CHAPTER 18 –TECHNICAL ASSISTANCE

SUBJECT:	**IMPLEMENTATION DATE**
INTERSTATE TRAVEL PROGRAM – CONVEYANCES AND SUPPORT FACILITIES (FY 14/15/16)	Upon Receipt
	COMPLETION DATE
	9/30/16

DATA REPORTING	
PRODUCT CODES	PROGRAM/ASSIGNMENT CODES
SAMPLES: WATER - 29WYY30 FOOD /SERVICE AREA(S) – INDUSTRY 51 Refer to the following website for the appropriate 7 digit product code: http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm	REPORT ACCOMPLISHMENTS UNDER THE FOLLOWING PAC CODES: 18029A Aircraft 18029B Buses 18029C Railroad 18029D Vessel 18029E Support Facility Construction 18029F Conveyances under construction

REPORTING PROCEDURES

A. **Action Recommendations to CFSAN**

All Administrative and Regulatory actions must receive concurrence from CFSAN's Office of Compliance.

Submit proposed **PROVISIONAL** and **NOT APPROVED** classification letters to CFSAN via MARCS-CMS system and follow procedures outlined in the Regulatory Procedures Manual. **Further operational instructions are provided in part V of this compliance program**.

B. **Attachment**

Attachment A: Orientation to the Food Code 2013 (or most current version)
Note: Email a copy to Interstate Travel Program (ITP) Manager

C. **Reports to Other Field Locations, Agencies and Industry**

1. Reports to Home Districts and other FDA Offices

If the company headquarters of the support facility is located in a separate District, send EIRs for support facilities that have been officially classified as **NOT APPROVED** (**USE PROHIBITED**) and **PROVISIONAL** with CFSAN concurrence to the FDA Home Districts and **to CFSAN ITP Manager (HFS-320).** Also send notification of a change in classification to the conveyance companies utilizing the facilities, and their corporate offices.

Notify the Director of Investigations Branch (DIBs) of the FDA Home District via electronic mail (ATTN: Interstate Travel Program Monitor) so that they may take the necessary action. Send a copy to ITP Manager(HFS-320) and the Division of Enforcement, Food Adulteration Assessment Branch (HFS-607) contact. (see part VI, Regulatory Contact)

The message must contain the following information:

- the name(s) of the establishment
- the location (e.g., address)
- the FEI number
- the carrier companies served by the establishment (for railroads, include the name of the railroad, and 'AMTRAK' if the user railroad(s) is under contract)
- the classification of the establishment and whether or not it is based on the conditions at the support facility, water quality (EPA), or a combination of both and include a brief summary of findings
- expiration date of classification, if applicable

2. Reports to other Agencies

Whenever a vessel support facility utilized by foreign flag vessels receives a Use-Prohibited classification, notify the Centers for Disease Control and Prevention (CDC), Vessel Sanitation Program Chief, at 770-488-3139.

State and local authorities must be contacted in matters involving mutual concern. For additional information contact ITP Manager.

Cooperative agencies such as State or Local Health Departments should be contacted at least annually. Health departments should be asked to advise the affected FDA District offices and ITP Manager immediately of recommended changes in compliance status for caterers, commissaries, watering points and servicing areas when interstate carrier operations could be adversely affected. Districts should follow procedures to use their State Liaisons when contacting State and Local Health Departments.

3. Reports to Industry

To enable conveyance companies to comply with the regulations, FDA must keep them informed of the compliance status of conveyance support facilities used by them so they discontinue use of a ‘Not Approved/Use Prohibited’ facility and locate an alternate 'Approved' facility, if necessary. For this reason, during any inspection of catering firms, commissaries, watering

points, and service areas, the investigator will routinely obtain a list of all carriers regularly using the facility, and make it a part of the report in order that the carriers can be immediately notified when a classification of a support facility changes. The information obtained is not intended for generation of a list of carriers but will be used as a tool to ensure that conveyance operators are aware of changes in the status of their support facilities. Districts should verify information on the list prior to sending classification change letters.

If 'Provisional' or 'Use-Prohibited' status is anticipated see Section V for options.

Note: If a conveyance company desires to use a support facility that is not currently inspected under the Interstate Travel Program, they may request that the FDA District covering that geographic area conduct an inspection. Once the inspection is completed, the conveyance company shall be notified of the inspection classification, and the support facility will be added to the national ITP OEI and the appropriate FDA listing of approved support facilities.

D. FACTS (MARCS-Domestic in future) Reporting

Note: Inspections of conveyances under construction made under **PAC 18029F** will require issuance of a form FDA 482. All construction-related visits to the conveyance builder require that a form FDA 482 be issued.

Report resources utilized for PACs 18029A-F (filth, decomposition, microbiological) into the FACTS as appropriate using the following Problem Area Flags PAF:

PAF	PAF Description
MIC	Microbiological analysis (includes rapid test kits for microanalysis)
ELE	Elements in Food & Water Analysis (includes heavy metals- Pb, Cu)

For a support facility under construction, use the appropriate establishment type code (e.g., U, V, J, K) to designate the type of support facility being constructed.

Watering Point (U) – Dispenses Potable Water
Servicing Area (V) – Handles Sewage
Caterer (J) – Prepares food
Commissary (K) – Stores food

For all ITP inspections, be sure to enter the appropriate five (5) character process code (Industry Code 51).

Proceed per instructions listed in the Establishment Inspection Report Conclusions and Decisions in ORA-Field Management Directive No. 86 at: http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm05624

6.htm.

For all inspections resulting in **PROVISIONAL** or **USE-PROHIBITED** classifications, write "ITP: Provisional" or "ITP: Use-Prohibited" as appropriate, in the remarks section of screen 1. This information is necessary to distinguish these two classifications in our data reporting system.

Report time for construction plan review not done as part of a construction inspection under **Operation Code 13**, “Domestic Investigation”. Do not use Operation Code 92 “Technical Assistance” to report plan review activities. Plan review done as part of a construction inspection and Orientation to the Food Code (only for new firms or management) should be reported under Operation Code 12, “Inspection”.

PART I – BACKGROUND

In June 1969 many activities formerly associated with the Public Health Service (PHS) were transferred to the Food and Drug Administration (FDA). Among these was the responsibility for carrying out the Interstate Quarantine Regulations (IQR). The IQR and the associated PHS activities originated with an Act passed by Congress on February 15, 1893 and promulgated by the Secretary of the Treasury on September 27, 1894. These regulations were applied by the PHS and cooperating State Boards of Health through the nation's first formal cooperative program.

The transfer of IQR to FDA occurred in 1975 and resulted in the establishment of the Interstate Travel Sanitation (ITS) program, now known as the Interstate Travel Program (ITP). These regulations are now found at Title 21 Code of Federal Regulations Parts 1240 Control of Communicable Diseases and 1250 Interstate Conveyance Sanitation.

Under ITP, FDA is charged with enforcement of the PHS Act and the Food Drug & Cosmetic Act (FD&C). A major objective under ITP is to prevent the introduction, transmission, or spread of communicable diseases from one state or U.S. Territory to another (interstate traffic) via conveyances. The terms "conveyance" and "interstate traffic" are defined in sections 21 CFR 1240.3 (Control of Communicable Disease-General Definition) and 21 CFR 1250.3 (Interstate Conveyances Sanitation-Definition). The conveyances inspected by FDA include aircraft, trains, buses and passenger vessels. We also inspect the support facilities for conveyances and these facilities include caterers, commissaries, watering points and service areas. FDA jurisdiction also applies to any company or firm that honors through bills-of-lading or through tickets for conveyances that have been issued on an interstate basis since each document legally demonstrates interstate traffic. However intrastate conveyances that sell interstate travel tickets do not meet this definition.

The size of the U.S. passenger conveyance industry is enormous. Collectively approximately 1 billion passengers are boarded on interstate conveyances each year. Passenger aircraft alone board approximately 700 million passengers annually. An August 2000 Research Triangle study entitled "Food Service in the Interstate Conveyance Industry" estimated the maximum number of passenger food service opportunities in the domestic transportation industry at 900 million. Many individuals have multiple exposures to the food offered on these conveyances because each time they travel on a conveyance they are counted as a passenger.

The Agency's effort in protecting the traveling public and crew includes:

- review of construction plans for conveyances and support facilities (plan submissions required by 21 CFR 1250.41 and 21 CFR 1250.62)
- inspection of interstate carrier conveyances under construction and the issuance of Certificates of Sanitary Construction for those conveyances
- inspection of interstate vessels in operation
- approval of a new support facility before an interstate carrier company can utilize the products or service of the facility
- inspections of existing support facilities that provide food, water, and waste handling services to interstate conveyances

On April 9, 2008, the Environmental Protection Agency (EPA) proposed to amend and consolidate the National Primary Drinking Water Regulations (NPDWR) for aircraft public water systems under the Safe Drinking Water Act (SDWA). Aircraft public water systems are subject to the requirements of SDWA and the

NPDWR. The final EPA Aircraft Drinking Water Rule (ADWR) published in the Federal Register on October 19, 2009 (Federal Register/Vol. 74, No. 200/Monday, October 19, 2009, pp. 53590 – 53625). Under Title ***40 CFR 141.804(b)(1) Aircraft Water System Operations and Maintenance Plan Watering Point Selection Requirement,*** *all Water sources must be from a FDA approved watering point in accordance with 21 CFR 1240.80*. Under the ADWR, airlines are required to sample and disinfect the drinking water systems on their own aircraft in accordance with manufacturer's operation and maintenance (O&M) cycles.

Taken together, FDA and EPA requirements clearly indicate that interstate carrier conveyances, specifically passenger aircraft with onboard water systems that meet the definition of a public water supply, are required by law and regulation to obtain their water supply from an FDA approved watering point and service area. To assure efficient enforcement of the SDWA and regulations and compliance by operators of aircraft, FDA has established and continues to maintain an internet accessible Official Classification List of FDA approved aircraft watering points and servicing areas for the use of operators of passenger aircraft with onboard water systems. This list is known as "Aircraft Watering Points and Servicing Areas Inventory Search" and is accessible at:
http://www.accessdata.fda.gov/scripts/AircraftWateringPoints/index.cfm

EPA entered into a legal agreement with AMTRAK in April 2012 requiring AMTRAK to disinfect and sample the drinking water systems on its railroad passenger cars at a frequency consistent with routine maintenance cycles and schedules. More information can be found at:
http://yosemite.epa.gov/opa/admpress.nsf/90829d899627a1d98525735900400c2b/8ba4f806e4f5a803852579ec006982ce!opendocument

The Food Safety Modernization Act will have an impact on specific types of ITP firms. FSMA re-inspection fees only apply to food firms (caterers and commissaries) that are required to be registered under the Bioterrorism Act of 2002 and are inspected under the FD&C Act.

PART II - IMPLEMENTATION

A. OBJECTIVES

To prevent the spread of communicable disease between states (including U.S. territories) and to protect the health of passengers and crews of interstate conveyances, FDA will:

- collect and analyze water samples from conveyance watering points as directed in the ITP ORA Work Plan and Sampling Collection Operation Planning Effort (SCOPE)
- examine the watering point inventory for each District and establish a priority inspection list to conduct the most important inspections first (see Part III- Inspectional)
- inspect conveyances, caterers, commissaries, watering points and servicing areas, both in operation and under construction, to develop information related to their compliance with the FDA regulations including 21 CFR Parts 110, 1240 and 1250, the last two promulgated under authority of the Public Health Service Act
- provide technical assistance to firms operating and servicing interstate conveyances through plan and equipment reviews
- inform caterers of the importance of addressing allergens per recommendations in the current version of the Investigations Operations Manual 5.4.6.6.3 and Section 2-102.11 of the FDA Food Code
- verify the District’s vessel inventory and inspect those vessels determined to be in interstate traffic
- review the specifications and plans of conveyances, equipment, and support facilities and issue letters of conformance/acceptance after review and concurrence for sanitary adequacy
- conduct orientation to the current Food Code for new firms or firms with new management including caterers, commissaries, vessels, and passenger trains in order to increase their understanding of the Food Code
- promote the completion of the Fundamentals of ITP (FD118) by all ITP personnel and FDA Food Code standardization of investigators that conduct catering facility inspections in accordance with FDA Procedures for the Standardization and Certification of Retail Food Inspection/Training Officers

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. Inspection Priorities

Inspection priorities for this program should cover the following:

a. caterers, commissaries, or food establishments that service interstate conveyances
b. aircraft* and rail watering points and sample collections
c. operational conveyances and conveyances under construction
d. support facilities (including those under construction)
e. watering points for non-aircraft conveyances

* Watering points at airports serving greater than 10,000 passengers annually are a priority.

NOTE: Criteria for Prioritizing Watering Point Inspections:

(1) watering Points located at sites accessible to conveyances that serve the largest number of passengers
(2) facilities that routinely draw large volumes of water(e.g. watering points serving *vessels and aircraft)*should be “large capacity”
(3) the last inspection date. (longest time since last inspection)

NOTE: Criteria for Prioritizing Vessel Inspections:

(1) vessels that serve or provide food and drink to passengers
(2) non-passenger vessels that serve or provide food and drinks
(3) all other vessels based on population

C. Planning Instructions

Note: The Guide to Inspections of Interstate Carriers and Support Facility, April 1995 or latest edition (ITP Inspection Guide) should be referenced for additional information.
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337416.pdf

Routine watering point inspections are of critical importance to the safe operations of all public conveyances by ensuring the delivery of a safe water supply to the crew and passengers.

Districts should follow Field Bulletin 44 so that the list of acceptable aircraft watering points and servicing areas will be maintained and updated on a quarterly basis. This is necessary for industry awareness of approved and use-prohibited supplies. The list is available at:
http://www.fda.gov/Food/ComplianceEnforcement/Inspections/ucm242960.htm

1. Inspection Frequency

Consistent with FSMA inspection frequencies, compliance status, and available work plan resources, conveyances and support facilities should be inspected at the following frequencies and as resources permit:

- Caterers at least once every three years
- passenger vessels and rail passenger cars with operating galleys at least once every three years
- watering points at least every three years
- servicing areas at least once every three years
- commissaries at least once every five years
- aircraft at airports are to be randomly inspected (not a required frequency, but when time and opportunity allow)
- buses at servicing areas are to be randomly inspected (not a required frequency, but when time and opportunity allow)

2. Plan and Specifications Reviews for Conveyances, Equipment, and Support Facilities

FDA must maintain contacts with conveyance and equipment construction firms and others in order to have early knowledge of and input into specifications and plan development. Refer to sections 7A, 7B and 7E of the ITP Inspection Guide for information on conducting plan and specifications review for equipment, conveyances, and support facilities, respectively. ITP personnel should keep informed about upcoming projects and industry trends in construction and food service through regular review of industry publications i.e. Marine Log and the internet. The CFSAN ITP Program Office also will provide information on developing technologies in construction and food service as needed.

Inspections are conducted during construction of conveyances and support facilities so that corrections may be initiated at a time that should assure compliance. Consider that the corrective actions are more easily taken prior to a conveyance entering passenger service. Submission of plans and specifications for new construction or major reconstruction of conveyances and support facilities is required by regulation (21 CFR 1250.41 for conveyances and 21 CFR 1250.62 for servicing areas). Foreign-built (imported) conveyances and equipment that operate under the FDA's jurisdiction in interstate commerce are also subject to construction and operational inspections. CFSAN will direct the plan review of conveyances intended for U.S. domestic use that are constructed in foreign countries.

D. Training Requirements for ITP Specialists/Investigators

The personnel conducting inspections of ITP firms should complete the following training:

- all basic CSO ORAU modules
- all other level I basic CSO work

- prerequisite review of ITP modules
- prerequisite Review of ITP videos and the related video manual
- FD118 Fundamentals of ITP
- FDA Food Code online training
- FD208 Plan Review for ITP
- FD218 Risk Based Inspections

Only FDA personnel standardized by CFSAN or Regional Retail Food Specialists in the Food Code or personnel with previous work experience and knowledge in the Food Code shall conduct food service establishment inspections of caterers, commissaries or conveyances where food service operations are present.

FDA personnel assigned plan and specification review shall complete FD208 ITP Plan Review or have previous work experience before conducting plan reviews. If this is not feasible the CSO should work with another CSO who has taken this training or who has extensive plan review experience. A list of trainings can be found at:

http://inside.fda.gov:9003/EmployeeResources/Training/ORAUCourses/default.htm for DHRD course listings.

E. Technical Assistance Meetings with Industry

To promote national uniformity and recognition of the FDA Food Code throughout the Interstate Travel Industry, FDA encourages District ITP personnel to assist and support industry in formulating training programs for employees engaged in FDA regulated operations related to the Interstate Travel Program. When requested, the ITP Manager will work with DHRD, ORA and District staffs to develop and supply guidelines and materials, including visual aids, for training activities.

F. Illness Investigations

1. Foodborne

Refer to IOM Subchapter 8.3, Investigation of Foodborne Outbreaks, for details and guidance in following up on suspected foodborne illnesses. (http://www.fda.gov/ora/inspect_ref/iom/default.htm). The District Emergency Response Coordinator (ERC) should be notified of all investigational findings. The District ERC will then contact CORE Signals Team and the ITP Manager as appropriate. When multiple Districts are involved in an investigation, coordination and communication are very important and as such a lead District should be designated.

For further guidance the International Association of Food Protection (IAFP) Procedures to Investigate Foodborne Illness 6th Edition (2011) and The American Public Health Association (APHA) Control of Communicable Diseases Manual 19th Edition (2008) should be consulted.

The CORE Signals Team should be contacted via the District ERCs for all

possible foodborne outbreaks/food emergencies via FDA email at CORE Signals Team or CORE Signals Team lead at coresignalsteam@fda.hhs.gov

2. Viral (Gastrointestinal/Person-to-Person)

Refer to IOM Subchapter 8.3.1.2, Outbreaks Involving Interstate Conveyances, (http://www.fda.gov/ora/inspect_ref/iom/default.htm) for details and guidance in following up on suspected gastrointestinal illness. If the illness level approaches 2% of passengers or crew, the District ERC should be notified. The District ERC should then notify the Regional ERC, District ITP Monitor, and CFSAN ITP. CFSAN ITP will then notify CORE Signals Team. If the outbreak investigation necessitates a site visit, the Outbreak Investigation Environmental Health Assessment Outline and Job Aid are available for review. http://inside.fda.gov:9003/ProgramsInitiatives/Food/InterstateTravelProgram/ucm390672.htm

3. Certain Communicable Diseases; Special Requirements

During the course of an illness investigation, if you suspect a person of being ill with a quarantinable disease, such as cholera, diphtheria, infectious tuberculosis, plague, suspected smallpox, yellow fever, or suspected viral hemorrhagic fevers immediately contact the District ERC who should contact the CDC.

4. Waterborne

During the course of an illness investigation, if a non-FDA regulated water source is suspected as the cause, contact the EPA Regional Drinking Water office. As CORE and District ERCs may be coordinating these investigations, the illness investigation lead should be notified in these cases to coordinate notification of EPA and/or State public health agencies. EPA Regional Drinking Water Office contacts can be found at: http://inside.fda.gov:9003/ProgramsInitiatives/Food/InterstateTravelProgram/ucm338551.htm

PART III - INSPECTIONS

During inspection of an ITP establishment, the District should verify whether the firm's practices are consistent with either the FDA Food Code or the recommendations in the ITP Handbook on Sanitation for each of the conveyances and their support facilities.

Inter-agency cooperation is encouraged with other Federal and State authorities that regulate passenger and cargo conveyances to achieve compliance with FDA regulations. (See Part V)

Inspect food service establishments in accordance with the most recent edition of the Food Code. Usage of the most current Food Code based on the best available science will provide better protection for the traveling public.

FDA investigators are to complete inspections using the current Food Code Food Establishment Inspection Report (Form 3-A) and report the findings to the firm's management. When critical Food Code deficiencies are found, they are to be correlated with 21 CFR 110 (caterers and commissaries) and 21 CFR 1250 (conveyances) sections and documented on the Form FDA 483 using the CFR citations within Turbo EIR. Form 3-A shall be submitted as an attachment to the EIR and also given to the operator with the Form FDA 483. If Food Code violations cannot be matched with CFR citations, these deficiencies should be noted during discussion with management and the EIR.

A non-turbo FDA-483 should be used for conveyance and support facility construction inspections. Citation references will mainly come from the construction guidelines, but keep in mind that some references could be from the CFRs.

A. Food Allergens

FDA inspections conducted per the FDA Food Code should cover allergens via conversation and questions with the firm's management for in-house usage of allergen alerts or declarations. If the investigator suspects a significant problem via undeclared or cross-contact of allergens, then the investigator should contact their supervisor and follow district procedures.

B. Orientation to the FDA Food Code
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337396.pdf

The form entitled "ORIENTATION TO THE FOOD CODE 2013- INTERSTATE TRAVEL PROGRAM" (ATTACHMENT A) may be used by the investigator to guide discussion of current Food Code changes with management during inspections of food service establishments (e.g., caterers, vessel galleys and rail galleys). The investigator should carefully review with management the five CDC risk factors most commonly associated with foodborne illness and the Food Code's five key public health interventions as well as the main provisions of the Food Code and its most recent revisions.

The five foodborne illness risk factors identified by CDC are:

1. improper holding temperatures
2. inadequate cooking temperatures
3. contaminated equipment
4. food from unsafe sources
5. poor personal hygiene

The five key Food Code interventions related to food safety that should be carefully addressed are:

1. demonstration of knowledge
2. employee health controls
3. controlling hands as a vehicle of contamination
4. time temperature parameters for controlling pathogens
5. consumer advisory

Note: If a food service operator requests a variance from a provision of the Food Code then the variance should be evaluated by the investigator per instructions listed in the Food Code at 8-103.10-12.

C. The field should emphasize the following activities:

- conducting inspections of caterers, commissaries, and conveyances with galleys
- conducting inspections of aircraft watering points, water trucks, carts, reels, and cabinets
- conducting inspections of rail and vessel watering points
- collecting samples for microbiological analysis per SCOPE sampling plan for the current fiscal year
- conducting vessel inventory verification and inspections
- informing and discussing the importance and concerns of undeclared allergens in food products with operators of food services

D. Interstate conveyances and support facilities as specified in Part II-Implementation, Section B.1.

1. Food Establishment Inspections (caterers, commissaries, galleys, etc.) – activities to be carried out per the current version of the Food Code:

   a. completing the current Food Establishment Inspection Report Form 3-A and email a scanned copy or forward a copy to HFS-615 to check for consistency in interpretation and application of the Food Code and to detect trends in the incidence of critical items

   b. conducting the Food Code Orientation as part of the exit interview with new management since the last inspection.

2. Watering Point Inspections – additional items not referenced in the CFRs to complete during the inspection:

   c. determine if the water supply and facility are municipal or private with an onsite well and distribution system

d. of an onsite system, determine if the facility's water system is routinely sampled per guidelines under the EPA Safe Drinking Water Act for bacterial, chemical and radiological levels

e. collect a copy of the last sample report (critical for watering points on private systems, for municipal systems sampling may not be conducted by the firm)

3. Vessel Verification and Inspection:

Using the District inventory, determine which of the U.S. flagged vessels are engaged in interstate traffic [21 CFR 1240.3(h)]. Inspect the U.S. flagged vessels add any new vessels to the District's inventory. Once the District list has been completed notify the ITP Manager, via E-mail, regarding how many new vessels have been added to the District's inventory along with the new total vessel inventory for the District.

4. Equipment, Conveyances, and Support Facilities under Construction – refer to Section 7 of the ITP Field Inspection Guide (Guide to Inspection of Interstate Carriers and Support Facilities, April 1995). http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337416.pdf

5. Operations of Conveyances – refer to Section 8 of the ITP Field Inspection Guide. http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337416.pdf

6. Support Facilities Operations – refer to Section 9 of the ITP Field Inspection Guide. http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337416.pdf

7. For conveyances and support facilities operating 24 hours a day, inspections should be scheduled to cover evening and night operations as well as daytime operations in order to evaluate conformance with good public health practices at all times. En route inspections and investigations of conveyances are appropriate as necessary to evaluate compliance.

E. Issue Certificates of Sanitary Construction (CSCs) in accordance with the Inspection Guide section 7D, Subsection on Vessels. http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337416.pdf

CSCs are to be assigned a unique serial number. The serial number shall consist of a 3-letter code which identifies the District e.g. "SEA"; followed by a hyphen and 2-digit fiscal year e.g. "-13" for FY 2013; followed by a hyphen and order of issuance e.g. "-05" for the 5th CSC issued in the fiscal year regardless of the type of conveyance the CSC is issued for. CSCs are available electronically on the Inside.FDA Forms catalogue.

If an airline wishes to have a new CSC issued for an aircraft which had a CSC when owned by another airline the purchasing airline must provided a copy of the original CSC to a FDA district office and the new CSC may be issued provide that no significant construction changes have been made since the original CSC issuance. Significant construction changes include the following:

- New/different or relocated galley shells
- Modification of the potable water sytems and/or it's tank(s) and fittings
- Modification of the sewage system and/or its tank(s) and fittings
- New or relocated restrooms
- Any other major structural modification of public health significance

- If significant deficiencies are uncorrected, withholding the certificate is an acceptable course of action with a letter sent to the construction company and/or conveyance operator outlining the reasons(s) for denial of certificate.

Note: Due to an increase in conveyance construction and lack of resources, several Districts are utilizing self-certification by conveyance manufacturers for issuance of Certificates of Sanitary Construction (CSC). Self-certification is briefly covered in OFFO-Inspection Guide of Interstate Carriers and Support Facilities under Section 7 - Construction of Equipment, Conveyances and Support Facilities, Subsection D - Certification of Conveyance Construction (pg. 7). However, more detailed instructions for self-certification programs will be issued by the Office of Food & Feed Operations (OFFO) (HFC-130) with cooperation from the Division of Field Programs and Guidance (HFS-615). In the interim please contact OFFO/DFFPOI/POB or CFSAN ITP for guidance. In addition, Certificates of Sanitary Construction, specific to self-certification (FDA 2371b) have been developed and must be used when a firm is self-certifying conveyances per a written agreement developed with the FDA District.

F. Sample Collection

Refer to 2014 IOM, Subchapter 4.3 Collection Technique for general information and instructions.

1. Food

- Collect samples for microbiological analysis as inspectional conditions warrant and as necessary as part of a suspected foodborne illness outbreak investigation.

2. Water

Because of the ADWR and EPA's agreement with AMTRAK, FDA needs to make drinking water sample collections at aircraft watering points and railroad watering points only and should not routinely collect water

samples from the operational conveyances themselves. Operational conveyance water systems should only be sampled when a suspected contamination has occurred, then a “for cause” sample should be taken as part of that investigation. Additionally operational conveyance systems should be sampled as directed by the FY Sampling Collection Operation Planning Effort (SCOPE).

- Water samples (2 subsamples) should be collected from conveyance watering points for microbiological analysis per current FY SCOPE. On the C/R indicate the date and time sampled as well as chlorine residual. See IOM 2014 instructions 4.3.6.3 "Collecting Water Samples" for collecting, preserving, and storing water samples. Onboard conveyance water systems should only be sampled “for cause” or per SCOPE.

Collect microbiological water samples (2 subsamples) during a conveyance construction inspection once it has been determined that the water supply has been properly designed and constructed. On the C/R indicate the date and time of sampling as well as chlorine residual. See IOM 2014 instructions 4.3.6.3 "Collecting Water Samples" for collecting, preserving, and storing water samples. As part of the certification process a FDA district may also use instead analytical results (acceptable to FDA) from a third party EPA-certified contract laboratory for a water sample coll ected from the conveyance. In lieu of sampling a third alternative is submission to FDA documentation of completed disinfection and flushing procedures used on the potable water system by the conveyance builder/renovator which are acceptable to FDA and are in accordance with EPA’s Aircraft Drinking Water Rule.

- It is highly recommended that sub-samples of water be collected from renovated vessels and rail passenger cars and be analyzed for presence of heavy metals in excess of Maximum Contamination Levels(MCLs) allowable under EPA’s National Primary Drinking Water Standards in 40 CFR 141.

  Instructions for heavy metal sampling can be found at: http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM353477.pdf

  NOTE: The designated servicing laboratory must be notified in advance when collecting microbiological water samples, so that the necessary media will be on hand when the samples reach the lab. These samples **must** be analyzed within 24 hours of collection.

G. Sample Submission

Submit water samples to the state or local health authority for analysis when part of a joint agreement or cooperative program with the District. Otherwise use the District designated servicing laboratory.

H. Import Activities

There are no direct import program activities under this program as foreign-built conveyances and equipment and other imported products are

covered under domestic activities of this program.

I. Reporting

Refer to FACTS Reporting in Section D of the Field Reporting Requirements on page 3 of the first section this Compliance Program.

J. OEI/FEI Management

The ITP Program and regulated conveyance firms are unique and present Official Establishment Inventory (OEI) development and maintenance issues that range from specific, static and defined to dynamic, previously undetermined and undocumented. Consistency across Districts will be the key to a uniform, accurate, and complete OEI.

ITP OEI and FEI decisions should be made based on guidance from:

- Field Management Directive (FMD) 130- OEI Development and Maintenance Procedures at http://www.fda.gov/iceci/inspections/fieldmanagementdirectives/ucm096034.htm

- ITP guidance provided at http://inside.fda.gov:9003/ProgramsInitiatives/Food/InterstateTravelProgram/default.htm

- Guidance generated during ITP Meetings at http://inside.fda.gov:9003/ProgramsInitiatives/Food/InterstateTravelProgram/ucm334352.htm.

ITP OEI/FEI concerns should be addressed with District OEI Coordinators in conjunction with the National OEI Coordinator.

PART IV - ANALYTICAL

A. ANALYZING LABORATORIES

1. Field Laboratories

a. Microbiological

1)	Indicator Organisms	All Regional Labs, DEN and SAN
2)	Determination of bacterial virulence or toxin production	All Regional Labs, DEN and SAN
3)	Water samples	All Regional Labs, DEN and SAN
4)	Salmonella speciation	ARL and DEN
5)	C. botulinum	All Regional Labs, DEN and SAN
6)	Salmonella antibiotic susceptibility testing	DEN

Note: ARL is the only lab performing mouse bioassay for botulinum.

b. Water Chemistry (Heavy Metals) KAN, SRL, SAN and NRL

2. CFSAN Laboratories

Mold Speciation	Office of Regulatory Science, HFS-712 Valerie H. Tournas (240) 402-1963

3. State or Local Health Laboratories

Districts collecting water samples may arrange for state and local health laboratories to conduct the sample analyses. Formal arrangements for these services can be made through joint partnership agreements or similar activities with the FDA.

B. ANALYSES TO BE CONDUCTED

FDA Field Laboratories

1. Water

Analyze microbiological samples within 24 hours of collection, for coliforms using either the "Standard Total Coliform MPN Tests" or the "Standard Total Coliform Membrane Filter Procedure" or "Colilert/Colisure" Method. Refer to the Standard Methods for the Examination of Water and Wastewater, 20th Edition, APHA, 2000 (or the most current edition as updated).

2. Foods

Use the following chart to determine appropriate methodology.

Type of Analysis	Source of Methodology
Microbiological Pathogens, Indicator Organisms, AOAC 17th Ed., Chapter 17 C. botulinum confirmation	Bacteriological Analytical Manual (BAM), see web link below
Heavy metals analysis (Pb, Cu, Cd, etc.) for potable water from systems on renovated vessels and rail passenger cars	Standard Methods for the Examination of Water and Wastewater, 20th Edition, APHA, 2000 (or the most current edition as updated) or other equivalent EPA approved or AOAC method

Note: AOAC website: http://www.aoac.org

BAM website: http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm114664.htm

Macro analytical Procedures Manual website: http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006953.htm

C. Analytical Reporting

Refer to FACTS Reporting in Section D of the Field Reporting Requirements on page 3 of this program.

PART V - REGULATORY/ADMINISTRATIVE

All cases must be submitted to CFSAN through the electronic Case Management System (CMS). See Item 4 Case Submission at the end of part V. No direct reference authority is provided to Districts under this Compliance Program.

This section covers:

- Conveyances in operation and under construction. These conveyances include passenger and cargo aircraft, vessels, trains and buses
- Conveyance support facilities in operation and under construction
  - o Watering points
  - o Caterers- prepare foods
  - o Commissaries-store foods
  - o Servicing areas- handle sewage

The authority for regulatory and administrative actions is found in the PHS Act, and the FD&C Act.

The PHS Act authorizes the Surgeon General to make and enforce regulations to Control Communicable Disease (42 U.S.C. 264). Delegations of authority are published in 21 CFR 199. FDA promulgated implementing regulations of 42 U.S.C. 264 in 21 CFR 1240 and 1250.

Title 21, CFR, Subpart C Equipment and Operation of Land and Air Conveyances, section 1250.41 requires firms to submit plans to FDA for construction or major reconstruction of sanitary equipment on conveyances for review of the conformity of the plans with FDA requirements.

VOLUNTARY COMPLIANCE

Districts having home offices with large conveyance or support facilities in their OEI should consider instituting programs that encourage self-correction by the industry, e.g., quality assurance programs, or self-inspection programs. The CFSAN ITP Manager (HFS-615) is available to discuss approaches that may apply to the District.

CASE INSTRUCTIONS

NOTE: An OAI classification should be considered immediately if continued operation of conveyance or support facility would cause serious illness, injury, or loss of life.

A. Conveyances in Operation

Based on the inspectional findings, the inspection will be classified NAI, VAI, or OAI. (See ORA Field Management Directive No. 86) Conveyance inspections classified NAI will be re-inspected on a routine basis. **Conveyances themselves shall not** be classified as **APPROVED, PROVISIONAL** or **NOT APPROVED (USE PROHIBITED)**.

Firms that make voluntary corrections will usually be classified as VAI. VAI classification may require accelerated follow-up through a re-inspection

within 90 days. The accomplishing District shall schedule a re-inspection based on the District's workload. If the conveyance will be leaving the FDA District's geographic jurisdiction, the District will coordinate a re-inspection of the same conveyance with other FDA District(s) based on the conveyance's itinerary. Accomplishing District should write a Memo for the Record to document this coordination and file it in the EIR file for the establishment where the conveyance was initially inspected with a copy sent to the District(s) that will conduct the re-inspection.

A Warning Letter (See Regulatory Procedures Manual Chapter 4) may be issued for a conveyance as a result of an OAI inspection. These letters must be submitted through the electronic Case Management System (CMS). See Item 4 Case Submission at the end of this Part V.

OAI classifications will require accelerated inspection follow-up based on acute health risks to the traveling public. Such health risks include foodborne or waterborne outbreaks; defective equipment (non-functional heating or refrigeration equipment for foods); or lack of backflow prevention devices where a high hazard cross-connection exists.

Health risks can be acute or long term. Long term exposure to public health risks found on conveyances can also be injurious to health and as severe as acute injury or illness if not mitigated.

Districts should propose compliance actions for all OAI inspections when submitting through CMS. Injunction or prosecutions are available compliance and enforcement actions. EIR(s) and supporting evidence must be submitted to CFSAN, Office of Compliance, through MARCS-CMS by the District Compliance Branch within 10 working days of the completion of the inspection.

Follow-up inspections and follow-up investigations for conveyances that operate across FDA Regional and District geographic areas need to be coordinated by the accomplishing District which originally documented the deficiencies. Copies of the documentation for all of these District compliance actions should be forwarded to the home District of the conveyance owner.

For example a United Airlines aircraft is inspected in Dallas. Its next destination for a re-inspection is Philadelphia. The Dallas District must coordinate the re-inspection with the Philadelphia District. Reports generated by Dallas and Philadelphia must be forwarded to Chicago District, which is the location of the United Airlines corporate offices, which owns and/or operates the airline.

Inter-agency cooperation is encouraged with other Federal and State authorities that regulate passenger and cargo conveyances to achieve compliance with FDA regulations.

Districts should coordinate their findings with the following Federal Agencies when OAI conditions are found. For example:

- For aircraft, contact and request the assistance of the Federal Aviation Administration (FAA). For example in some circumstances FAA may ground the aircraft in cases of severe vermin infestation. FAA has the authority to remove the airworthiness certificate from an aircraft

and may apply other administrative measures that will cause an airline operator to immediately correct problems. http://www.faa.gov/regulations_policies/handbooks_manuals/

- For railroad cars contact the Federal Railroad Administration (FRA). If warranted FRA may remove railcars from passenger train service. http://www.fra.dot.gov/Page/P0001

- For vessels contact the U.S. Coast Guard (USCG). USCG may issue a "Captain of the Port" order if the vessel is:
  - a hazard to navigation, and/or
  - its operation is polluting navigable waters with waste, and/or
  - crew members are at such health risk that operating the vessel will result in its becoming a hazard to navigation. http://www.uscg.mil/

- As part of the US Department of Transportation (DOT) the Federal Motor Carrier Safety Administration (FMCSA) is the bus and truck safety Agency for interstate travel. It was established as a separate administration within DOT in January 1, 2000. The regulations are found at Title 49 CFR Part 374 Passenger Carrier authorized by 49 U.S.C. pursuant to the Motor Carrier Safety and Improvement Act of 1999. http://www.fmcsa.dot.gov/

- U.S. Environmental Protection Agency maintains a list of acceptable community public drinking water supplies. http://www.epa.gov

Regulations for these federal agencies may be accessed through: http://www.gpoaccess.gov/topics/transportation.html

Districts are encouraged to maintain a relationship with their local FAA, FRA, US Coast Guard, EPA and DOT offices.

B. Conveyance Support Facilities

These facilities include watering points, caterers, commissaries and servicing areas that support the operation of passenger and cargo conveyances. Conveyances may only use support facilities that are approved by the U.S. Food and Drug Administration per 21 CFR 1240 and 1250 under the authority of 42 USC 264 of the Public Health Service Act. It is a violation of these regulations for a conveyance to use an unapproved watering point and servicing area (21 CFR 1250.60) or obtain food and drink from an unapproved source (21 CFR 1250.25).

All conveyance support facilities are classified as **APPROVED, PROVISIONAL, or NOT APPROVED (USE PROHIBITED)**.These classifications are comparable to inspectional classifications of NAI, VAI and OAI, respectively.

A **PROVISIONAL** classification requires issuance of a Warning Letter and requires a follow-up inspection within 30 days by FDA to determine if corrections were made. After corrections have been made and verified by FDA, the classification of the support facility may return to **APPROVED** classification. **PROVISIONAL letters are similar to Warning Letters and may be issued prior to taking further administrative action to classify a support**

facility as USE PROHIBITED. The District can return a firm to approved status after re-inspection. The District can submit the case to CFSAN ITP for consultation if they need guidance.

A **NOT APPROVED (USE PROHIBITED)** classification requires the firm submit corrective actions and request re-inspection by the District before being returned to Approved status. The case needs to be submitted to CFSAN ITP before the firm can be returned to Approved status.

Immediately notify user conveyance companies (local and headquarters offices) whenever support facilities are assigned **PROVISIONAL** or **USE-PROHIBITED** classification, with the appropriate documentation. Continuation of an **APPROVED** classification does not require notification.

Send a **PROVISIONAL** or **USE-PROHIBITED** notification by certified mail, including copies of the appropriately redacted Warning Letter (if any), FDA 483 and completed ITP inspection report form to the affected ITP conveyance company.

Also use certified mail to notify conveyance companies of an **APPROVED** classification for a support facility that is new, or for any upgrade from **PROVISIONAL** or **USE-PROHIBITED** to **APPROVED** classification.

Each change in classification of a support facility requires a written notification from FDA District to the conveyance companies using the support facility. Written notification can be an e-mail followed up with a hard copy of the notification to the conveyance company management.

CFSAN's ITP Program Manager must be immediately notified of changes in classification to maintain listings of approved conveyance support facilities.

4. CASE SUBMISSION

All cases should be submitted to CFSAN through MARCS-CMS. Users can access the system by navigating through INSIDE.FDA.GOV; http://intranetapps.fda.gov/scripts/vts/. A user's Guide is available within the application under the User's Guide link located at the top of the MARCS-CMS Main Screen.

PART VI – REFERENCES, PROGRAM CONTACTS AND ATTACHMENTS

A. REFERENCES

2013 IOM 3.2.4.3, "Centers for Disease Control and Prevention"; IOM 3.2.11.1, "EPA MOU'S; and IOM Subchapter 3.3, "State Operational Authority."

42 USC 264, Regulations to Control Communicable Disease:
http://www.fda.gov/RegulatoryInformation/Legislation/ucm149429.htm

42 USC 268 Quarantine & Inspection:
http://www.fda.gov/RegulatoryInformation/Legislation/ucm149435.htm

42 USC 271 Quarantine Violation Penalties:
http://www.fda.gov/RegulatoryInformation/Legislation/ucm149438.htm

Food Code, U.S. Public Health Service, FDA 2013. Copies of the Food Code are available for public sale by the U.S. Department of Commerce, National Technical Information Service:
http://www.ntis.gov/products/food-code.aspx.

Office of Food & Feed (DFFPOI) Fieled Bulletins Index, Bulletin 44:
http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/FieldInvestigations/ucm010365.htm

Field Management Directive #86: Establishment Inspection Report Conclusions and Decisions:
http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm056246.htm.

Field Management Directive #122: Interstate Travel Potable Water on Interstate Carrier Conveyances and at Watering Points:
http://www.fda.gov/ICECI/Inspections/FieldManagementDirectives/ucm056246.htm.

Guide to Inspection of Interstate Carriers and Support Facilities, April 1995:
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337416.pdf

Interstate Travel Program intranet website:
http://inside.fda.gov:9003/ProgramsInitiatives/Food/InterstateTravelProgram/default.htm

Food Code Inspection Report (Form 3-A)
http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337396.pdf

B. PROGRAM CONTACTS

1. Center Contacts

Compliance Program Inquiries:	Mildred L. McCray, OC/DFPG/PAMB(HFS-615); 240-402-2482; mildred.mccray@fda.hhs.gov
ITP Manager Technical Inquiries	Bruce E. Kummer, Office of Food Safety, Retail Food Protection Staff (HFS-320); 240-402-2142; bruce.kummer@fda.hhs.gov
Regulatory Inquiries:	Leslie Hintz, Division of Enforcement, Food Adulteration Assessment Branch, HFS-607, (240) 402-2073, leslie.hintz@fda.hhs.gov Sheena Crutchfield, Division of Enforcement, Food Adulteration Assessment Branch, HFS-607, (240) 402-5165, sheena.crutchfield@fda.hhs.gov
2. **ORA Contacts: Investigational**	Timothy (Matt) Albright, Office of Food and Feed Operations, HFC-130; 301-796-5453; Timothy.albright@fda.hhs.gov Kathryn Nagy, OFFO, HFC-130 (404) 253-1224; kathryn.nagy@fda.hhs.gov
Scientific Inquiries:	Sarah Skorupsky, ORA/ORS HFC-140, 240-402-4459, sarah.skorupsky@fda.hhs.gov
ITP Certificates	Timothy(Matt)Albright, OFFO, HFC-130, 301-796-5453; Timothy.albright@fda.hhs.gov
(FDA 2371, 2371A, 2372)	

C. ATTACHMENT

Attachment A: Orientation to the Food Code 2013.

PART VII - CENTER RESPONSIBILITIES

Program Office

The ITP Program Manager has the responsibility to prepare periodic formal evaluations of this compliance program. When completed and cleared, the evaluations will be available for Agency personnel on CFSAN's OC Field Programs Intranet site at: http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm015369.htm.

Coordinated Outbreak Response and Evaluation (CORE)

CORE coordinates, streamlines and strengthens FDA's efforts to prevent, detect, investigate, respond to, evaluate and apply lessons learned from foodborne outbreaks and public health incidents. Along with ORA and others in FDA, CORE helps to determine the strategy for and manage the implementation of outbreak response activities. CORE also evaluates environmental, epidemiologic, and laboratory data to inform assignments and direction of outbreak investigations including outbreaks involving ITP conveyances and facilities.

ORIENTATION TO THE FOOD CODE 2013
INTERSTATE TRAVEL PROGRAM

(New Management Orientation to the Food Code Interventions, Risk Factors and Provisions)

Region/District: _____ Date: _____

Specialist's Name: _____ Time In: _____ Time Out: _____

Purpose of meeting FOOD CODE ORIENTATION

The Name of Firm: _____

Address of Firm: _____

Type of Firm: ≤ Caterer ≤ Commissary ≤ Galley Other

Name/Title/Telephone # of Group Contact Person: _____

_____

Date and time conducted: _____

Level of responsibility of persons in attendance: _____

_____

Number of persons in attendance: ___ Hours of Preparation/Presentation: ___

Significant points discussed during the meeting (check all that apply):

☐ Interventions ☐ Risk Factors

☐ Variance Process and HACCP ☐ GRPs

☐ Others Significant Provisions (Please describe): _____

_____

_____
_

Feedback regarding the points discussed:
_____

_____
_

_____
_

Questions discussed requiring follow-up:

1. _____
_

_____
_

2. _____
_

_____
_

3. _____
_

_____
_

The person to contact for follow-up:
_____

Telephone #: _____ FAX #:
_____

Internet
Address:_____

(For guidance of discussion with management)