import (FY 08/09/10) (7304.019)</p> <p>http://www.fda.gov/ICECI/Inspections/IOM/default.htm</p>			

Food Safety Comparability Element	United States Reference ^{7 8}	Comparable Element	Reference or Citation for Comparable Element ⁹	Differences with United States Reference
<p>Program element(s) for food recalls, consumer complaints, food industry inspection complaints and documentation</p>	<p>http://www.fda.gov/RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticActFDCAct/FDCActChapterIVFood/ucm088549.htm Section 1005 FFDC Sec. 417. [21 USC 350f] Reportable food registry.</p> <p>http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm</p> <p>http://www.fda.gov/ICECI/Inspections/IOM/ucm123363.htm</p> <p>http://www.fda.gov/downloads/ICECI/Inspections/IOM/UCM123515.pdf</p> <p>http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators/default.htm</p> <p>http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm177304.htm</p>			

Food Safety Comparability Element	United States Reference^{7 8}	Comparable Element	Reference or Citation for Comparable Element⁹	Differences with United States Reference
Program element(s) for food recalls, consumer complaints, food industry inspection complaints and documentation (Continued)	http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm179133.htm			

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Self-Assessment Worksheet for Standard 4 - Program Assessment and Inspection Audit Program

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

The Laws, Regulations, Rules, Ordinances and Provisions in a comparable food safety system do not have to be identical if it can be demonstrated that the same effect is achieved.

Food Safety Comparability Element	United States^{10 11} Reference	Comparable Element	Reference or Citation for Comparable Element¹²	Differences with United States Reference
Program element(s) to provide systematic evaluation of inspection and sample collection responsibilities to ensure that the activities and information are accurate, complete and comply with written	http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm http://www.fda.gov/RegulatoryInformation/Legislation/ucm148797.htm Bioterrorism Act of 2002			

¹⁰ Some of the FDA references in the following worksheet are directly related to FDA Compliance Programs. Inspections and sampling criteria are specified in these documents. Annual work plans providing specific numbers of inspections and sample collections and analyses to be accomplished are generated based on these documents. Sample results and inspections based in these work plans are tracked and tabulated annually and the results used to evaluate these Compliance Programs. The Compliance Programs and work plans are adjusted as needed based on these evaluation results.

Two programs, the Milk Safety Program (FY09/10/11) (7318.003) and the Molluscan Shellfish Program ((FY09/10/11) (7318.004), include evaluations and onsite audits, conducted by the FDA, of State inspection and certification programs. These audits and the associated documentation of these audits may be used as an example of all program elements in this worksheet. These State inspections and certifications and federal audits of them, are used to credential the National Milk Shipment’s and National Shellfish Shipper’s lists of acceptable sources for these high risk foods.

¹¹ These references will be updated from time to time. Use the most current version for each of these references.

¹² Provide internet link or electronic copy if available. Otherwise provide hard copy with submission.

Food Safety Comparability Element	United States ^{10 11} Reference	Comparable Element	Reference or Citation for Comparable Element ¹²	Differences with United States Reference
procedures/ policies	Legislation			
<p>Program element(s) to provide systematic evaluation of inspection and sample collection responsibilities to ensure that the activities and information are accurate, complete and comply with written procedures and policies (Continued)</p>	<p>http://www.fda.gov/ICE/CI/ComplianceManuals/CompliancePolicyGuidanceManual/UCM122900</p> <p>http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm</p> <p>Domestic Acidified & Low-Acid Canned Food (FY 03/04/05) (7303.803A)</p> <p>Domestic Fish and Fishery Products Inspection (FY 08/09/10) (7303.842)</p> <p>Includes Pen & Ink changes as of 02/06/09 to Part III, IV, V, VI</p> <p>Includes Pen & Ink changes as of 08/12/09 to Part II</p>			

Food Safety Comparability Element	United States ^{10 11} Reference	Comparable Element	Reference or Citation for Comparable Element ¹²	Differences with United States Reference
<p>Program element(s) to provide systematic evaluation of inspection and sample collection responsibilities to ensure that the activities and information are accurate, complete and comply with written procedures and policies (Continued)</p>	<p>Domestic Food Safety (FY 07/08) (7303.803)</p> <p>Import Acidified & Low-Acid Canned Food (FY 06/07/08) (7303.003)</p> <p>Import Foods - General (FY 06/07/08) (7303.819)</p> <p>Import Food and Color Additives (FY 09/10/11) (7309.006)</p> <p>Import Seafood Products (FY 07/08/09) (7303.844) Includes Pen & Ink changes as of 02/05/08 to Part IV, Section C</p> <p>Infant Formula - Domestic and Import (FY 06/07/08) (7321.006)</p> <p>Juice HACCP Inspection (FY 07/08/09) (7303.847)</p> <p>Medical Foods - Domestic and Import (FY 06/07/08) (7321.002)</p>			

Food Safety Comparability Element	United States ^{10 11} Reference	Comparable Element	Reference or Citation for Comparable Element ¹²	Differences with United States Reference
<p>Program element(s) to provide systematic evaluation of inspection and sample collection responsibilities to ensure that the activities and information are accurate, complete and comply with written procedures and policies (Continued)</p>	<p>Milk Safety (FY 09/10/11) (7318.003)</p> <p>Molluscan Shellfish (FY 09/10/11) (7318.004)</p> <p>Mycotoxins in Food - Domestic and Import (FY 07/08) (7307.001)</p> <p>Pesticides and Industrial Chemicals in Food - Domestic and Import (FY 06/07/08) (7304.004A)</p> <p>Toxic Elements in Food and Foodware, and Radionuclides in Food - Domestic and Import (FY 08/09/10) (7304.019)</p> <p>http://www.fda.gov/ICEC/Inspections/IOM/default.htm</p>			

Food Safety Comparability Element	United States ^{10 11} Reference	Comparable Element	Reference or Citation for Comparable Element ¹²	Differences with United States Reference
<p>Program element(s) to provide reviews of evaluation reports to ensure that reports are being carried out as outlined by the competent food safety authority protocols</p>	<p>http://www.fda.gov/IC/ECI/ComplianceManuals/RegulatoryProceduresManual/ucm176710</p> <p>Milk Safety (FY 09/10/11) (7318.003)</p> <p>Molluscan Shellfish(FY 09/10/11) (7318.004) .htm</p> <p>http://www.fda.gov/IC/ECI/ComplianceManuals/RegulatoryProceduresManual/ucm177304.htm</p> <p>http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129814.pdf</p>			

Food Safety Comparability Element	United States^{10 11} Reference	Comparable Element	Reference or Citation for Comparable Element¹²	Differences with United States Reference
<p>Program element(s) related to the competent authority's maintenance of written documents describing program assessment and inspection audit programs and records of previous assessments and audits, including any resulting improvement plans and/or corrective action plans</p>	<p>Milk Safety (FY 09/10/11) (7318.003)</p> <p>Molluscan Shellfish (FY 09/10/11) (7318.004)</p> <p>Note: U.S. food inspection Compliance Programs are all evaluated periodically. Different programs are evaluated differently. See the column of this table for examples.</p>			

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Self-Assessment Worksheet for Standard 5 - Food-related Illness and Outbreaks

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

The Laws, Regulations, Rules, Ordinances and Provisions in a comparable food safety system do not have to be identical if it can be demonstrated that the same effect is achieved.

Food Safety Program Element	United States Reference	Comparable Provision	Reference or Citation for Comparable Provision	Differences with United States Reference
Use of epidemiological information (supplied by local, regional, or national authorities) to detect incidents or outbreaks of foodborne illness or injury	National programs include: FoodNet – a national network for foodborne disease surveillance and epidemiological study: http://www.cdc.gov/foodnet/			
Investigation of reports, correlate and analyze data to determine the extent of foodborne incidents or outbreaks	National programs include: PulseNet - a network of laboratories that coordinate data related to food safety issues: http://www.cdc.gov/pulsenet/			

Food Safety Program Element	United States Reference	Comparable Provision	Reference or Citation for Comparable Provision	Differences with United States Reference
	<p>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 http://fernlab.org/</p> <p>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)</p>			

Food Safety Program Element	United States Reference	Comparable Provision	Reference or Citation for Comparable Provision	Differences with United States Reference
<p>Ability to conduct trace-back and trace-forward investigations of food implicated in an illness, injury or outbreak</p>	<p>FDA regulations regarding establishment and maintenance of records: http://www.fda.gov/Food/FoodDefense/Bioterrorism/Recordkeeping/UCM061476</p> <p>FDA Food Protection Plan 2007: http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/FoodProtectionPlan2007/ucm132705.htm</p>			

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Food Safety Program Element	United States Reference	Comparable Provision	Reference or Citation for Comparable Provision	Differences with United States Reference
Communication and dissemination of information to the public	<p>Web access for the public regarding food recalls and other timely information, including an “Ask the experts” link and a link to report food safety problems, including an explanation of how the government responds: www.foodsafety.gov</p> <p>Consumers can also connect to FDA resources via social networking tools (Twitter) and RSS feed, and access podcasts for additional information.</p>			

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Food Safety Program Element	United States Reference	Comparable Provision	Reference or Citation for Comparable Provision	Differences with United States Reference
<p>Maintenance of written documents describing:</p> <ul style="list-style-type: none"> • 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; and • Investigation reports and summaries. 	<p>Reportable Food Registry – portals for industry and consumers to report food safety issues directly to the FDA: http://www.fda.gov/Food/FoodSafety/FoodSafetyPrograms/RFR/default.htm</p>			

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Self-Assessment Worksheet for Standard 6 – Compliance and Enforcement

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

Strategies, procedures and actions to enforce food safety laws, regulations, rules, ordinances and provisions to achieve compliance and to evaluate the effectiveness of its compliance and enforcement program

Food Safety Comparability Element	United States Reference ¹³	Comparable Element	Reference or Citation for Comparable Element ¹⁴	Differences with United States Reference
Established enforcement strategies for food safety compliance activities	Regulatory Procedures Manual http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm2005380.htm			
Mechanism to track critical and chronic violations and violators	Regulatory Procedures Manual http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm2005380.htm			
Employs a risk-based system to determine when follow-up activities or re-inspection is warranted	Regulatory Procedures Manual http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm2005380.htm Investigations Operations Manual http://www.fda.gov/ICECI/Inspections/IOM/default.htm			

¹³ These references are very comprehensive in nature. Please select specific sections that are relevant examples for comparability purposes.

¹⁴ Provide internet link or electronic copy if available. Otherwise provide hard copy with submission.

Food Safety Comparability Element	United States Reference¹³	Comparable Element	Reference or Citation for Comparable Element¹⁴	Differences with United States Reference
Procedure to manage progressive enforcement actions	Regulatory Procedures Manual http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm2005380.htm			
Procedures to communicate compliance and enforcement policy and guidance to managerial and non-managerial staff	Compliance Policy Guides http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm119194.htm			
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.	Compliance Program Manual http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm2005382.htm#Foods			
Periodic review of enforcement actions to assess areas in need of improvement or corrective action, and updates policies and practices based on findings	Compliance Program Manual http://www.fda.gov/ICECI/ComplianceManuals/ComplianceProgramManual/ucm2005382.htm#Foods CFSAN Enforcement Actions http://www.fda.gov/ICECI/EnforcementActions/EnforcementStory/default.htm http://www.fda.gov/downloads/ICECI/EnforcementActions/EnforcementStory/UCM129814.pdf			
Written procedures that describe compliance and enforcement programs and records of periodic review and follow-up activity	Field Management Directives http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/UCM056246			

Self-Assessment Worksheet for Standard 7 - Industry and Community Relations

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

The Laws, Regulations, Rules, Ordinances and Provisions in a comparable food safety system do not have to be identical if it can be demonstrated that the same effect is achieved.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or citation for comparable Element¹⁵	Differences with United States Reference
<p>Provide information on what activities and communication tools are utilized by the competent food safety authority to interact with industry and consumers; and what records are maintained on those activities</p>	<p>http://www.fda.gov/ http://www.fda.gov/ForIndustry/default.htm http://www.fda.gov/ForConsumers/default.htm http://www.fda.gov/ForFederalStateandLocalOfficials/default.htm http://www.fda.gov/AdvisoryCommittees/default.htm</p>			

¹⁵ Provide internet link or electronic copy if available. Otherwise provide hard copy with submission

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or citation for comparable Element¹⁵	Differences with United States Reference
Provide information on what activities and communication tools are utilized by the competent food safety authority to interact with industry and consumers; and what records are maintained on those activities (continued)	http://www.fda.gov/AboutFDA/ContactFDA/FindanOfficeorStaffMember/FDAPublicAffairsSpecialists/default.htm http://www.foodsafety.gov/			

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Self-Assessment Worksheet for Standard 8 - Program Resources

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element¹⁶	Differences with United States Reference
Adequate staffing is available	<p>Field workplans allocating resources (start on pg 12): http://www.fda.gov/AboutFDA/CentersOffices/ORA/ORAElectronicReadingRoom/ucm180154.htm</p> <p>Example of available staff and offices http://www.fda.gov/AboutFDA/CentersOffices/ORA/ucm135269.htm</p> <p>Planning and oversight http://www.fda.gov/AboutFDA/CentersOffices/OC/OfficeofPolicyPlanningandPreparedness/default.htm</p>			

¹⁶ Provide internet link or electronic copy if available. Otherwise provide hard copy with submission.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹⁶	Differences with United States Reference
<p>Adequate equipment is available as warranted</p>	<p>Example of established procurement policies http://www.fda.gov/AboutFDA/ReportsManualsForms/StaffManualGuides/ucm186856.htm</p> <p>Example of funding available for buildings and supplies (GSA): http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/UCM205762.pdf</p> <p>Example of instructions on field equipment maintenance http://www.fda.gov/ICECI/Inspections/IOM/UCM122505#1.6.2.1</p> <p>Example of facility inventory: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2006FDABudgetSummary/ucm112765.htm</p> <p>Example of interagency resources: http://www.gsa.gov/Portal/gsa/ep/contentView.do?contentType=GSA_BASIC&contentId=12724</p>			

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹⁶	Differences with United States Reference
Adequate funding is in place	<p>Example of performance budget overview: http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2007FDABudgetSummary/UCM121013.pdf</p> <p>Example of Budget Proposal: http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/BudgetReports/2006FDABudgetSummary/ucm113021.htm</p>			

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Self-Assessment Worksheet for Standard 9 - International Communication and Harmonization

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element¹⁷	Differences with United States Reference
Participation in international food safety organizations and consideration of international food safety standards	Active member of Codex Alimentarius www.codexalimentarius.net The US Codex Office is under the USDA Food Safety and Inspection Service: http://www.fsis.usda.gov/Codex_Alimentarius/index.asp			

¹⁷ Provide internet link or electronic copy if available. Otherwise provide hard copy with submission

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹⁷	Differences with United States Reference
Participation in international food safety organizations and consideration of international food safety standards (continued)	Federal Code citation regarding review of Codex Alimentarius Food Standards: 21CFR130.6 http://frwebgate4.access.gpo.gov/cgi-bin/TEXTgate.cgi?WAISdocID=563211371730+4+1+0&WAISaction=retrieve			
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: http://www.fas.usda.gov/itp/OSTA_IRSD/WTO_SPS_Committee_Enquiry_Point.asp US TBT Enquiry Point: http://ts.nist.gov/Standards/Information/tbtmotif.cfm			

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹⁷	Differences with United States Reference
Communication with INFOSAN	FDA Harmonization and Multilateral Relations: http://www.fda.gov/InternationalPrograms/HarmonizationInitiatives/default.htm FDA Communication info: http://www.fda.gov/InternationalPrograms/InternationalCommunications/default.htm			
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: http://www.fas.usda.gov/ofso/overseas_post_directory/ovs_directory_search.asp and FDA officials posted overseas: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm103036.htm			

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹⁷	Differences with United States Reference
Participation in bilateral exchange with trading partners	<p>Food safety bilateral exchange, including capacity building partnerships and technical exchange: http://www.fas.usda.gov/internationaldevelopment.asp</p> <p>FDA CFSAN international outreach and technical assistance: http://www.fda.gov/Food/InternationalActivities/ucm103051.htm</p> <p>Additional information on international arrangements: http://www.fda.gov/InternationalPrograms/Agreements/default.htm</p>			

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element¹⁷	Differences with United States Reference
<p>Communication with international authorities during food safety incidents or emergencies</p>	<p>Direct communication with trading partners through US Embassies, including USDA Foreign Agricultural Service Foreign Service Officers: http://www.fas.usda.gov/ofso/overseas_post_directory/ovs_directory_search.asp and FDA officials posted overseas: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm103036.htm</p>			

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Self-Assessment Worksheet for Standard 10 - Laboratory Support

Please describe how your food safety program meets the individual comparability elements identified in the following table. A food safety program may contain provisions that are the same or have the same effect as those contained in the referenced U.S. citation. If the provisions contained in the relevant sections of your food safety program are not the same as those contained in the corresponding U.S. citations, please identify any differences between the two.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹⁸	Differences with United States Reference
Laboratory access (for analysis of food, environmental, and clinical samples)	The FDA Office of Regulatory Affairs (ORA) laboratories operates permanent facilities in five regions across the United States and Puerto Rico. ORA may operate mobile laboratories as extensions to specified fixed laboratory sites. For more information see: http://www.fda.gov/ScienceResearch/FieldScience/default.htm			

¹⁸ Provide internet link or electronic copy if available. Otherwise provide hard copy with submission.

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element¹⁸	Differences with United States Reference
<p>Records/documentation of services for routine and non-routine analyses such as biological hazard determinations.</p>	<p>Office of Regulatory Affairs (ORA) Laboratory Manual, section 4.13 <i>Control of Records</i> http://www.fda.gov/ScienceResearch/FieldScience/default.htm</p>			
<p>For outside/contract laboratories (if applicable): Description of contract or written agreement</p>	<p>Office of Regulatory Affairs (ORA) Laboratory Manual, section 4.5 <i>Subcontracting of Tests</i> http://www.fda.gov/ScienceResearch/FieldScience/default.htm</p>			

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Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹⁸	Differences with United States Reference
<p>Are laboratories accredited or certified or have written Quality Assurance Programs (QAP)??</p>	<p>Office of Regulatory Affairs (ORA) Laboratory Manual, section 3 states: “ORA laboratories are committed to laboratory accreditation according to the requirements of ISO/IEC 17025.” See: http://www.fda.gov/ScienceResearch/FieldScience/default.htm</p> <p>Additional information: Guidance for Industry - Submission Of Laboratory Packages By Accredited Laboratories http://www.fda.gov/RegulatoryInformation/Guidances/ucm125434.htm</p> <p>For information regarding internationally recognized accreditation bodies, see the International Laboratory Accreditation Cooperation: http://www.ilac.org/</p>			

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element ¹⁸	Differences with United States Reference
<p>If laboratories are accredited or certified, what criteria are used for the accreditation?</p>	<p>As stipulated in the Guidance for Industry - Submission Of Laboratory Packages By Accredited Laboratories http://www.fda.gov/RegulatoryInformation/Guidances/ucm125434.htm :</p> <p><i>“The accreditation of a testing laboratory should be issued by an accreditation body operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011, General requirements for accreditation bodies accrediting conformity assessment bodies.”</i></p>			

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element¹⁸	Differences with United States Reference
<p>If laboratories are accredited or certified, what criteria are used for the accreditation? (continued)</p>	<p>Signatories to the International Laboratory Accreditation Cooperative (ILAC) Mutual Recognition Arrangement agree to maintain conformity with the current version of ISO/IEC 17011 and also agree to ensure that all laboratories that they accredit comply with appropriate laboratory standards. For more information on ILAC: http://www.ilac.org/documents/ILAC_Mut_Rec_Arr_jun_2007.pdf</p>			

Food Safety Comparability Element	United States Reference	Comparable Element	Reference or Citation for Comparable Element¹⁸	Differences with United States Reference
<p>Written quality assurance program (QAP), requiring:</p> <ul style="list-style-type: none"> • 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 	<p>Office of Regulatory Affairs (ORA) Laboratory Manual, specifically section 5: <i>Technical Requirements</i></p> <p>http://www.fda.gov/ScienceResearch/FieldScience/default.htm</p>			