

CHAPTER 18 -TECHNICAL ASSISTANCE

SUBJECT: INTERSTATE TRAVEL PROGRAM - CONVEYANCES AND SUPPORT FACILITIES (FY 07/08)		IMPLEMENTATION DATE 10/01/06
This program has completed a Good Guidance Practice clearance by CFSAN's ORP and OC/DEP/CPB in September 2006.		COMPLETION DATE 9/30/08
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES	
SAMPLES: WATER - 29WYY30 OTHER - Use appropriate 7 digit code	1.	<u>REPORT INSPECTIONS UNDER THE FOLLOWING PACS:</u> 18029A Aircraft 18029B Buses 18029C Railroad 18029D Vessel 18029E Support Facility Construction *18029F Conveyances under construction (new)
Note: (*) indicated changes/revisions		

Note: Material that is not releasable under the Freedom of Information Act (FOIA) has been redacted/deleted from this electronic version of the program. Deletions are marked as follows: (#) denotes one or more words were deleted; (&) denotes one or more paragraphs were deleted; and (%) denotes an entire attachment was deleted.

FIELD REPORTS TO HEADQUARTERS

A. Reports to Headquarters

*All Warning Letter recommendations must clear CFSAN's Program Office through CFSAN's Division of Enforcement. Recommendations should include:

- Inspection Forms issued;
- Inspection Observations FDA Form 483; and,
- Summary of Findings

B. Attachment

*Attachment A: Orientation to the Food Code 2005

Note: Food Code 2005 - Submit only for new firms or new management; Forward to HFS-636, ATTN: ITP General Inquires Contact.

C. Reports to Other Field Locations, Agencies and Industry

1. Reports to Home Districts and other FDA Offices.

Send EIRs with recommendations for Use-Prohibited and Provisional equipment, conveyances or support facilities to the appropriate FDA Home District(s) and ***to CFSAN ITP Manager (HFS-615)***. When appropriate send notification of a change in classification to the home district of the facilities' corporate office, the home district of conveyances utilizing the facilities, and their corporate offices. Routine notification of headquarters offices is not necessary.

Notify the affected FDA units via electronic mail (ATTN: Interstate Travel Program) so that they may take the necessary action. Send a copy to ITP Manager and the Division of Enforcement, Chief of Domestic Branch (HFS-607), (see regulatory contact, part VI). The message must contain the following information:

- a. The name(s) of the establishment;
- b. The location (e.g., address);
- c. FEI number;
- d. 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;
- e. The classification of the establishment and whether or not it is based on the condition of the support facility, water quality (EPA), or combination of both. Include a brief summary of findings; and
- f. Classification and 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, Vessel Sanitation Program Chief, David Forney at 770-488-73333.

***The MOU with Canada regarding "U.S.A. Interstate Travel Sanitation Program and the Canadian Common Carrier Program" ended 7/26/98. There is a possibility of negotiating another MOU. It is being discussed. At this time consult ITP Manager for additional information*.**

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 regularly contacted and reminded of the need to advise the FDA immediately of recommended changes of classification based on inspections where interstate carrier operations could adversely be affected.

3. Reports to Industry

To enable conveyances to comply with the regulations, FDA must keep them informed of the status of ITP support facilities employed by them, so, if necessary, they can locate an alternate 'Approved' backup facility.

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 using the facility, and make it a part of the report in order that the carriers be immediately notified when a support facility classification changes. This list is not intended to generate a list of carriers but as a tool to make sure conveyances are aware of changes in the status of their potential support facilities. Districts should verify list prior to sending classification letter.

Immediately notify user conveyance companies (local and headquarters offices) whenever conveyances, support facilities, or related facilities are assigned:

- A Provisional or Use-Prohibited classification, with the appropriate documentation. Continuation of an Approved classification does not require re-notification; and
- Follow up a Provisional or Use-Prohibited notification by certified mail, including copies of appropriately redacted Warning Letter (if any), FDA 483 and completed ITP inspection report form;

Also use certified mail to notify conveyance companies of an Approved classification to a support facility that is new, or any upgraded classification from Provisional or Use-Prohibited.

Note: If a conveyance company desires to use a facility that is not currently inspected under the Interstate Travel Program, they may make a request for the FDA to conduct an inspection. Once the inspection is completed, the conveyance company shall be notified of its classification, and the facility is then added to the district's ITP OEI.

D. FACTS Reporting

***Note: PAC 18029F:** All visits will require that a form FDA 482 be issued. These are now considered inspections as per ORA workplan for conveyance under construction is new to the program. All visits will 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:

<u>PAF</u>	<u>PAF Description</u>
FIL	Mold, arthropod, bird, animal, foreign object, filth analysis
FIL	Decomposition, other than fishery products
MIC	Microbiological analysis (includes rapid test kits for microanalysis)

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.

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", ORA-Field Management Directive No. 86 at www.fda.gov/inspect_ref/fmd/fmd86.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 under **Operation Code 13**, "Domestic Investigation". The operation code has been changed from 98 to 12 so that visits to conveyances under construction will be treated, as an inspection and a form FDA 482 must be issued. Orientation to the Food Code (only for new firms or management) should be reported under Operation Code 12 - Inspection*.

PART I - BACKGROUND

The Food and Drug Administration is charged with enforcement of the Interstate Travel Program (ITP) under the Public Health Service (PHS) Act. A major objective under the ITP is to prevent the introduction, transmission, or spread of communicable diseases from one state to another. This includes US territories, via interstate conveyances as defined, in addition to sections 21 CFR 1240.3 (Control of Communicable Disease-General Definition) and 21 CFR 1250.3 (Interstate Conveyances Sanitation-Definition) for any company or firm **that** honors through bills-of-lading or through tickets (each legally demonstrates interstate commerce) that have been issued on an interstate basis (this does not include intrastate conveyances that sell interstate tickets). The Agency's effort in protecting the traveling public and crew includes:

- Review of construction plans for conveyances and support facilities;
- Approval of a support facility before an interstate carrier company can utilize the products or service of the facility;
- Inspection of interstate carrier conveyances and the issuance of Certificates of Sanitary Construction for Conveyances; and
- Inspection of support facilities that provide food, water and waste handling services to interstate conveyances.

Inspections are conducted during construction of conveyances and support facilities so that corrections may be initiated at a time that should assure compliance. Submission of plans and specifications for new construction or major reconstruction of conveyances and support facilities is required by regulation. A company that is planning to construct new conveyances and buildings should be encouraged to fill out the first section of the FDA Plan Review Guide and forward that to the ITP Manager(HFS-615) as part of the planning process. 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 to be constructed in foreign countries.

Routine watering point inspections are of critical importance to the safe operations of public conveyances by ensuring the delivery of a safe water supply to the crew and passengers. The maintenance of a list of acceptable facilities for water is necessary for industry awareness of approved and use-prohibited supplies.

Upon inspection of an ITP establishment, the district should collect information to evaluate whether the firm's practices are consistent with either the FDA Food Code 2005 or the recommendations in the ITP Handbook on Sanitation for each of the conveyances and their support facilities.

Inspect establishments in accordance with the Food Code 2005 is preferable because the Food Code is more complete and up-to-date than the outdated 1976 Food Service Sanitation Manual (FSSM). Thus, usage of the most current Food Code will provide better protection for the traveling public.

FDA inspectors are to complete inspections using the Food Code inspection report and report the findings to the firm's management. When Food Code deficiencies are found, they are to be documented on the Form FDA 483 only when the findings support a deviation from a CFR provision. Warning Letters and enforcement actions as a result of the inspection should be based on direction from your district office and/or CFSAN ITP Manager and regulatory contacts (concurrence from the Office of Enforcement).

- *A. FDA inspections conducted per the Food Code 2005 (Annex 5 HACCP Guidelines, 2(b)(e) Food Allergens) should cover allergens via conversation and questions with the firm's management for in-house usage of allergen alerts or declarations. If the inspector suspects a significant problem via undeclared or cross-contact of allergens, then the inspector should contact DE for Center recommendations..
- B. Orientation to the Food Code 2005 (www.cfan.fda.gov/~dms/foodcode.html)

During an inspection, if the investigator is informed that the firm is under new management since the last inspection, then the investigator should discuss the Food Code 2005 with the new management of conveyances and support facilities. The form-Attachment A should be completed to document this encounter and it should be forwarded to ITP General Inquires Contact.*.

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 by the following:

1. Collect and evaluate information to address deficiencies and classifications of inspections per Field Management Directive No. 86;
2. *Verify the district's vessel inventory and inspect those vessels determined to be in interstate commerce (using the ITP national registry of vessels as transmitted to districts via headquarters);
3. Collect and analyze water samples from conveyances as directed in the ITP work plan;*
4. 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);
5. *Inform caterers of the importance of addressing allergens per recommendations in the Food Code 2005*;
6. Inspect conveyances and support facilities, both in operation and under construction, to develop information related to their compliance with the FDA regulations including 21 CFR Parts 1240 and 1250 promulgated under authority of the Public Health Service Act;
7. Provide technical assistance to firms operating and servicing interstate conveyances through plan and equipment reviews;
8. Review the specifications and plans of conveyances, equipment, and support facilities for sanitary adequacy;
9. *For new firms or firms under new management, conduct orientation to the Food Code 2005 with the in-flight, vessel, and rail industries in order to increase their understanding of the Food Code 2005*; and
10. Promote the completion of the ITP Basic Inspection Video and Training Program by all ITP personnel.

B. PROGRAM MANAGEMENT INSTRUCTIONS

1. Inspection Priorities

Inspection priorities for this program should cover the following:

- a. *Vessel conveyances, caterers, commissaries, or food establishments that service interstate conveyances, and collecting water samples onboard conveyances*;
- b. Operating conveyances and conveyances under construction based on the degree of risk to the largest number of people;
- c. Support facilities (including those under construction) at the frequency specified in Section C.1 below; and
- d. Watering points based on the criteria set forth in Part III, 2(a).

*C. Planning Instructions

Note: The Guide to Inspections of Interstate Carriers and Support Facility, April 1995 (ITP Inspection Guide) should be referred to for additional information or if the item is not referred to in this compliance program. See www.fda.gov/ora/inspect_ref/default.htm for additional information.

1. Inspection Frequency: consistent with available work plan resources, #

Passenger vessel and Passenger rail with operating galleys - #

Berthing and Common Areas on conveyances: #

Caterers and Commissaries - #

Aircraft: # inspections when at airport;

Watering Points: #

Servicing areas and waste facilities: #

All other conveyances-vessels without galleys: #
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 mentioned above for information on conducting plan and specifications review for equipment, conveyances, and support facilities, respectively.

D. Training Requirements for ITP Specialists/Investigators

Only FDA specialists standardized by headquarters or Regional Retail Food Specialists in the Food Code 2005 should be conducting food establishment inspections of ITP establishments or conveyances where food service operations are present. Part of the revitalization of the ITP consists of comprehensive training video given to all ITP personnel in areas of inspection techniques and recognition of critical violations. The purpose for the video is to provide basic ITP training in the program and identify inspection criteria for new and seasoned ITP specialists and to promote national uniformity. Copies of the video have been provided to all FDA district offices and district ITP personnel. All ITP personnel should review the videos and take the examination. When successfully completed, the field personnel should notify the ITP General Inquires Contact of successful completion. Also, <http://web.ora.fda.gov>, under header: **User Training** has level I & II training for ITP personnel. Please note that there are standard level I and Level II requirements that are the same for many programs and then there are Level II Program Specific requirements that apply only to the Interstate Travel Program.

E. Technical Assistance Meetings with Industry

To promote national uniformity and recognition of the Food Code 2005 throughout the Interstate Travel Industry, FDA encourages district ITP personnel to assist and support industry in formulating training programs for employees engaged in the FDA regulated operations related to the Interstate Travel Program. When requested, the ITP Manager (HFS-615) will work with the Outreach Team (HFS-32) in the Office of Food Defense, Communication and Emergency Response, ORA, and district staffs to develop and supply guidelines and materials, including visual aids, for training activities.

F. Food Borne Illness Investigations

Refer to 2006 IOM, Subchapter 8.3, or as updated, Investigation of Food borne Outbreaks and Field Management Directive, No. 64, Epidemiological Investigations Alert Reporting Procedures for details and guidance in following up on suspected food borne illnesses (www.fda.gov/ora/inspect-ref/iom/default.htm). When multiple districts are involved, a lead district should be designated. Investigational findings should be distributed to other units, including the **ITP Manager** at OC/DFP/HFS-615, and Dr Patrick McCarthy of OSAS/DMST/EB/HFS-728. The American Public Health Association (APHA) publication Control of Communicable Diseases Manual (2000/17th edition or the most current edition as updated) should also be reviewed for further guidance.

The CFSAN Emergency Response Staff should be contacted for all possible food borne out breaks/food emergencies via FDA's email at CFSAN-FER or Chief of the Emergency Response and Surveillance Branch in the Office of Food Defense, Communications and Emergency Response at 301-436-1608.

PART III - INSPECTIONAL

OPERATIONS

***Note:** The field should emphasize the following:

- Conduct vessel inventory verification and inspections;
- Collect water samples for analysis from conveyance water systems. At least two of the samples being taken from aircraft water systems (see 2006 IOM 4.3.6.3, or as updated); and
- Inform and discuss the importance and concerns of allergens in food products*.

A. Inspect interstate conveyances and support facilities as specified in Part II-Implementation, B.1.

1. Food Establishment Inspections (caterers, commissaries, galleys, etc.) - activities to be carried out per the Food Code 2005:
 - a. Fill out the 2005 Food Establishment Inspection Form (located in the Food Code 2005) and fax or forward a copy to HFS-636 for tabulation;
 - b. Conduct the Food Code Orientation as part of the exit interview with management (if appropriate).
2. Watering Points:
 - a. Criteria for Prioritizing Inspections:
 - (1) Watering Points located at sites accessible to conveyances that serve the largest number of passengers.
 - (2) Facilities that routinely draw large volumes (tonnage) of water (e.g. watering points serving vessels, aircraft);
 - (3) The last inspection date (inspect only those prioritized facilities inspected prior to 1997).

Note: Watering points should be inspected on a thirty-six month cycle. This guideline supercedes those specified in the FDA Guide to Inspections of Interstate Carriers and Support Facilities.
 - b. Additional Items to check during the inspection:
 - (1) 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. Collect a copy of the last sampled report (critical for watering points on private systems).
 - (2) Determine if the water supply and facility are municipal or on-site.
3. ***Vessel Verification and Inspection:** using the list as provided by CFSAN, determine which of the listed vessels are engaged in interstate traffic [21 CFR 1240.3(h)] and inspect the ones that are and add them 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, and the new total vessel inventory for the district.

NOTE: The Priorities for Vessel Inspection are:(1) vessels that serve or provide food and drink to passengers;(2) Vessels that serve or provide food or drink and then (3) all other vessels based on population served*.

4. Equipment, Conveyances, and Support Facilities under Construction - Section 7 of the ITP Field Inspection Guide (Guide to Inspection of Interstate Carriers and Support Facilities, April 1995).
 5. Operations of Conveyances - Section 8 of the ITP Field Inspection Guide.
 6. Support Facilities Operations - Section 9 of the ITP Field Inspection Guide.
 7. 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 of conveyances are appropriate as necessary to evaluate compliance.
- B. Issue Certificates of Sanitary Construction and Certificates of Sanitation in accordance with the Inspection Guide section 7D and 8C, Subsection on Vessels.

Note: Due to an increase in conveyance construction and lack of resources, more districts are utilizing self-certification by conveyance manufacturers for issuance of Certificates of Sanitary Construction (CSC). Self-certification is briefly covered in DFI-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 Division of Field Investigations (HFC-130) with cooperation from the Division of Field Programs (HFS-615). 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. Contact HFC-150 for a supply of these certificates.

- C.* Orientation to the Food Code 2005 (www.cfsan.fda.gov/~dms/foodcode.html)

Food Code Orientations are to be conducted only for new management and new firms and may be pre-announced visits to food establishments (e.g., caterers, commissaries, vessels and rail galleys) scheduled for the purpose of affording the ITP Personnel an opportunity to carefully review with management the Food Code's five key interventions and risk factors leading to food borne illness*

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

1. Demonstration of Knowledge;
2. Employee Health - Disease or Medical Condition;
3. Hands as a vehicle of contamination, proper hand washing and no bare-hand contact with ready to eat food;

4. Destruction and Limitation of organisms of public health concern (Time and Temperature Controls); and
5. Consumer Advisory-Consumption of raw or undercooked animal foods.

Note: If the investigator finds any variance from the above provisions then the variance should be evaluated per instructions listed in the Food Code 2005 at 8-103.10.

D. Sample Collection

Refer to 2006 IOM, Subchapter 4.1, or as updated, for general information and instructions.

1. Food

- Collect samples for microbiological analysis as inspectional conditions warrant and as necessary as part of an epidemiological investigation.

2. Water

- *Field personnel should randomly collect water samples from on-board conveyance water system outlets, ex: faucets, taps, as close to the water holding tanks as possible. At least two of these samples per district should be taken from aircraft*.
- Collect water samples during a 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. See IOM instructions "Collecting Water Samples" (IOM 2006, Section 4.3.6.3 or as updated), when collecting, preserving, and storing water samples.

NOTE: The servicing laboratory must be notified in advance when collecting 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.

E. Sample Submission

Submit water samples to the state or local health authority for analysis when part of a joint agreement or cooperative program or the district. See the current ORA Field Work Plan for District servicing labs.

F. 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.

G. Reporting

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

PART IV - ANALYTICAL

A. ANALYZING LABORATORIES1. Field Laboratories

- | | | |
|----|---|--|
| a. | Filt, Mold and Foreign
Objects: Macroscopic
and Microscopic | All Regional labs,
DEN, KAN and SAN |
| b. | Decomposition | All Regional labs,
and SAN |
| c. | 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 |
| 5) | C. botulinum | All Regional Labs, DEN and SAN |
| 6) | Salmonella antibiotic
susceptibility testing | DEN |

Note: SRL and PRL-NW are the only labs performing mouse bioassay

2. CFSAN Laboratories

- | | |
|------------------------|---|
| Mold Speciation | Division of Natural
Products(HFS-315)
Valerie H. Tournas
(301) 436-1963 |
| Botulinum Confirmation | Richard C. Whiting
Office of Plant and Diary
Foods and Beverages, HFS-300
(301) 436-1925 |

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 CONDUCTEDFDA Field Laboratories1. Water

Analyze 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" Method is used." 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

Filth, Mold and Foreign Objects

Official Methods of Analysis of the Association of Official Analytical Chemist (AOAC) International, 17th or most current edition, Ed., Chap 16; JAOAC (Interim Official First Action Methods); Microanalytical Procedures Manual (or locate on the Intranet site:
<http://vm.cfsan.fda.gov/> under header: Program Areas

Decomposition:

AOAC, 17th or most current Ed. for chemical indices.

Microbiological Pathogens, Indicator Organisms, Salmonella serotyping, C. botulinum confirmation

Bacteriological Analytical Manual (BAM), 8th Ed. Revision A, 1998 or AOAC 17th Ed., Chapter 17

Note: BAM website: <http://vm.cfsan.fda.gov/> under header: Program Areas

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

1. VOLUNTARY COMPLIANCE

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

2. CASE INSTRUCTIONS

Note: The district should submit the recommendation via electronic copy (e.g., doc, pdf files, etc) via the "Compliance Management System" link located on Inside FDA's IT Applications Page under CFSAN Applications:#. The Center is requesting legible digital copies of labels and all supporting documentation be submitted via the internet site as well.

A. General

For instructions concerning ITP conveyance and support facilities see the following documents: Field Management Directive #86 - Establishment Inspection Report Conclusions and Decisions, and Data Codes Manual Inspection/Conclusion/Decision Section. These instructions also apply to inspections conducted by state authorities (including local officials) in cooperation with the FDA under the Interstate Travel Program.

1.Regulatory or administrative actions may be recommended for evaluation against conveyances, support facilities or equipment that are:

(a) under construction, when necessary to assure compliance under operational conditions; or

(b) associated with passenger, crew, or employee food-borne illness or other diseases of public health importance in the interstate travel program area.

2.Classifications of food service operations including support facilities and conveyances should be based on the establishment's inspectional and critical item findings. See DFI-Guide to Inspections of Interstate Carriers and Support Facilities, April 1995, or as updated.

3.Operating conveyances or support facilities that are classified Provisional or Use-Prohibited as a result of an inspection classified as official action indicated should be evaluated for a Warning Letter recommendation (Operation 66) to operator and user because assigning conveyances or support facilities a "Use-Prohibited" is considered an Administrative Action (Operation 68-Classification Changes). Therefore, the recommendation must be Center evaluated prior to issuance to the operator and its user(s).

4.To enable conveyance companies to comply with the regulations, they must be kept informed of the classification of conveyance

support facilities (refer to reporting requirements in this compliance program).

*B. Warning Letter Procedure:

All Warning Letter recommendations should be reviewed by OCC before issuance. Contact your District ORA Compliance Branch and see Regulatory Procedures Manual (March 2006), Chapter 4-Advisory Actions at http://www.fda.gov/ora/compliance_ref/rpm/.

For Support Facilities: If an inspection of a support facility following the issuance of a Warning Letter reveals that the facility has not corrected the critical deficiencies noted in the Warning Letter or if the corrections made are inadequate and the firm has additional critical deficiencies, then the Center may evaluate the new information for classifying the facility as Use-Prohibited and/or pursue further regulatory action such as injunction.

For Conveyances: If an inspection of the conveyance following the issuance of a Warning Letter reveals that the critical deficiencies cited in the Warning Letter were not corrected or were inadequately corrected and/or there are additional deficiencies, then the Center may evaluate the new information for rescinding the certificate of sanitation on a vessel and/or pursue further regulatory actions such as an injunction*.

C. *EPA Water Supply Classification and Facility Status:

MOU with the EPA regarding drinking water on Interstate Conveyances and refer to 2006 IOM 3.2.11.1, or as updated, for further guidance. ITP Manager can assist with EPA contact and notification*.

PART VI - REFERENCES, PROGRAM CONTACTS AND ATTACHMENTS**A. REFERENCES**

See 2006 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."

See Food Code, U.S. Public Health Service, FDA 2005. For public sale by the U.S. Department of Commerce, National Technical Information Service, (703) 605-6000. Refer to Report Number PB 2005-102200.

Field Management Directive # 86: Establishment Inspection Report Conclusions and Decisions, www.fda.gov/ora/inspect_ref/fmd/fmd86.htm

Field Management Directive # 122: Interstate Travel Potable Water on Interstate Carrier Conveyances and at Watering Points, www.fda.gov/ora/inspect_ref/fmd/fmd122.htm.

Guide to Inspection of Interstate Carriers and Support Facilities, April 1995, www.fda.gov/ora/inspect_ref/default.htm

B. PROGRAM CONTACTS**1. Center Contacts****Compliance Program Inquiries:**

***Glenn Bass**, Compliance Programs Branch, HFS-636, (301) 436-2774, FAX (301) 436-2657; Glenn.Bass@fda.hhs.gov*

**ITP Manager
Technical Inquires**

***Dean Davidson**, Division of Field Programs, HFS-615 (301) 436-1413; Dean.Davidson@fda.hhs.gov*

Regulatory Inquiries:

***Dwayne Johnson**, Division of Enforcement, Domestic Branch, HFS-607, (301) 436-1782, Dwayne.Johnson@fda.hhs.gov

***Brandon Bridgman**, Division of Enforcement, Domestic Branch, HFS-607, (301) 436-2073, Brandon.Bridgman@fda.hhs.gov

2. ORA Contacts: Investigational Inquiries

Barbara Marcelletti, Division of Field Investigation, DFI HFC-132, (301) 827-5635; Barbara.Marcelletti@fda.hhs.gov

Scientific Inquiries:

Division of Field Science, (DFS), HFC-141, (301) 827-1027. (Filth)

ITP Certificate
(FDA 2371, 2371A, 2372):

Marsha Hayden, DFS, HFC-141,
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George Salem, DFS, HFC-141,
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Norm Fogg, Division
Of Field Investigations (DFI)
HFC-130, 301-827-5645;
Normon.Fogg@fda.hhs.gov

C. ATTACHMENT

Attachment A: Orientation to the Food Code 2005

PART VII - CENTER RESPONSIBILITIES

The Program Manager for Interstate Travel Program 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 #. Additionally, the evaluations should appear on CFSAN's Intranet website.

ORIENTATION TO THE FOOD CODE 2005
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):

- Interventionsdescribe): _____
- Interventions Risk Factors
- Variance Process and HACCP
- Risk Factors
- 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: _____

Submit this form to: ITP, General Program Inquiries Contact, Compliance Programs Branch, HFS-636; 5100 Paint Branch Pkwy, College Park, Maryland 20740 OR FAX: (301) 436-2657.