

## CHAPTER 18 – TECHNICAL ASSISTANCE

<b>SUBJECT:</b> <b>INTERSTATE TRAVEL PROGRAM-CONVEYANCES AND SUPPORT FACILITIES (FY 20-22)</b>		<b>IMPLEMENTATION DATE:</b> Upon Receipt
<b>DATA REPORTING</b>		
<b>PRODUCT CODES</b>	<b>PRODUCT/ASSIGNMENT CODES</b>	
<u>SAMPLES:</u> 29WYY30  Food/Service Areas- Industry 51 Conveyance Caterers- See CPGM 03.040 with reference to 18029A-D depending on conveyance for accountability See <a href="http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm">http://www.accessdata.fda.gov/scripts/ora/pcb/pcb.htm</a>	<u>REPORT ACCOMPLISHMENTS UNDER THE FOLLOWING PAC CODES:</u>  18029A Aircraft, accounting for caterers 18029B Buses, accounting for caterers 18029C Railroad, accounting for caterers 18029D Vessels, accounting for caterers 18029E Support Facility Construction 18029F Conveyances Under Construction 03040F & L Conveyance Caterers	

### FIELD REPORTING REQUIREMENTS:

#### District Follow-Up

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

Submit proposed **PROVISIONAL** and **NOT APPROVED** classification letters for watering points and servicing areas, as well as Warning Letters for Official Action Indicated (OAI) conveyance inspections 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: Sample Division Letter for New Approved Aircraft Watering Points and Servicing Areas

**Note:** Email a copy of letter to Interstate Travel Program (ITP) Manager

**C. Reports to Home Divisions and other FDA Offices**

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

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in classification to the conveyance companies, utilizing the facilities, and their corporate offices.

Notify the Director of Investigations Branch (DIBs) of the FDA Home Division 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; and
- expiration date of classification, if applicable.

## Contents

PART I - BACKGROUND .....	4
PART II - IMPLEMENTATION .....	7
1. Objective .....	7
2. Program Management Instructions .....	8
3. Program Interaction .....	8
PART III - INSPECTIONAL .....	
1. Operations- General .....	13
A. Inspections .....	13
1. Food Allergens	
2. Verifying Food Manager's Knowledge	
3. Field Emphasis and Priorities	13
4-9. Interstate Conveyance and Support Facility Inspections	14-5
10. Plan/Specification Review for Construction Inspections	16-18
B. Illness Investigations .....	18-9
C. Sample Collections .....	20
D. Sample Submission .....	21
E. Import Activities .....	21
F,G. Reporting- OEI/FEI Management, Workplanning .....	22
PART IV - ANALYTICAL .....	23
1. Analyzing Laboratories .....	23
2. Analyses to be Conducted .....	24
3. Methodology .....	24
4. Reporting .....	25
PART V - REGULATORY/ADMINISTRATIVE STRATEGY .....	26
PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS .....	31
1. References (Use headings 1-3 as needed)	16
FDA/ORA Regulatory Procedures Manual (Including Updates)	
Investigations Operations Manual (Most Current)	16
2. Attachments .....	32
3. Program Contacts .....	32
PART VII - CENTER RESPONSIBILITIES .....	34
ATTACHMENT A .....	35

## 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 under the Public Health Service (PHS) Act. 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 Federal Food Drug & Cosmetic Act (FD&C Act). 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 servicing areas. Caterers and commissaries are now inspected under the Preventive Controls Rule section of 21 CFR 117. 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 for other conveyances do not meet this definition.

The size of the U.S. passenger conveyance industry is enormous. Passenger aircraft boarded approximately 870 million passengers annually in a yearlong period between 2017-18. Also there were 31.7 million passenger trips on AMTRAK in FY 2017, 95 interstate passenger vessels with 100-200 passengers and crew per voyage and the large cruise vessel "Pride Of America" with 17-18 million passengers and crew annually. This does not include interstate commuter ferry boats. 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 servicing 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: <https://www.fda.gov/food/food-inspection-programs/aircraft-watering-points-servicing-areas>

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:

<https://www.epa.gov/dc/epa-amtrak-agreement-helps-ensure-drinking-water-safety-trains>

The FDA Food Safety Modernization Act (FSMA) has made an impact on specific types of ITP firms. The Preventive Control Rules in particular and all relevant sections of 21 CFR 117 apply to conveyance caterers and commissaries. FDA's Office of the Chief Counsel ruled in the fall of 2019 that the ITP classification rules using "Approved", "Provisional" and "Not Approved/Use Prohibited" could no longer be applied to conveyance caterers and commissaries and could not be referenced in Warning Letters for these firms.



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## PART II - IMPLEMENTATION

### 1. 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 Division and establish a priority inspection list to conduct the most important inspections first (see Part III- Inspectional);
- inspect passenger conveyances, watering points and servicing areas, both in operation and under construction, to develop information related to their compliance with the FDA regulations in 21 CFR Parts 1240 and 1250 (which were promulgated under authority of the PHS Act);
- when inspecting caterers and commissaries in operation under 21 CFR 117 (see CP 7303.040) include a couple of hours under PAC 18029A, 18029C, or 18029D and establishment type "J," so that these inspections may be tracked;
- provide technical assistance to firms operating and servicing interstate conveyances through plan and equipment reviews;
- verify the Division'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;
- inspect food service operations onboard conveyances in accordance with FDA Food Code requirements and relate any violations back to 21 CFR Part 1250;
- verify that the current Food Code is understood and being followed via active managerial control particularly onboard vessels and passenger trains with food service;
- promote the completion of the Interstate Travel Inspections (FD118) course by all ITP personnel and the online FDA Food Code course by investigators that conduct food service inspections onboard conveyances. An ITP certification/standardization procedure has been proposed to incorporate demonstration of this knowledge.

## 2. Program Management Instructions

### 1. Inspection Priorities

Inspection priorities for this program should cover the following:

- a. operational conveyances emphasizing passenger vessels and railroad passenger cars and conveyances under construction;
- b. aircraft and railroad watering points with related water sample collections under workplan and SCOPE sampling;
- c. support facilities (including those under construction); and
- d. watering points for non-aircraft conveyances

\* Watering points at airports serving more than 10,000 passengers annually are a higher 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 numerous aircraft );"
- (3) the last inspection date (longest time since last inspection should not exceed 3 years).

NOTE: Criteria for Prioritizing Vessel and Train Inspections:

- (1) vessels and trains that serve or provide food and drink to passengers;
  - (2) non-passenger vessels that serve or provide food and drinks; and
  - (3) all other vessels based on crew of 13 or more
- e. Note: conveyance caterers and commissaries are high-priority under 21 CFR 117 and CP 7303.040

### 3. Program Interaction

#### 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 for watering points and servicing areas, as well as



Warning Letters for OAI conveyance inspections 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.**

Attachment A: Sample Division Letter for New Approved Aircraft Watering Points and Servicing Areas

**Note:** Email copy of letter to CFSAN ITP Manager

#### B. 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.

#### C. 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 watering points and servicing 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. Divisions 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 ITP, they may request that the FDA Division 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. Since the on-line listing of aircraft watering point and servicing areas is only updated every 3 months,

the Division should provide a letter of acceptance or equivalent e-mail to the carrier, if acceptable results are found during the inspection as soon as possible after the inspection. (see Attachment A below)

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 eNSpect, as appropriate using the following Problem Area Flags PAF:

PAF Problem Area Flag (Description)

MIC Microbiological analysis (rapid microanalytical test kits included)  
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, bags ice

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/ucm056246.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 should be reported under Operation Code 12, "Inspection."

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

FDA must maintain contacts with conveyance companies and equipment construction firms and others in order to have early knowledge of and input into specifications and plan development. 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.

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. Keep in mind that EPA has a new lead-free certification requirement for potable water piping on new-built and renovated conveyances and at conveyance support facilities.

Greater detail regarding information needed from a conveyance builder/renovator or the conveyance operator is covered under Section III of this document.

F. Training Requirements for ITP Specialists/Investigators

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

- all basic CSO ORAU modules and other level I basic CSO work
- prerequisite review of ITP modules;
- FD118 Interstate Travel Inspections (online);
- FDA Food Code online training;
- FD208 Plan Review for ITP;
- FD218 Risk Based Inspections; and
- FD333 Aircraft Construction and Certification (districts with builders).

Only FDA personnel trained in the Food Code or personnel with previous work experience and knowledge in the Food Code shall conduct inspections of conveyances where food service operations are present. Training in Preventive Control Rules inspections and 21 CFR 117 is necessary for inspections of caterers and commissaries. An ITP certification/standardization procedure has been proposed for future development. This would include inspections of caterers, commissaries, watering points and servicing areas, as well as a plan review for a conveyance or support facility.

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 Consumer Safety Officer (CSO) should work with another CSO, who has taken this training or has extensive plan review experience. FD333 Aircraft Construction is necessary for those conducting aircraft certification and construction inspections. A list of training courses can be found at:

<https://orauportal.fda.gov/stc/ORA/psciis.dll?CLASS=ORA&CODE>  
for OTED course listings.

G. Technical Assistance Meetings with Industry

To promote national uniformity and recognition of the FDA Food Code throughout the Interstate Travel Industry, FDA encourages Division 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 OTED, ORA, and Division staffs to develop and supply guidelines and materials, including visual aids, for training activities.

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**PART III - INSPECTIONAL****A.****GENERAL**

During inspection of an ITP establishment, the Division should verify whether the firm's practices are consistent with either 21 CFR 117 (for caterers and commissaries), the FDA Food Code (for conveyance food service inspections), or the recommendations in the appropriate ITP Handbook on Sanitation for 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 of this document)

Inspect food service operations onboard conveyances 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), as a guide for onboard conveyances and report the findings to the firm's management. 21 CFR 117 is to be used during inspections of caterers and commissaries and 21 CFR 1250 and 21 CFR 1240 are to be used during conveyance inspections. Objectionable conditions are to be linked to these CFR sections and documented on the Form FDA 483 using the CFR citations within eNSpect. Form 3-A may be submitted as an attachment to the EIR, but does not need to be given to the conveyance 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 in the EIR.

A non-eNSpect 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.

**1. Food Allergens**

FDA inspections at caterers and commissaries will be conducted under CP 7303.040 and 21 CFR 117, so discussing concerns about undeclared allergens with management at these food establishments is essential.

**2. Verifying the food manager's knowledge of risk factors during conveyance food service inspections**

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; and
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; and
5. consumer advisory.

Note: If a food service operator onboard a conveyance requests a variance from a provision of the Food Code then the variance should be submitted to CFSAN ITP for evaluation by CFSAN Retail Food Protection Staff.

3. The field should emphasize the following activities:

- conducting onboard inspections of conveyances with galleys using the FDA Food Code.
- conducting inspections of aircraft watering points, water trucks, carts, reels, and cabinets in support of EPA's Aircraft Drinking Water Rule.
- 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.
- Note: inspection of caterers and commissaries under the Preventive Controls Rule (CP 7303.040) is also high priority.

4. Interstate conveyances and support facilities

- a. Food service onboard inspections (train and vessel galleys, etc.) - activities to be carried out per the current version of the Food Code:
  1. Using the current FDA Form 3-A as a guide for food service operations on conveyances and including it in the EIR as an option per policy set by individual Divisions.
  2. Verifying management's knowledge of current Food Code as part of the onboard conveyance food service inspection.
- b. Obtain a list of customers from all support facilities in order that the information would be available in case of future Warning Letters for the violative facility.

- c. Watering Point Inspections - additional items not referenced in the CFRs to complete during the inspection:
1. determine if the water supply and facility are municipal or private with an onsite well and distribution system
  2. if 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.
  3. collect a copy of the last water sample report (critical for watering points on private systems, for municipal systems sampling may not be conducted by the firm).

5. Vessel Verification and Inspection:

Using the Division 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 and add any new vessels to the Division's inventory. Once the Division list has been completed, notify the CFSAN ITP Manager, via e-mail (see section c of the field reporting requirements above) regarding how many new vessels have been added to the Division's inventory along with the new total vessel inventory for the Division.

6. 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>
7. Operations of Conveyances - refer to Section 8 of the ITP Field Inspection Guide.  
<http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337416.pdf>
8. Support Facilities Operations - refer to Section 9 of the ITP Field Inspection Guide.  
<http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/InterstateTravelProgram/UCM337416.pdf>
9. 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.

10. Plan And Specification Reviews For Construction Inspections

a. Typically the following information, plans and specifications should be requested for review for a **vessel under construction**:

1. total number of passengers and crew
2. total capacity of potable water tanks and sewage retention tanks
3. maximum daily capacity of potable water distiller or RO water purifier and sewage treatment system (if it has both of these)
4. itinerary that vessel will take, showing number of days in port and number enroute to determine if there is sufficient refrigeration capacity
5. promotional brochure for voyages if applicable
6. drawings of outboard and inboard profile, deck layout
7. potable water system drawing with backflow preventer & lead-free piping certification information
8. sewage system drawing, including typical toilet design
9. tank plan showing the perimeters of potable water and sewage tanks, capacities
10. specifications and equipment list for all food areas, lighting for these areas
11. drainage system drawing
12. layout of galley, dining areas, food storage spaces, scullery, and other food spaces
13. scantling or hull plan showing location of black and grey water overboard discharges as well as sea chest(s) where suction is provided for potable water production unit(s)
14. ventilation system
15. refrigeration capacity
16. schedule of floor, ceiling and bulkhead coverings
17. vermin exclusion measures (insect, rodent, etc.)

b. Typically, the following information, plans and specifications should be requested for review for an **aircraft or rail passenger cars under construction**:

1. total capacity of potable water tanks and sewage retention tanks
2. potable water system drawing and related backflow prevention devices and lead-free piping certification
3. sewage and drainage system drawings
4. layout of aircraft or rail passenger car showing the locations of potable water and sewage tanks
5. specifications and equipment list for all food areas
6. layout of galley, dining areas, food storage spaces, scullery, and other food spaces
7. number of passengers and crew
8. schedule of floor, ceiling and bulkhead coverings
9. restroom design
10. vermin exclusion measures (insect, rodent, etc.)

c. Typically the following information, plans and specifications should be requested for review for a **conveyance watering point or servicing area**



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**under construction:**

1. potable water system drawing and related backflow prevention devices and lead-free piping certification information
2. sewage and drainage system drawings
3. sketch of lavatory dump pit
4. sketch of potable water hose storage cabinet
5. site drawing showing location relative to other facilities and connections to municipal water supply, sewage and storm drain systems
6. employee restrooms

d. Typically the following information, plans and specifications should be requested for review for a **catering kitchen or commissary under construction:**

1. total number of meals to be prepared each day
2. potable water system drawing with backflow preventer & lead-free piping certification information
3. sewage and drainage system drawings
4. meal volume to determine if sufficient refrigeration capacity
5. specifications and equipment list for all food areas
6. layout of cooking and food production areas, dining areas, food storage spaces, dishwashing and other food spaces; lighting and ventilation for these areas
7. site drawing showing location relative to other facilities and connections to municipal water supply, sewage and storm drain systems
8. schedule of floor, ceiling and bulkhead coverings
9. employee restrooms
10. number of employees
11. pest control measure

e. Inspections are conducted during construction of conveyances and support facilities, so that corrections may be initiated at a time when compliance is more easily achieved. 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. .

f. 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 calendar year e.g. "- 20" for calendar year 2020; followed by a hyphen and order of issuance e.g. "-05" for the 5<sup>th</sup> CSC issued in

the fiscal year regardless of the type of conveyance the CSC is issued for. CSCs are available electronically at the following links:

<http://inside.fda.gov:9003/downloads/administrative/forms/fda/ucm034236.pdf>

<http://inside.fda.gov:9003/downloads/administrative/forms/fda/ucm034218.pdf>

<http://inside.fda.gov:9003/downloads/administrative/forms/fda/ucm034235.pdf>

The prior CSC numbering system was intended for use through FY 2019.

The Food Division Director shall sign the conveyance CSCs but copies shall be kept in the appropriate District and Division files.

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 provide a copy of the original CSC to a FDA district/division office and the new CSC may be issued provided 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 system and/or its 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 the CSC.

**Note:** Due to an increase in conveyance construction and lack of resources, several Divisions are utilizing self-certification by conveyance manufacturers for issuance of Certificates of Sanitary Construction (CSC). Self-certification is covered at the ITP intranet website at [inside.fda>Programs and Initiatives→Food→ITP 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.

## B. 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. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual>

The Division Emergency Response Coordinator (ERC) should be notified of all investigational findings. The Division ERC will then contact CORE Signals Team and the ITP Manager as appropriate. When multiple Divisions are involved in an investigation, coordination and communication are very important and as such a lead Division should be designated. For further guidance the International Association of Food Protection (IAFP) Procedures to Investigate Foodborne Illness 6<sup>th</sup> Edition (2011) and The American Public Health Association (APHA) Control of Communicable Diseases Manual 20<sup>th</sup> Edition should be used.

The CORE Signals Team should be contacted via the Division 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](mailto:coresignalsteam@fda.hhs.gov)

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

Refer to IOM Subchapter 8.3.1.2, Outbreaks Involving Interstate Conveyances <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual>

for details and guidance in following up on suspected gastrointestinal illness. If the illness level is at 2% of passengers or crew, the Division ERC should be notified. The Division ERC should then notify the Regional ERC, Division ITP Monitor(s), and CFSAN ITP. CFSAN ITP will then notify CORE Signals Team. If the outbreak investigation necessitates a site visit, see the Outbreak Investigation Environmental Health Assessment Outline and Job Aid 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 disease requiring quarantine, such as cholera, diphtheria, infectious tuberculosis, plague, suspected smallpox, yellow fever, or suspected viral hemorrhagic fevers immediately contact the Division 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 Division 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>

C. Sample Collection

Refer to 2020 IOM, Subchapter 4.3 Collection Technique for general

information and instructions.

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual>

## 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 Aircraft Drinking Water Rule 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 conveyance themselves. Operational conveyance water systems should only be sampled when a suspected contamination has occurred, and 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 sub-samples) 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 2020 section 4.3.6.3 "Collecting Water Samples" for collecting, preserving, and storing water samples. Emphasis should be placed on sampling water from potable water carts and trucks since most airports with municipal water supplies are sampled routinely in accordance with EPA rules. When sampling carts and trucks also collect additional subsample(s) from the location(s) where the carts or trucks are filled to verify source water quality. Watering points at smaller airports or those supplied from wells also should be emphasized. 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 section. 2020 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 collected from the conveyance. In lieu of sampling a third alternative is submission to FDA documentation of completed effective 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. Effectiveness of these procedures must be shown through repeated verifiable results over a period which is acceptable to the

Division ITP staff. This third alternative is most applicable for builders/renovators with long experience with FDA disinfection and flushing procedures.

- 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.

D. 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 Division. Otherwise use the Division designated servicing laboratory.

E. 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.

F. Reporting

1. Refer to FACTS Reporting in Section D of the Field Reporting Requirements on page 9 of section II of this Compliance Program document.

2. 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 Divisions 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://sharepoint.fda.gov/search/InsideFDA/SearchCenter/Pages/results.aspx?k=Field+Management+Directive&s=Inside.FDA&x=9&y=7>  
<https://www.fda.gov/media/87643/download>

- ITP guidance provided at <http://inside.fda.gov:9003/ProgramsInitiatives/Food/InterstateTravelProgram/ucm334369.htm>
- Guidance generated during ITP Meetings at <http://inside.fda.gov:9003/ProgramsInitiatives/Food/InterstateTravelProgram/ucm334352.htm>.
- Additional program information at the ITP intranet website at <http://inside.fda.gov:9003/ProgramsInitiatives/Food/InterstateTravelProgram/default.htm>

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

#### G. Work-planning

1. For purposes of time efficiency and reduced travel expenditure, it is recommended that all aircraft watering points, servicing areas, and commissaries at a particular airport, be scheduled for inspection at the same time. The OEI should be checked to assure that all firms previously inspected at a geographic location are revisited at that time and to make OEI changes, if those facilities are no longer located there. Time efficiency will be improved by working with employees of the airport manager's office or its maintenance department, since they are familiar with the location of facilities, piping and backflow preventers, and appropriate responsible personnel at the airlines, who can expedite any corrections needed.

M. Import Sample Collections - no import samples are collected for the Interstate Travel Program

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## PART IV - ANALYTICAL

### A. ANALYZING LABORATORIES

#### 1. Field Laboratories

##### a. Microbiological

- 1) Indicator Organisms All Regional Labs, DEN and SAN
- 2) Determination of All Regional Labs, DEN and bacterial virulence SAN or toxin production
- 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 DEN susceptibility testing

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

Divisions 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 CONDUCTEDFDA Field Laboratories1. 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 <http://dl.icdst.org/pdfs/files/9b8d1f12b54f3154c8c648e0ec810185.pdf> ).

2. Foods

Use the following chart to determine appropriate methodology.

Type of AnalysisSource of Methodology

Microbiological Pathogens,  
Indicator Organisms,  
AOAC 17<sup>th</sup> 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, 20<sup>th</sup> Edition,  
APHA, 2000 (or the most  
current edition as updated),  
other equivalent EPA approved  
AOAC method

**Note: AOAC website:** <http://www.aoac.org>

**BAM website:**

<https://www.fda.gov/food/laboratory-methods-food/bacteriological-analytical-manual-bam>

**Macro analytical Procedures Manual website:**

<http://www.fda.gov/Food/FoodScienceResearch/LaboratoryMethods/ucm2006953.htm>



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C. Analytical Reporting

Refer to FACTS Reporting in Section D "Field Reporting Requirements" of this document .

## PART V - REGULATORY/ADMINISTRATIVE STRATEGY

### 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 of this document. 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**

Divisions 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-320) is available to discuss approaches that may apply to the Division.

### **CASE INSTRUCTIONS**

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

## A. Conveyances in Operation

Based on the inspectional findings, the inspection will be classified as No Action Indicated ("NAI"), Voluntary Action Indicated ("VAI") or Official Action Indicated ("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 Division shall schedule a re-inspection based on the Division's workload. If the conveyance will be leaving the FDA Division's geographic jurisdiction, the Division will coordinate a re-inspection of the same conveyance with other FDA Division(s) based on the conveyance's itinerary. The accomplishing Division 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 Division(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 but ITP inspection classifications ("Approved", "Provisional", "Not Approved/Use Prohibited") shall not be used. These letters must be submitted through the electronic Case Management System (CMS). See Item 4 Case Submission at the end of Part V of this document.

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.

Divisions 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's Office of Compliance, through MARCS-CMS by the Division 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 Division geographic areas need to be coordinated by the accomplishing Division which originally documented the deficiencies. Copies of the documentation for all of these Division compliance actions should be forwarded to the home Division of the conveyance owner.

For example, a United Airlines aircraft is inspected in Dallas. Its next

destination for a re-inspection is Philadelphia. Human and Animal Foods (HAF) 3W (3 West) must coordinate the re-inspection with HAF 2E (2 East).

Reports generated by HAF 3W and HAF 2E must be forwarded to HAF 6E, 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.

Divisions 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/](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:
  - o a hazard to navigation, and/or
  - o its operation is polluting navigable waters with waste, and/or
  - o 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:

<https://www.transportation.gov/office-policy/transportation-policy/transportation-safety-regulation-united-states-government>

Divisions 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 (21 CFR 1240.80) and servicing area (21 CFR 1250.60) or obtain food and drink from an unacceptable source (21 CFR 1250.25). Information regarding specific customers using support facilities should be routinely obtained during all inspections of watering points and servicing areas for future reference should violative conditions warrant assignment of "Provisional" or "Not Approved" classification to those facilities.

Watering points and servicing areas are classified as **APPROVED, PROVISIONAL, or NOT APPROVED (USE PROHIBITED)**. These classifications are comparable to inspectional classifications of NAI, VAI, and OAI, respectively. As a result of a ruling by FDA's Office of Chief Counsel in October 2019, the ITP classification system shall not be applied to conveyance caterers and commissaries. Warning Letters to these firms should cite violations of 21 CFR 117's Preventive Controls Rule but not reference "Approved", "Provisional" or "Not Approved/Use Prohibited" classifications in their content.

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 watering point or servicing area 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 Division can return a firm to **APPROVED** status after re-inspection. The Division can submit the case to CFSAN ITP for consultation if they need guidance.

A **NOT APPROVED (USE PROHIBITED)** classification for a watering point or servicing areas requires the firm submit corrective actions and request re-inspection by the Division 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. Airlines using new aircraft watering points and servicing areas that have been inspected and found acceptable to FDA should be notified by letter or e-mail immediately since the on-line "approved" list is only updated every 3 months. (See Attachment A)

Send a **PROVISIONAL** or **USE-PROHIBITED** notification by certified mail,

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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 Division 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 of aircraft watering points and servicing areas to maintain the listings of these approved conveyance support facilities.

### **C. CASE SUBMISSION**

All cases should be submitted to CFSAN through MARCS-CMS. Users can access the system by navigating through INSIDE.FDA.GOV or this link:

<http://cms.fda.gov/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.

**Import Compliance Actions:** There are no import compliance actions for the Interstate Travel Program

**PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS****1. References**

FDA/ORA Regulatory Procedures Manual (Including Updates) Investigations Operations Manual (Most Current)

2020 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."

<https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual>

42 USC 264, Regulations to Control Communicable Disease:

<https://www.govinfo.gov/content/pkg/USCODE-2011-title42/html/USCODE-2011-title42-chap6A-subchapII-partG.htm>

42 USC 268 Quarantine & Inspection:

<https://www.govinfo.gov/content/pkg/USCODE-2011-title42/html/USCODE-2011-title42-chap6A-subchapII-partG.htm>

42 USC 271 Quarantine Violation Penalties:

<https://www.govinfo.gov/content/pkg/USCODE-2011-title42/html/USCODE-2011-title42-chap6A-subchapII-partG.htm>

Food Code, U.S. Public Health Service, FDA 2017. Copies of the Food Code are available for public sale at:

<https://www.bing.com/shop?q=purchase+2017+fda+food+code&FORM=SHOPPA&originIGUID=8F3A2F736D4E43BFBACDC13482CB935F>

Office of Food & Feed (DFFPOI) Field Bulletins Index, Bulletin 44:

<http://inside.fda.gov:9003/PolicyProcedures/GuidanceRegulations/FieldInvestigations/ucm010365.htm>

Office of Human and Animal Food (OHAFO) Field Bulletins Index, Bulletin 56:

<http://inside.fda.gov:9003/downloads/PolicyProcedures/GuidanceRegulations/FieldInvestigations/UCM478911.pdf>

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, 4/95:

<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>

"EPA's Summary of the Reduction of Lead in Drinking Water Act and Frequently Asked Questions"

at <http://water.epa.gov/drink/info/lead/upload/epa815s13003.pdf>

## 2. Attachments

A. Sample Division Letter for New Approved Aircraft Watering Points and Servicing Areas

## 3. Program Contacts

**Compliance Program Inquiries:** Dr. Jeffery L. Sumter  
OC/DFPG/PAMB(HFS-615); 240-402-3037; jeffery.sumter@fda.hhs.gov

**ITP Technical/Policy Inquiries:**

**CFSAN/OFS/RFPS**

RFPS Director Glenda R. Lewis,  
(HFS-320) 240-402-2150;  
glenda.lewis@fda.hhs.gov

**Regulatory Inquiries:**

Nicholas Long Division of  
Enforcement, Food Adulteration  
Assessment Branch, HFS-607, (240)  
402-1612, nicholas.long@fda.hhs.gov

**ORA Contacts: Investigational**

Larry Stringer, Office of Human and  
Animal Food Operations, HFC-130;  
301-796-6523;  
Larry.stringer@fda.hhs.gov

**ITP Certificates (2371,2371A, 2372)**

Larry Stringer, Office of Human &  
Animal Food Operations, HFC-130,  
301-796-6523;  
Larry.stringer@fda.hhs.gov



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**SCIENTIFIC METHOD ANALYSIS CONTACTS:****Scientific Inquiries:**

Office of Regulatory Science,  
(ORS), HFC-141, (301) 796-1027.  
(Filth)

ORS, HFC-141, (301) 796-  
(Microbiology and Chemistry);

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**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.

**ATTACHMENT A**

ATTACHMENT A: Sample Division Letter for New Approved Aircraft Watering Points and Servicing Areas

Division Director  
Human & Animal Foods 1 East Div.  
Food and Drug Administration  
222 Rockaway Boulevard  
Queens, New York XXXXX

May 1, 2020

Mr. Floyd Butternut, President/CEO  
Northeastern Airlines  
L1011 Landing Zone Drive  
Portland, Maine XXXXX

Subject: Aircraft Watering Points at Syracuse, New York Airport

Dear Mr. Butternut

This letter is being sent to inform you that your new watering points at Gates A-1 and A-2 at Syracuse, New York airport were inspected by investigators from our FDA Division HAF 1East office on April 22, 2020. These watering points were found to be constructed, maintained, and operated in accordance with FDA's requirements set forth in 21 CFR 1240 and 1250 and the Handbook on Sanitation of Airlines. As a result, we are assigning "Approved" classification to these watering points. This means that the facilities may be used to water your aircraft and those of any customers.

FDA's official listing of "approved" aircraft watering points and servicing areas on the fda.gov website, under the "Aircraft Watering Points and Servicing Areas Inventory Search" heading, is updated on a quarterly basis. The next update is not scheduled until June 30, 2020.

This interim letter serves to inform you that the referenced aircraft watering points are currently "Approved," although they may not appear on the fda.gov website around June 30, 2020.

Sincerely

Walter P. Mittendorf  
Division Director, HAF 1E