

**CHAPTER 03: FOODBORNE MICROBIOLOGICAL HAZARDS**

SUBJECT: PREVENTIVE CONTROLS AND SANITARY HUMAN FOOD OPERATIONS		IMPLEMENTATION DATE: 10/15/2020
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES (PAC)	
USE APPROPRIATE PRODUCT CODES	<p>REPORT PROGRAM ACTIVITIES UNDER THE FOLLOWING PAC CODES:</p> <p><b>03040</b> (FOOD CGMP INSPECTIONS)  <b>03040L</b> (LIMITED SCOPE PCHF INSPECTIONS)  <b>03040F</b> (FULL SCOPE PCHF INSPECTIONS)  <b>03040Q</b> (MODIFIED REQUIREMENTS INSPECTIONS AT QUALIFIED FACILITIES)  <b>03040R</b> (MODIFIED REQUIREMENTS INSPECTIONS AT FACILITIES SOLELY ENGAGED IN STORAGE OF UNEXPOSED PACKAGED FOOD THAT REQUIRE TIME/TEMPERATURE CONTROLS FOR SAFETY)  <b>03040T</b> (HUMAN FOODS SANITARY TRANSPORTATION INSPECTIONS)  <b>03040U</b> (PCHF FOLLOW-UP INSPECTIONS)</p>	
	<p><b>03S040</b> (STATE CONTRACT FOOD CGMP INSPECTIONS)  <b>03S041</b> (STATE CONTRACT LIMITED SCOPE PCHF INSPECTIONS)  <b>03S042</b> (STATE CONTACT FULL SCOPE PCHF INSPECTIONS)  <b>03S043</b> (STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT QUALIFIED FACILITIES)  <b>03S044</b> (STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT FACILITIES SOLELY ENGAGED IN STORAGE OF UNEXPOSED PACKAGED FOOD THAT REQUIRE TIME/TEMPERATURE CONTROLS FOR SAFETY)  <b>03S045</b> (STATE CONTRACT PCHF FOLLOW-UP INSPECTIONS)</p>	

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**FIELD REPORTING REQUIREMENTS:**

Establishment inspection reports (EIRs) must be completed in eNspect per [Investigations Operations Manual \(IOM\)](#) subchapter 5.11 *Reporting*. Investigational reports must be prepared per IOM subchapter 8.10 *General Investigation Reporting*. Corrective actions taken during inspections must be documented in the Observation and Corrective Action Reporting (OCAR) system within eNspect.

## Contents

PART I – BACKGROUND..... 6

1. Summary of Requirements ..... 6

    A. Subpart A: General Provisions ..... 6

    B. Subpart B: Current Good Manufacturing Practice ..... 7

    C. Subpart C: Hazard Analysis and Risk-Based Preventive Controls ..... 7

    D. Subpart D: Modified Requirements ..... 7

    E. Subpart E: Withdrawal of a Qualified Facility Exemption ..... 8

    F. Subpart F: Requirements Applying to Records That Must be Established and Maintained.... 8

    G. Subpart G: Supply-Chain Programs ..... 8

2. Exemptions and Modified Requirements..... 8

3. Compliance Dates and Enforcement Discretion ..... 9

PART II - IMPLEMENTATION..... 10

1. Objectives ..... 10

2. Program Management Instructions ..... 10

    A. Inspection Priorities..... 10

    B. Selection of High-Risk Food and process combination(s) for Coverage During Inspections 11

    C. Planning Instructions..... 11

    D. Program Interactions ..... 13

    E. Food Defense Measures and Food Registration..... 19

    F. Interactions with Federal Agencies, State and Local Counterparts, and Foreign Authorities 19

    G. When to Contact Other Offices within the FDA ..... 20

PART III – INSPECTIONAL..... 22

1. Operations ..... 22

    A. Inspections..... 22

    B. Investigations ..... 26

    C. Sample Collections..... 26

    D. Import Activities ..... 26

    E. Other..... 26

2. Reporting..... 26

PART IV – ANALYTICAL ..... 27

PART V - REGULATORY/ADMINISTRATIVE STRATEGY..... 28

1. Findings.....	28
A. Critical Observations.....	28
B. Major Observations.....	28
C. Minor Observations.....	29
D. Factors to Consider.....	29
2. Charges .....	30
3. Actions.....	30
A. Administrative and Legal Actions for Imminent Public Health Hazards .....	30
B. Compliance Activities.....	31
C. Additional Information.....	34
4. Follow-Up.....	34
A. Regulatory Follow-Up.....	34
B. Other.....	35
PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS.....	36
1. References.....	36
A. Investigations Operations Manual (IOM) .....	36
B. Regulatory Procedures Manual (RPM).....	36
C. Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Foods.....	36
D. 21 CFR part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food.....	36
2. Attachments .....	36
A. Human Food Sanitary Transportation Inspections.....	36
3. Program Contacts.....	36
A. CFSAN.....	36
B. ORA .....	36
PART VII - CENTER RESPONSIBILITIES.....	37
ATTACHMENT A: HUMAN FOOD SANITARY TRANSPORTATION INSPECTIONS .....	38

## Change History

Item	Change	Date
Issuance	CPGM 7303.040 initial issuance	10/17/2019
Update	CPGM 7303.040 update	10/15/2020
	Sanitary Transportation program content added in Part I <i>Background</i> and in <a href="#">attachment A Human Food Sanitary Transportation Inspections</a>	
	PCHF Follow-up inspections content added in <a href="#">Parts II Implementation</a> and <a href="#">III Inspectional</a> .	
	General program updates added including new PAC reporting codes for sanitary transportation inspections and PCHF follow-up inspections, and incorporating additional program interaction language for <a href="#">CPGM 7307.001 Mycotoxins in Foods – Domestic and Import</a> and <a href="#">CPGM 7371.000 Comprehensive Animal Food Inspections</a>	

## PART I – BACKGROUND

The FDA Food Safety Modernization Act (FSMA) was signed into law on 01/04/2011 and amended the [Federal Food, Drug, and Cosmetic Act \(FD&C Act\)](#) to include new sections with the purpose of improving our capacity to prevent, detect, and respond to food safety issues, and to ensure the safety of imported food. FSMA added Section [418 Hazard Analysis and Risk-Based Preventive Controls](#) to the FD&C Act, which stipulates that the owner, operator, or agent in charge of a facility shall evaluate the hazards that could affect food manufactured, processed, packed, or held by their facility; identify and implement preventive controls to significantly minimize or prevent the occurrence of such hazards; monitor the performance of those controls; and maintain records of required monitoring, verification activities, and corrective actions; and provide assurances that such food is not adulterated under section 402 or misbranded due to undeclared allergens under section 403(w). FSMA also added section [416 Sanitary Transportation of Human and Animal Food](#) to advance FDA's efforts to protect foods from farm to table by keeping food safe from contamination and temperature abuse during transportation.

The final rule establishing [21 CFR part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food](#) (CGMP & PCHF rule) was published on 09/17/2015 to implement Section 418 of the FD&C Act. In addition to establishing new requirements for hazard analysis and risk-based preventive controls, the CGMP & PCHF rule modernized the Current Good Manufacturing Practices (CGMPs).

The Final Rule establishing [21 CFR part 1, Subpart O Sanitary Transportation of Human and Animal Food](#) (ST rule) was published on 04/06/2016 to implement Section 416 of the FD&C Act. The goal of the ST rule is to prevent practices during transportation that may render food unsafe such as improper temperature controls, inadequate cleaning of vehicles between loads, and inability to properly protect food from cross-contamination and allergen cross-contact. The ST rule builds on safeguards envisioned in the 2005 Sanitary Food Transportation Act (2005 SFTA).

### 1. Summary of Requirements

This compliance program covers inspections of all businesses subject to the CGMP & PCHF rule and/or the ST Rule. The major requirements for businesses subject to the CGMP & PCHF rule are summarized below. Information pertaining to the ST rule may be found in [attachment A](#).

#### A. Subpart A: General Provisions

Management of each establishment must ensure compliance with 21 CFR 117.4 *Qualifications of Individuals Who Manufacture, Process, Pack, or Hold Food* under Subpart A *General Provisions*. Per 21 CFR 117.4, all individuals engaged in manufacturing, processing, packing, or holding food must be qualified through education, training, or experience (or a combination thereof) as appropriate to perform their assigned duties, and receive training in food hygiene/food safety. Food production supervisors must also have the education, training, or experience (or a combination thereof) necessary to supervise the production of clean and safe food. Businesses must maintain records that document required

food safety and food hygiene training as appropriate to the food, the facility, and the individual's assigned duties.

**B. Subpart B: Current Good Manufacturing Practice**

Management of each establishment must ensure compliance with Subpart B *Current Good Manufacturing Practice*. Specifically, they must ensure that all requirements are met pertaining to personnel, plants and grounds, sanitary operations, sanitary facilities and controls, equipment and utensils, processes and controls, warehousing and distribution, holding and distribution of human food by-products for use as animal food, and defect action levels.

**C. Subpart C: Hazard Analysis and Risk-Based Preventive Controls**

Facilities that are subject to subpart C are required to prepare and implement a written Food Safety Plan (FSP) that includes, at a minimum, a written hazard analysis. If the hazard analysis reveals one or more hazards requiring a preventive control, then the facility must have and implement preventive controls, which must be written, to provide assurances that the hazards will be significantly minimized or prevented. Preventive controls include process controls, food allergen controls, sanitation controls, supply-chain controls, other controls, and a recall plan. The FSP must be developed by or under the oversight of a preventive controls qualified individual (PCQI), and the plan must be reanalyzed every three years at a minimum.

Under certain circumstances, a manufacturer/processor does not have to implement a control for a hazard that requires a preventive control, such as if the food cannot be consumed without application of a control, or if the hazard(s) will be controlled later in distribution and the food is accompanied by a disclosure that the food is “not processed to control [identified hazard].” There is currently enforcement discretion with respect to the written assurances requirements when a manufacturer/processor relies on other downstream entities (commercial customers, not consumers) in the distribution chain to control certain identified hazards (i.e. when there will be further processing of the food before it reaches consumers). Enforcement Discretion means that FDA will not assess compliance with applicable regulatory requirements, will not list associated observations on an FDA 483 *Inspectional Observations*, and will not base enforcement action on those requirements. For more information, see the [Enforcement Discretion for Certain FSMA Provisions](#) fact sheet and [Guidance for Industry: Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs](#)

**D. Subpart D: Modified Requirements**

Subpart D covers regulatory requirements for businesses that have attested to being qualified facilities, such as very small businesses. These qualified facilities are exempt from Subparts C & G. Subpart D also covers regulatory requirements for foods that require temperature control for safety in facilities solely engaged in the storage of unexposed packaged food. Facilities solely engaged in the storage of unexposed packaged food are exempt from Subparts C and G.

#### E. Subpart E: Withdrawal of a Qualified Facility Exemption

Subpart E covers the circumstances and administrative procedures for FDA to withdraw a qualified facility exemption and for a facility to appeal an order to withdraw. FDA is not required to withdraw a qualified facility exemption to consider enforcement action.

#### F. Subpart F: Requirements Applying to Records That Must be Established and Maintained

Subpart F covers the requirements pertaining to records in subparts A, C, D, & G that must be established and maintained.

#### G. Subpart G: Supply-Chain Programs

Subpart G covers the requirements for a supply-chain program. If a manufacturer/processor that is subject to subparts C and G (i.e. a receiving facility) identifies the need for a supply-chain preventive control based on their hazard analysis, the facility must include a written supply-chain program as part of their FSP. The basic required components include using approved suppliers and determining, conducting, and documenting supplier verification activities. The supply-chain program must provide assurance that any hazards requiring a supply-chain-applied control have been significantly minimized or prevented.

If a need for a supply-chain-applied control for an imported food is identified and the manufacturer/processor is also the importer, they are not required to conduct supplier verification activities if they are in compliance with [21 CFR 1 subpart L Foreign Supplier Verification Programs for Importers of Food for Humans and Animals](#) (FSVP) for the food. Further guidance covering the interaction between FSVP and Preventive Controls (PC) supply-chain programs can be found [here](#).

## 2. Exemptions and Modified Requirements

The CGMP & PCHF rule identifies several exemptions from Subpart C *Hazard Analysis and Risk-Based Preventive Controls* and Subpart G *Supply-Chain Program* in [21 CFR 117.5 Exemptions](#). In general, food facilities that are required to register under section 415 of the FD&C Act are subject to the preventive control requirements in subparts C and G and must comply with the CGMP requirements, unless an exemption in 21 CFR part 117 applies. Firms that are NOT subject to food facility registration are not subject to the preventive control requirements in subparts C & G; however, those firms may still be subject to the CGMP requirements, primarily in subpart B of 21 CFR part 117. It is important to note that applicability of the CGMPs is not dependent upon whether a facility is required to register.

Requirements pertaining to facilities solely engaged in the storage of unexposed packaged food can be found in [21 CFR 117.7 Applicability of subparts C, D, and G of this part to a facility solely engaged in the storage of unexposed packaged food](#). Requirements pertaining to facilities solely engaged in the storage of unexposed packaged food that requires time/temperature control for

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safety and to qualified facilities can be found in [21 CFR Part 117, Subpart D Modified Requirements](#).

Information on ST rule exemptions and modified requirements may be found in Part I(2) of [attachment A](#).

### 3. **Compliance Dates and Enforcement Discretion**

All nonexempt businesses are required to be in compliance with the CGMP & PCHF rule at this time. Among other things, enforcement discretion from the preventive controls requirements and/or the CGMP requirements has been granted for facilities that would qualify as secondary activity farms except for ownership of the facility, for facilities solely engaged in packing and/or holding activities on produce raw agricultural commodities (RAC), and facilities that color RACs. Information regarding the enforcement discretion for these operations can be found [here](#). See [attachment A](#) for ST rule compliance date information.

## PART II - IMPLEMENTATION

### 1. Objectives

- Conduct CGMP and preventive controls inspections of human food facilities subject to 21 CFR part 117.
- Conduct Sanitary Transportation (ST) inspections at human food facilities that conduct transportation operations as a shipper, loader, carrier, or receiver and are subject to 21 CFR part 1, subpart O.
- Conduct inspections within mandated FSMA frequencies and enforcement follow-up timeframes.
- Ascertain compliance and verify implementation of corrective actions taken during and after an inspection.
- Document inspectional findings and initiate compliance action for conditions as warranted.

### 2. Program Management Instructions

#### A. Inspection Priorities

The [FSMA Tracker](#) in ORADSS includes a list of FSMA high-risk (FFHR) and non-high-risk (FFNR) food facilities that are due for inspection. The tracker also identifies, in part, the likely scope of inspection for each facility (e.g. full scope PCHF or CGMP). The Division may change the scope of inspection based on the type of operations known to be performed by the facility or those observed during the inspection.

Divisions should prioritize the following types of facilities subject to subparts C and G for full scope PCHF inspections:

- Facilities that have been responsible for a Class I recall since the previous inspection. Facilities responsible for a Class I recall associated with pathogens or allergen cross-contact **must** have a full scope PCHF inspection.
- The facility's previous inspection was classified "Official Action Indicated" (OAI).
- The facility is known to manufacture high-risk foods as designated in [part II\(2\)\(B\)](#) of this program.
- The facility is implicated in an event that may impact public health. The FDA may obtain this information from federal, state, local, or tribal partners; foreign competent authorities (e.g. the rapid alert system for food and feed (RASFF) or information shared by a foreign competent authority under a cooperative arrangement); from the Reportable Food Registry (RFR); or from consumer complaints.

PCHF follow-up inspections according to [Part III\(1\)\(A\)\(6\)](#) of this program may be performed when the scope of the previous inspection was full scope PCHF and the inspection is being initiated as a regulatory follow-up to significant preventive controls observations.

ORA/DFHAFO is responsible for selecting foreign facilities from the foreign workplan per the criteria identified above. Inspection priority information pertaining to sanitary transportation inspections may be found in [Attachment A](#).

## B. Selection of High-Risk Food and process combination(s) for Coverage During Inspections

Whenever possible, the highest risk food and process combination(s) should be covered during the inspection. High-risk foods include those associated with one or more significant hazards including pathogen growth and/or toxin formation, pathogen cross-contamination, allergen cross-contact, and undeclared allergen hazards that must be controlled at the inspected facility to ensure food safety. High-risk foods and processes that should be prioritized for inspection coverage include:

- Ready-to-eat (RTE) foods for which pathogen cross-contamination is a significant hazard because food is exposed to the environment prior to packaging and does not undergo further processing or otherwise contain a control measure to significantly minimize pathogens. Ready-to-eat is defined in [21 CFR 117.3 Definitions](#) as any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards.
- Foods for which allergen cross-contact or undeclared allergens is a significant hazard.
- Any foods that require a process control (such as cooking, refrigeration) whereby the food may be rendered unsafe if the control is not implemented properly.

Additional prioritization instructions for sanitary transportation inspections may be found in [attachment A](#). **Please note that the term “high-risk food” used throughout this document does not necessarily refer to foods on the traceability list under Section 204 of FSMA.**

## C. Planning Instructions

### (1) Inspections

Full scope PCHF inspections are to be performed at prioritized facilities subject to subpart C as indicated in [Part II\(2\)\(A\)](#) of this program. For all other facilities, Divisions are responsible for determining the scope of inspection and the appropriate reporting PAC code.

Facilities inspected under this compliance program may be identified as FSMA High-Risk (HR) or FSMA Non-High-Risk (NHR) and may have FFHR or FFNR risk identifiers in the Firm Management Services (FMS). **Divisions will receive credit towards the work plan if the inspection or investigation is the first visit to the facility within the FSMA inspection cycle.**

### (2) Sampling

Compliance (for-cause) and surveillance samples may be collected during inspections covered by this compliance program. These samples may be collected in accordance with interacting programs listed in [Part II\(2\)\(D\)](#) of this program, under routine surveillance sampling programs such as the [Sample Collection Operation Planning Effort \(SCOPE\)](#), under CFSAN or ORA [active assignments](#), or as directed for compliance purposes. If a facility is involved in ongoing compliance activities or the current inspection may be classified OAI, the Division should consult with their Compliance Branch to determine whether collection of samples for surveillance purposes is appropriate.

### (3) Resources and Reporting

Divisions should make every effort to coordinate resources so that inspections conducted under this program also meet inspection obligations from other programs. See table 1 below for additional resource and reporting information.

<b>Table 1 - Resources and Reporting</b>	
<b>Reporting PAC</b>	<p><b>03040</b> Food CGMP Inspections  <b>03040L</b> Limited Scope PCHF Inspections  <b>03040F</b> Full Scope PCHF Inspections  <b>03040Q</b> Modified Requirements Inspections at Qualified Facilities  <b>03040R</b> Modified Requirements Inspections at Facilities Solely Engaged in the Storage of Unexposed Packaged Food that Require Time/Temperature Controls for Safety  <b>03040T</b> Human Foods Sanitary Transportation Inspections  <b>03040U</b> PCHF Follow-Up Inspections</p> <p><b><u>State Contract PAC Codes</u></b></p> <p><b>03S040</b> State Contract Food CGMP Inspections  <b>03S041</b> State Contract Limited Scope PCHF Inspections  <b>03S042</b> State Contract Full Scope PCHF Inspections  <b>03S043</b> State Contract Modified Requirements Inspections at Qualified Facilities  <b>03S044</b> State Contract Modified Requirements Inspections at Facilities Solely Engaged in the Storage of Unexposed Packaged Food that Require Time/Temperature Controls for Safety  <b>03S045</b> State Contract PCHF Follow-Up Inspections</p>
<b>Planning PAC</b>	<p><b>03040F</b> Full Scope PCHF Inspections  <b>03F813</b> Responsive Investigative/Laboratory Operations:</p>

	Follow-up OAI inspections <b>03040T</b> Human Foods Sanitary Transportation Inspections
<b>Inspection Op. Code</b>	11 (foreign), 12 (domestic)
<b>Investigation Op. Code</b>	15 (foreign), 13 (domestic)

#### D. Program Interactions

If a facility is inspected under this program and the covered food is subject to additional regulations, compliance programs, or assignments outside the scope of this compliance program, then additional inspection and reporting requirements should be covered per the respective interacting programs. Resources that FDA staff may use to determine the scope of each inspection include the [FDA Compliance Programs Intranet Page](#), [FDA Active Assignments Intranet Page](#), [resource library](#), and the [PC SharePoint site](#). **In most cases, inspection hours should no longer be reported under the 03803 PAC code unless the business is subject to enforcement discretion as detailed in part [I\(3\)](#) of this program.**

**ST program interaction information may be found in [attachment A](#).** Programs that interact with this compliance program include the following:

##### **[\(1\) Domestic Food Safety Program \(CPGM 7303.803\)](#)**

As of September 17, 2018, the compliance dates for all businesses subject to the CGMP & PCHF rule have passed (see Part [I\(3\)](#) of this program for more information). For all inspectional activities covering foods subject to the CGMP & PCHF rule, use the inspectional, reporting, and enforcement instructions provided in this program (CPGM 7303.040). Continue to implement the following sections of the domestic food safety compliance program until further notice:

- Foodborne biological hazards sampling and analysis instructions found in attachment A of the Domestic Food Safety compliance program.
- Chemical contaminants sampling and analysis instructions found in attachment B of the Domestic Food Safety compliance program.

##### **[\(2\) Seafood Processor Inspection Program \(CPGM 7303.842\)](#)**

Foods covered by [21 CFR part 123 Fish and Fishery Products](#) (seafood HACCP) are exempt from 21 CFR part 117 Subparts C and G. Observations regarding any CGMP requirements from Subpart B, with the exception of observations associated with human food by-product for use as animal food, should be cited under 21 CFR part 123. Inspectional accomplishment hours for coverage of subparts A (training), B (only human food by-product for use as animal food), and F (training records) must be reported under the 03040 PAC code.

### **(3) Juice HACCP Inspection Program (CPGM 7303.847)**

Foods covered by [21 CFR part 120 Hazard Analysis and Critical Control Point \(HACCP\) Systems](#) (juice HACCP) are exempt from 21 CFR part 117 Subparts C and G. Observations regarding any CGMP requirements from Subpart B, with the exception of observations associated with human food by-product for use as animal food, should be cited under 21 CFR 120. Inspectional accomplishment hours for coverage of subparts A, B (only for human food by-product for use as animal food), and F (training records) must be reported under the 03040 PAC code.

### **(4) Domestic Acidified and Low-Acid Canned Foods Program (CPGM 7303.803A)**

#### **(a) Low-acid Canned Foods (LACF)**

LACF are subject to the CGMP & PCHF rule. However, subparts C and G do not apply to activities covered by [21 CFR part 113 Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers \(LACF\)](#) which is intended to control microorganisms of public health significance (*C. botulinum* and other microbiological hazards). Hazards that are not controlled by thermal processing requirements in 21 CFR part 113 and that require a control are covered by 21 CFR part 117 Subparts C and G.

Accomplishment hours should be reported under 03803A for requirements specific to [21 CFR part 108 Emergency Permit Control](#) and [21 CFR part 113 Thermally Processed Low-Acid Foods Packaged in Hermetically Sealed Containers \(LACF\)](#). Accomplishment hours for coverage of the CGMP & PCHF rule should be reported under the appropriate PAC in [part II\(2\)\(C\)\(3\)](#) of this program.

#### **(b) Acidified Foods**

Acidified foods are subject to the CGMP & PCHF rule. An acidified food that is subject to subpart C must have an FSP that covers *C. botulinum* and other microorganisms of public health significance, along with any chemical or physical hazards that may require preventive controls. It is acceptable for the FSP to reference and/or incorporate the scheduled processes, operating procedures, and records established and maintained in accordance with 21 CFR part 114.

When an acidified food covered during an inspection is subject to subpart C, there are many cases in which observations should be cited under 21 CFR part 117, 21 CFR part 108, or 21 CFR part 114. For example, not implementing a scheduled process should be cited under 21 CFR part 117 and not 21 CFR part 114 when the scheduled process is included in the FSP to control a significant hazard. Not being registered as a food canning establishment and/or not having a filed process would be cited under 21 CFR part 108, and not having controls for pathogen survival/growth hazards might be cited under 21 CFR part 117 during the same inspection. Observations could also be cited under 21 CFR part 114 when they are unique to the acidified food rule (e.g. can coding

requirements, and raw material examinations) or when the food or facility is exempt from subparts C and G. Additional program interactions between acidified foods and the CGMP & PCHF rule are detailed in the Conducting Acidified Food Inspections job aid which may be found on the [resource library](#) and on the [PC SharePoint site for FDA staff](#).

Accomplishment hours should be reported under 03803A for requirements specific to [21 CFR part 108 Emergency Permit Control](#) and [21 CFR part 114 Acidified Foods](#). Accomplishment hours for coverage of the CGMP & PCHF rule should be reported under the appropriate PAC in [part II\(2\)\(C\)\(3\)](#) of this program.

**(5) Cheese and Cheese Products Program (CPGM 7303.037)**

Cheese and cheese products are subject to the CGMP & PCHF rule. Inspectional accomplishment hours should be reported against the appropriate PAC identified in [part II\(2\)\(C\)\(3\)](#) of this program; however, any accomplishment hours associated with specific sampling requirements of the cheese and cheese products compliance program should be reported under the 03037 PAC.

**(6) Dietary Supplements Program (CPGM 7321.008)**

Dietary supplements are covered under [21 CFR part 111 Current Good Manufacturing Practice in Manufacturing, Packaging, Labeling, or Holding Operations for Dietary Supplements](#) and are exempt from Subparts C and G of the CGMP & PCHF rule. However, dietary supplements are subject to Subparts A, B, and F of the CGMP & PCHF rule. Subpart B CGMP conditions may be cited under the CGMP & PCHF rule only when the requirement is not specified in 21 CFR part 111. Further, if any facility is manufacturing, packing, labeling, or holding dietary ingredients or other raw materials (e.g., vitamins, minerals, amino acids, herbs, botanicals, other food ingredients (e.g. excipients) or is a dietary ingredient supplier, then 21 CFR part 117 is applicable to the extent the firm is not co-manufacturing with another dietary supplement manufacturer or for a dietary supplement distributor (i.e., premix and pre-blends).

If field inspection staff run into a co-manufacturing scenario, Divisions should consult with CFSAN's Office of Compliance, Dietary Supplement and Labeling Assessment Branch to determine further applicability of 21 CFR part 111.

**(7) Infant Formula Program (CPGM 7321.006)**

Infant formula is subject to the CGMP & PCHF rule and inspections are covered under this program and the infant formula compliance program. Inspectional accomplishment hours associated with the coverage of the CGMP & PCHF rule should be reported under the appropriate PAC code in [part II\(2\)\(C\)\(3\)](#) of this program. Inspectional accomplishment hours associated with the infant formula compliance program should be reported under the 21006 PAC code.

**(8) Medical Foods Program (CPGM 7321.002)**

Medical foods are subject to the CGMP & PCHF rule and inspections of medical foods are covered under this program and the medical foods compliance program. Inspectional accomplishment hours should primarily be reported against the appropriate PAC in [part II\(2\)\(C\)\(3\)](#) of this program; however, any hours associated with specific requirements of the medical foods compliance program should be reported under the 21002 PAC.

**(9) Interstate Travel Program (CPGM 7318.029)**

CSOs conducting inspections of food operations on Interstate Travel Program (ITP) conveyances must be trained in use of the FDA Food Code. In addition, CSOs conducting inspections of ITP caterers and commissaries must have training and experience in conducting inspections in accordance with the CGMP & PCHF rule.

The primary regulations pertaining to ITP conveyances are found in [21 CFR part 1240 Control of Communicable Diseases](#) and 21 CFR part [1250 Interstate Conveyance Sanitation](#), with the bulk of operational requirements found in 1250.

Caterers (establishment type “J”) and commissaries (establishment type “K”) that manufacture/process, pack, or hold food are generally required to register as a food facility and are subject to 21 CFR part 117; these facilities are to be inspected under applicable subparts of the regulation. For example, a commissary that only holds unexposed packaged foods that do not require temperature control for safety are not subject to subparts C, D, or G; however, if such a commissary also is holding food that requires temperature control for safety, the modified requirements in 117.206 of subpart D would apply.

If an operation is not required to register with FDA as a food facility, it would not be subject to the preventive controls requirements of 21 CFR part 117. For example, ITP caterers and commissaries that operate as retail food establishments (e.g. primarily sell food directly to consumers from that establishment location) are not required to register with FDA. Food service operations on ITP conveyances (establishment type “F” i.e. airplanes, buses, passenger trains, and vessels) are not required to register as a food facility because they operate as retail establishments. Conveyance watering points (establishment type “U”), conveyance servicing areas (establishment type “V”) and conveyance construction companies (establishment type “H”) are not food operations and as such not required to register. However, watering points that also provide ice, coffee, or packaged shelf-stable foods to conveyances, typically to airplanes, are considered commissaries and would be required to register. Commissaries are subject to relevant subparts of 117 based on their specific operation.

When conducting inspections at facilities that are caterers (establishment type “J”) and commissaries (establishment type “K”) for interstate conveyances, please include the appropriate PAC codes as follows: 18029A (airlines), 18029B (buses), 18029C (railroad passenger cars), and 18029D (vessels). Report accomplishment hours spent covering the CGMP & PCHF rule under the appropriate PAC code(s) in [part II\(2\)\(C\)\(3\)](#) of this program.

Report accomplishment hours spent covering ITP portions of the inspection under the applicable PAC code(s) from CPGM 7318.029.

**Note: Meat and Poultry products manufactured by airline caterers and shipped in interstate commerce fall under FDA authority and may be inspected as they are not inspected by USDA FSIS.**

**(10) [NLEA, Nutrient Sample Analysis, and General Food Labeling Requirements Program \(CPGM 7321.005\)](#)**

Coverage of the NLEA and FALCPA is to be accomplished during ALL routine inspections of firms that are manufacturing and/or labeling or re-labeling food products at the site inspected. The evaluation of allergen controls during a full scope PCHF inspection is covered under this program (CPGM 7303.040) and associated accomplishment hours should be reported under the appropriate PAC code in [part II\(2\)\(C\)\(3\)](#). All label review accomplishment hours should be reported under the 21005 PAC code.

**(11) [Milk Safety Program \(CPGM 7318.003\)](#)**

**Consult with your Regional Milk Specialist to determine if a dairy plant is on the IMS list prior to scheduling an inspection.** Under the IMS agreement, regulatory inspection and enforcement action are the responsibility of state agencies for Grade “A” dairy products, which are IMS listed. Preventive controls for human foods are covered under Appendix T of the Pasteurized Milk Ordinance (PMO) for these products. Grade A dairy products that are not covered by the IMS, and non-Grade A dairy products are appropriate for FDA CGMP & PCHF rule coverage. See IOM subchapter 5.4.9.3 *Grade A Dairy Plant Inspections* for additional information.

The USDA has two voluntary inspection programs for dry milk plants: the Plant Inspection Program (PIP) and the Resident Inspection and Grading Program. If a firm is operating in compliance with either of these two programs, it will appear on the [USDA’s List of Dairy Plants Surveyed and approved for USDA Grading Service](#). Under MOUs with USDA, FDA agrees not to (routinely) inspect dry milk product plants that are covered by one of the USDA’s voluntary inspection programs, or routinely sample dry milk for *Salmonella* testing if the plant is operating under one of these two programs. See IOM subchapter 3.2.1.5 *Agricultural Marketing Service (AMS)/ USDA (MOUs) MOU #8* for additional information.

FDA is piloting programs to leverage state grade A inspection activities and FDA check-ratings to accomplish non-grade A inspections that count toward FSMA inspection frequencies per [FSMA section 201](#). This CPGM will be updated with additional information if these inspections become a permanent part of FDA operations.

**(12) [Pesticides and Industrial Chemicals in Food Program \(CPGM 7304.004\)](#)**

The pesticides and industrial chemicals in food compliance program covers sampling of domestic and imported foods to enforce pesticide residue tolerances in foods established by the U.S. Environmental Protection Agency (EPA). Incorrect application and storage of industrial and household chemicals in food facilities covered under the cGMP & PCHF rule are covered under this compliance program (CPGM 7303.040). Mis-use of pesticide chemicals (did not follow label instruction when applied) observed during a domestic inspection should be reported to the regional EPA office according to part III(D) of CPGM 7304.004.

**(13) Domestic and Import Food Additives and Color Additives (CPGM 7309.006)**

The domestic and import food additives and color additives compliance program covers food and color additives sampling and inspectional instructions. Field inspection staff should reference CP 7309.006 whenever they conduct an inspection at a facility that uses a food and/or color additive in a food or during inspections of food and/or color additive manufacturers.

Food and color additives are subject to 21 CFR part 117 and accomplishment hours associated with an inspection should be reported under the appropriate PAC code in [part II\(2\)\(C\)\(3\)](#) of this program (CPGM 7303.040). Inspectional operations should not be reported under the PAC codes in CP 7309.006 as they are solely associated with sampling activities.

**(14) Mycotoxins in Food – Domestic and Import (CPGM 7307.001)**

The Mycotoxins in Food – Domestic and Import compliance program covers sampling instructions and analytical methods for mycotoxins; aflatoxin, patulin, deoxynivalenol, fumonisin, and ochratoxin. If a compliance sample collected under CPGM 7303.001 reveals any mycotoxin amount greater than the action, guidance, or advisory level, a follow-up inspection under this program (CPGM 7303.040) may be required. Sample collections covered under CPGM 7307.001 should be reported under PAC 07001 and inspections of foods containing mycotoxins should be reported under the appropriate PAC code from this program (CPGM 7303.040).

**(15) Comprehensive Animal Food Inspections (CPGM 7371.000)**

**CPGM 7371.000 has not been issued as of the issuance date of CPGM 7303.040. The following content does not apply until CPGM 7371.000 is issued.**

Some human food facilities also manufacture, process, pack or hold animal food. For example, some ingredient manufacturers may produce ingredients for both human and animal food. Other human food manufacturers may have by-products of their manufacturing processes that are used as animal food. Some manufacturers may perform certain processes for both human and animal food, such as irradiators that irradiate both produce and pet treats.

Divisions may choose to perform an inspection according to CPGM 7371.000 during an inspection covered by this compliance program (CPGM 7303.040) according to the animal food workplan when the facility manufactures, processes, packs, or holds animal food. Divisions should utilize the criteria found in CPGM 7371.000 to determine whether the facility is eligible for an animal food inspection.

If a facility is not further manufacturing/processing human food by-product for use as animal food, the facility would be inspected under 21 CFR part 117.95  *Holding and Distribution CGMPs* according to this CPGM (7303.040). When significant conditions associated with an animal food are observed during a human food inspection, the Division should contact the program contacts in CPGM 7371.000 to determine whether an animal food inspection should be performed.

## **(16) Interacting Assignments**

There are a number of interacting programs that are currently being implemented as assignments and will eventually be incorporated into the compliance program framework. These include, but are not limited to, foreign supplier verification programs (FSVP) inspections, intentional adulteration quick-check inspections, produce safety inspections, voluntary qualified importer inspections, and environmental sampling inspections. Divisions should make every effort to coordinate resources so that inspections conducted under this program also meet inspection obligations from other interacting assignments. When compliance programs covering these interacting programs are implemented, this program will be updated with more information.

### **E. Food Defense Measures and Food Registration**

Field inspection staff should confirm that each facility inspected under this program has a current food facility registration per the 2002 Bioterrorism Act and [Section 415 of the FD&C Act](#). If registration information obtained during the inspection (foreign and domestic) is different from the information in the Food Facility Registration Module (FFRM), send an email to [CFSANFoodFacilityRegistration@fda.hhs.gov](mailto:CFSANFoodFacilityRegistration@fda.hhs.gov) in accordance with IOM subchapter 5.4.1.5.2 *Food Facility Registration Resources*.

A food defense component, conducted in accordance with IOM subchapter 5.4.1.4 *Food Defense Activities*, should be included in all inspections conducted under this program. As such, reconciliation exams should be performed during each inspection. This program will be updated at a later date to include information concerning the implementation of [21 CFR 121 Mitigation Strategies to Protect Food Against Intentional Adulteration](#).

### **F. Interactions with Federal Agencies, State and Local Counterparts, and Foreign Authorities**

#### **(1) Federal Agencies**

Follow IOM subchapter 3.1.2 *Discussion with Federal Inspector* when federal officials from other agencies are present during FDA inspections or investigations. See IOM

subchapter 3.2 *Federal Agency Interaction* for a list of Memorandums of Understanding (MOUs) between the FDA and other Federal agencies that may be applicable to inspections conducted under this program. A complete list of MOUs may be found [here](#).

## **(2) State and Local Counterparts**

Divisions will collaborate with contracted State agencies to make them aware of the requirements of this program and deadlines for deliverables. Divisions will offer State agencies opportunities to accompany FDA on inspections or assist as necessary and this communication should be initiated no later than two weeks prior to an inspection.

Under the human food contract, all participating States are required to perform limited scope PCHF inspections and CGMP inspections (also referred to as Basic Work). Some States have also elected to perform full scope PCHF inspections under the human food contract. The course and field training requirements for limited scope PCHF, full scope PCHF, and CGMP inspections are outlined in the Statement of Work (SOW). The FDA Program Division Director or designee is responsible for issuing contract inspection assignments and monitoring performance.

Coordination between the FDA Program Division Director or designee, ORA Produce Safety Network (PSN), the produce safety State Produce Implementation Cooperative Agreement Program (CAP) grantee, and the state contract for Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Foods (PC/GMP) inspections is important for inspections at farm mixed-type facilities on farms. Coordination would need to extend to multiple states, with the assistance of the State Liaison (SL) and PSN, if a farm crosses state lines (e.g., facility is in one state and farm is in another). Whenever possible, produce safety inspections should be performed concurrently with inspections conducted under this assignment. A farm mixed-type facility is defined as an establishment that is a farm, but also conducts activities outside the farm definition that require the establishment to be registered and therefore would be subject to 21 CFR part 117.

## **(3) Foreign Authorities**

Follow ORA/DFHAFO procedures and IOM 5.11.4.3.3 when foreign competent authorities are present during FDA foreign inspections or investigations.

### **G. When to Contact Other Offices within the FDA**

#### **Regulator Technical Assistance Network (rTAN)**

The rTAN is a resource primarily for FDA and state field inspection staff to request information assistance before and during inspections. It is not intended to replace the current enforcement communication mechanism between field inspection staff, supervisors, and compliance officers or states.

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The rTAN is an information assistance system designed to connect field inspection staff with SMEs to get answers and clarification on FSMA rule interpretation and commodity-specific questions as needed. A list of rTAN commodity-specific SMEs, ORA National Expert SMEs, and lead program contacts (rTAN list) can be found in the [resource library](#) or [PC SharePoint site for FDA staff](#). Field inspection staff should submit inquiries through the rTAN e-mail inbox at [rTANWorkgroup@fda.hhs.gov](mailto:rTANWorkgroup@fda.hhs.gov). If an inspection is in-progress and an answer is required as soon as possible, field inspection staff should indicate that in the e-mail subject heading.

While the rTAN e-mail inbox is the preferred method of communication for ongoing inspections, FDA field inspection staff may also contact the appropriate SMEs from the rTAN to request that they operate in a reasonable “on-call” capacity during an inspection window. This will ensure that SMEs are available to answer questions or respond to concerns during an inspection. If field inspection staff want to reach out to several SMEs, please send one email to everyone to minimize duplication of effort and to ensure consistency of guidance.

## PART III – INSPECTIONAL

### 1. Operations

Inspections conducted under this compliance program should evaluate the establishment's adherence to the CGMP & PCHF rule and, as necessary, the ST rule. See [attachment A](#) for additional information concerning ST inspections. **Voluntary corrections should be encouraged during the inspection and corrective actions taken by the facility shall be verified and documented in the corrective action reporting (CAR) system. Field inspection staff are encouraged to take the [web-based CAR training](#).**

Information on how to respond to the FDA 483 *Inspectional Observations* should be provided to the facility's management. **For foreign inspections, FDA 483 responses should be sent to [FDA483responseinternational@fda.hhs.gov](mailto:FDA483responseinternational@fda.hhs.gov).** Field inspection staff must inform the facility that the adequacy of their response to the FDA 483 may impact FDA's determination of the need for follow-up action(s). FDA expects the facility to respond to the FDA 483 within 15 business days of the end date of the inspection.

For all initial inspections conducted under this program, the [FDA Firms Resources Handout](#) must be provided to the facility's management and discussed. During inspections at facilities that are also importers, [Foreign Supplier Verification Programs: What Do Manufacturers/Processors Covered by the PC Supply-Chain Program Need to know about FSVP?](#) should be provided to the facility's management.

#### A. Inspections

##### (1) Food CGMP Inspections

Food CGMP inspections should be performed at facilities subject to 21 CFR part 117 subparts A, B, and F. Most commonly, food CGMP inspections will be components of inspections with broader scopes such as modified requirements inspections, full or limited scope PCHF inspections, or seafood HACCP inspections. However, food CGMP inspections may be standalone if other subparts of 21 CFR part 117 do not apply and the food is not covered by an interacting program. Accomplishment hours for food CGMP inspections must be reported under the 03040 PAC code (FDA) or the 03S040 PAC code (state). **Additional PAC codes must be added depending on the scope of inspection (e.g. a limited scope PCHF inspection would include PAC codes 03040 AND 03040L).**

##### (a) Subpart A Training Requirements and Subpart F Record Requirements

Inspections should cover the training requirements found in Subpart A and the training record requirements found in Subpart F. To assess the firm's compliance with these subparts, field inspection staff should:

- Identify key personnel associated with the covered product/process during the initial walkthrough and request information on each individual's qualifications and

training to perform his/her job. If through interview and/or observation, it is determined that the personnel are not qualified or trained, advise the firm of the new requirements concerning training and qualifications.

- Request training records on food hygiene/food safety for three to five key individuals associated with the covered product/process. If there are significant CGMP deficiencies observed, training records on food hygiene/food safety for responsible employees should be reviewed. If no training records exist, advise the firm of the new training requirements including mandatory records of said training.
- If the firm has training records, assess them against the general recordkeeping requirements in subpart F. Advise the firm if there are general recordkeeping deficiencies that need to be addressed.

#### (b) Subpart B Current Good Manufacturing Practice (CGMPs)

CGMPs identified in 21 CFR part 117 Subpart B include human food by-products for use as animal food, specific requirements for preventing allergen cross-contact, and other CGMP provisions.

### (2) Limited Scope PCHF Inspections

Limited scope PCHF inspections may be performed at facilities subject to 21 CFR part 117 subparts C and G. Field inspection staff are required to have successfully completed the web-based training titled [GMP/Limited Scope PC Inspection Webinar](#) and be prepared to do a broad assessment of process, sanitation, or allergen preventive controls (as necessary) prior to conducting a limited scope PCHF inspection under this program. Accomplishment hours for limited scope PCHF inspections must be reported under the 03040L PAC code (FDA) or the 03S041 PAC code (state).

**Field inspection staff should not conduct their own hazard analysis or review written food safety plans, including the facility's hazard analysis, preventive control programs, supply-chain programs, or recall plan, as part of their broad assessment.**

#### (a) Broad Assessment of Sanitation Controls

If the facility is processing RTE food that is exposed to environmental conditions where contamination with environmental pathogens could occur, field inspection staff should:

- assess the facility's sanitation controls including equipment cleaning and sanitizing as well as observe employee practices, and
- assess the facility's environmental monitoring program.

#### (b) Broad Assessment of Food Allergen Controls

If the facility is receiving, storing, and using any ingredients composed in whole or in part of major allergens, field inspection staff should:

- assess and observe the facility's allergen controls for allergen cross-contact, including employee practices, equipment cleaning between products with different allergen profiles, dedicated equipment and/or employees for allergen and non-allergen containing products, physical separation of allergenic ingredients, and process scheduling, and
- assess the facility's controls for labeling products containing allergens.

### (c) Broad Assessment of Process Controls

Field inspection staff should assess any process controls that the facility has implemented to control significant hazards. Such controls may include cooking, formulation (pH,  $a_w$ , etc.), cooling, and refrigeration. If the controls appear to be adequate, no further action is required. If the controls appear to be inadequate to eliminate or reduce a hazard to an acceptable level, field inspection staff should notify an FDA supervisor.

**Field inspection staff should notify Division management when egregious conditions are observed pertaining to the control of significant hazards to determine whether a full scope PCHF inspection is warranted. Do not conduct a limited scope PCHF inspection when environmental sampling is being conducted during the inspection. Environmental inspections covering processes subject to subpart C must be either full scope PCHF or PCHF follow-up inspections.**

### (3) Full Scope PCHF Inspections

Full scope PCHF inspections should be performed at prioritized facilities according to [Part II\(2\)\(A\)](#) of this program. These inspections include coverage of 21 CFR part 117 subparts C and G. Field inspection staff are required to have successfully completed the FSPCA Preventive Controls Alliance course, web-based training titled [GMP/Limited Scope Preventive Controls Inspections Webinar](#), and FD 254 Preventive Controls for Human Food Regulators course prior to conducting full scope PCHF inspections. They are also required to have participated in a PC on-the-job experience (OJE) where they lead an inspection with the assistance of PC-trained inspection staff. Accomplishment hours for full scope PCHF inspections must be reported under the 03040F PAC code (FDA) or the 03S042 PAC code (State).

### (4) Modified Requirements Inspections at Qualified Facilities

Modified Requirements Inspections at Qualified Facilities will be performed at all facilities that submit attestations per subpart D (21 CFR 117.201). Field inspection staff must view the 03/21/19 FSMA chat titled [Overview of PCHF Inspections at Qualified Facilities](#) prior to performing modified requirements inspections at qualified facilities.

Field inspection staff will need to check the firm's status in FURLS or OSAR FIRM 360 to determine if the facility has attested as a qualified facility and the provision under which the facility has attested (i.e., 21 CFR 117.201(a)(2)(i) or 21 CFR 117.201(a)(2)(ii)).

Commissioned State partners performing inspections under contract should check the Qualified Facility Attestation Module to determine whether the firm has attested as a qualified facility prior to each inspection. Users should visit [www.access.fda.gov](http://www.access.fda.gov) to login with their FURLS account ID and password to access the module. Accomplishment hours for modified requirements inspections at qualified facilities must be reported under the 03040Q PAC code (FDA) or the 03S043 PAC code (State).

**(5) Modified Requirements Inspections at Facilities Solely Engaged in Storage of Unexposed Packaged Food that Requires Time/Temperature Controls for Safety**

Modified requirements inspections will be performed at all facilities solely engaged in the storage of unexposed packaged foods when covering foods that require refrigeration to control pathogen growth and/or toxin formation and that are subject to the modified requirements in subpart D (21 CFR 117.206). Accomplishment hours for modified requirements inspections at these facilities must be reported under the 03040R PAC code (FDA) or the 03S044 PAC code (State).

**(6) PCHF Follow-Up Inspections**

PCHF follow-up inspections allow Divisions to utilize fewer resources during for-cause follow-up inspections by covering only those parts of subparts C and G related to ongoing compliance activities. PCHF follow-up inspections may only be performed when a full scope preventive controls inspection has been performed at the facility within the preceding three years and a compliance follow-up inspection is being performed that may not require comprehensive subpart C and G coverage. For example, if a full scope preventive controls inspection was performed and yielded significant observations pertaining only to allergen controls, the compliance follow-up inspection at this facility could be a focused allergen controls inspection.

PCHF follow-up inspections should never be performed during an initial inspection of a facility, an initial for-cause inspection, or when the facility has never had a full scope PCHF inspection. PCHF follow-up inspections may include coverage of one or more types of preventive controls including process controls, sanitation controls, allergen controls, or other controls as determined by the Division. The purpose and scope of the PCHF follow-up inspection must be stated clearly in the EIR summary and endorsement text.

Investigators must meet the same training requirements as for full scope PCHF inspections to perform focused PCHF inspections. Divisions may make the decision to perform a full scope PCHF inspection or a focused PCHF inspection during follow-up inspections meeting the above criteria depending on available resources. Accomplishments should be reported under 03040U for FDA inspections and 03S045 for State contract inspections.

## B. Investigations

Domestic or foreign investigations (OP 13 or OP 15, respectively) may be performed at facilities covered by this program. See IOM subchapter 8.10 *General Investigation Reporting* for guidance covering how to conduct and report an investigation.

## C. Sample Collections

Compliance (for-cause) and surveillance samples, including environmental samples, may be collected during inspections covered by this compliance program. These samples may be covered under interacting compliance programs listed in [Part II\(2\)\(D\)](#) of this program, under routine surveillance sampling programs such as the [Sample Collection Operation Planning Effort \(SCOPE\)](#), under CFSAN or ORA [active assignments](#), or as directed for compliance purposes.

## D. Import Activities

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## E. Other

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## 2. Reporting

Establishment inspection reports must be completed in eNSpect per IOM subchapter 5.11 *Reporting*. eNSpect inspection protocols (IP) must be completed for full scope PCHF inspections, PCHF follow-up inspections, and sanitary transportation inspections. Investigational memorandums must be prepared per IOM subchapter 8.10 *General Investigation Reporting*. EIRs must be comprehensive for all initial inspections performed under this compliance program regardless of inspection history. EIR templates and reporting information may be found on the [PC SharePoint site for FDA staff](#).

All discussion items and corrective actions taken by a facility in response to inspectional observations must be documented in the Corrective Action Reporting (CAR) system, accessible via eNSpect and CMS. Voluntary corrections should be encouraged for all observations and, when possible, be verified prior to the close of the inspection. Use eNSpect to report corrective actions observed during the inspection and those received after the inspection but before the inspection report is finalized in eNSpect. Use CMS to report and assess any corrective actions received after the EIR has been finalized in eNSpect.

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**PART IV – ANALYTICAL****1. Analyzing Laboratories**

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**2. Analyses to be Conducted**

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**3. Methodology**

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**4. Reporting**

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## PART V - REGULATORY/ADMINISTRATIVE STRATEGY

### 1. Findings

The goal of this regulatory strategy is to obtain high rates of industry compliance with the CGMP & PCHF Rule and ST rule and gain prompt voluntary correction of deficiencies; however, appropriate swift enforcement action will be taken when significant violations present a threat to public health. If a Division determines that there is a direct threat to public health during an inspection, such as a shipment of food found to be positive for pathogens or containing undeclared allergens, the Division should immediately contact CFSAN/OC to discuss administrative options. Divisions should also consider their State partners' ability and willingness to request industry's prompt voluntary correction of deficiencies or pursue state enforcement action. Information covering the regulatory/administrative strategy for the ST rule is found in [attachment A](#).

Refer to the [resource library](#) or [PC SharePoint site for FDA staff](#) for the 21 CFR part 117 citations ranking document which provides a starting point for determining regulatory significance based on public health. Public health significance of observations and appropriate follow-up activities must be determined on a case-by-case basis.

#### A. Critical Observations

Observations that are categorized as "critical" are the most serious deviations from the CGMP & PCHF rule. Specifically, the facility has a breakdown of a preventive control(s) that results in a reasonable probability of causing serious adverse health consequences or death to humans or animals (SAHCODHA). We expect the classification of observations as "critical" to be limited to situations that are likely to pose an imminent public health threat. CFSAN requests that Divisions contact the CFSAN/OC program contacts during the inspection when critical observations are identified.

An inspection of a food facility that identifies one or more observations categorized as "critical" will generally be classified as OAI and require immediate action to address violative product. Divisions should urge the facility to cease production and shipping operations, to promptly address conditions in the plant, and to determine the root cause, whether affected food should be recalled, and the disposition of affected food held within their facility. The Division should also consider swift enforcement action if warranted, including but not limited to mandatory recall, administrative detention, and suspension of food facility registration.

#### B. Major Observations

Observations that are categorized as "major" are of significant public health concern. Specifically, the facility has a deficiency that results in unsatisfactory conditions that present a food safety risk and are likely to result in a system breakdown. These major observations are significant and should be included on an FDA 483.

An inspection of a food facility that does not identify a critical observation but does document one or more observations categorized as “major,” may be classified as OAI and issued an advisory action. Certain situations may be classified VAI. See [table 2](#) for more information.

Unless direct reference is provided, all advisory actions will require CFSAN review and concurrence.

### C. Minor Observations

Observations that are categorized as “minor” are not of significant public health concern. Specifically, the facility has a deficiency that results in unsatisfactory conditions that, if not addressed, may lead to a risk to food safety but is not likely to cause a system breakdown. These minor observations are typically discussion items.

An inspection of a food facility that does not identify a “critical” or “major” observation, but does document one or more observations categorized as “minor,” will generally be classified as “No Action Indicated” (NAI) and the observations will be discussed with facility management. Although “minor” observations are generally not considered significant from a public health perspective, facilities should be encouraged to address minor observations during the inspection before closeout. Corrections should be verified and documented prior to closing the inspection. A pattern or history of the same minor violation at a facility should be considered significant (major), and as such, this finding should be classified as "Voluntary Action Indicated" (VAI). See [table 2](#) for more information.

### D. Factors to Consider

The following factors should be considered when ranking deviations and considering enforcement action:

- **Is the food ready-to-eat?** Ready-to-eat is defined in the CGMP & PCHF rule as any food that is normally eaten in its raw state or any other food, including a processed food, for which it is reasonably foreseeable that the food will be eaten without further processing that would significantly minimize biological hazards. Insanitary conditions in RTE operations where the food is exposed to the environment and not subsequently processed to control pathogens are generally more significant than those observed in operations where food will be further processed with an adequate “kill-step” and not subsequently exposed to the environment.
- **Can the observation be corrected during the inspection?** It may be possible to verify and document correction of “minor” observations; however, this is less likely for significant observations as those generally require more time and resources to adequately address.
- **Is the deficiency indicative of an isolated problem or system failure?** An isolated issue (e.g., a crack on the processing room floor) may be “minor,” whereas, a repeat problem or pattern of deviations (e.g., a follow-up inspection revealing floors throughout the facility in poor condition) may be considered “major”.

- **Are controls in place?** A facility that is missing records or a component of their food safety plan may be implementing adequate controls for significant hazards in practice.
- **Is the facility or food associated with a recent outbreak or recall?** If so, observations likely associated with the root cause of the outbreak or recall may rise to a “critical” ranking. Refer to [table 2](#) for more information.
- **Is the finding a first-time observation or repeat over multiple inspections?** Repeat observations may become “major” if they are indicative of a general lack of control and inability to make lasting corrections.
- **Is the facility a qualified facility?** Some facilities (e.g. qualified facilities) will be subject to modified requirements and are exempt from Subparts C and G. Therefore, significant observations indicating noncompliance with their attestation would be cited as “major” deviations from the modified requirements in subpart D.

## 2. Charges

Charges that may be applicable to this program include:

- An article of food is adulterated under section 402(a)(4) of the Act [21 U.S.C. 342(a)(4)] if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.
- The article of food is misbranded under section 403(w) of the Act [21 U.S.C. 343(w)] in that the label fails to identify all major food allergens present in the products, as required by 21 U.S.C. 343(w)(1).
- The failure of the owner, operator, or agent in charge of a covered facility to comply with the preventive controls provisions of the CGMP & PCHF rule is prohibited by section 301(uu) of the Act (21 U.S.C. 331(uu)).

## 3. Actions

**Please note that all reasonable steps should be taken to obtain voluntary compliance prior to initiating regulatory action. All possible administrative and legal regulatory actions should be discussed with state regulatory counterparts before moving forward.** Divisions should take into consideration state partner’s ability and willingness to request industry’s prompt voluntary correction of deficiencies or pursue state enforcement action. Refer to part [V\(1\)](#) and table 2 of this program to determine appropriate actions based on findings. If the facility’s response is inadequate to protect public health, all available administrative and legal tools should be considered, such as a regulatory meeting, untitled letter, warning letter, administrative detention, registration suspension, mandatory recall, seizure, or injunction, and prosecution. If the Division feels that administrative or legal action is warranted, management should initiate a preliminary assessment call with CFSAN Office of Compliance Division of Enforcement (DE). Refer to the [Regulatory Procedures Manual](#) (RPM) for more information.

### A. Administrative and Legal Actions for Imminent Public Health Hazards

- **FDA-Requested Recall or Mandatory Recall Order**

Although unusual in the absence of demonstrating specific product contamination, an FDA-requested recall could be considered in urgent situations and based on a Class I health hazard evaluation. Refer to RPM Chapter 7 for more information. If a determination is made that there is reasonable probability that an article of food is adulterated under section 402 of the FD&C Act and will cause serious adverse health consequences or death to humans or animals (SAHCODHA) and the facility refuses to take voluntary corrective actions, including recall, after FDA request, mandatory recall under section 423 may be warranted.

- **Administrative Detention**

If a determination is made that there is reason to believe that an article of food is adulterated or misbranded, administrative detention under section 304 of the FD&C Act may be considered to prevent the movement of such food while FDA prepares for additional action (e.g. seizure, injunction).

- **Seizure/ Injunction**

When the facility’s response is inadequate to protect public health and/or the facility refuses to conduct a voluntary recall, a seizure and/or injunction should be considered.

- **Suspension of Food Facility Registration**

If a facility registered under section 415(a) manufactures, processes, packs, receives, or holds food that has a reasonable probability of causing SAHCODHA; and that facility created, caused, or was otherwise responsible for that reasonable probability of SAHCODHA; or knew of, or had reason to know of, the reasonable probability of SAHCODHA, and packed, received, or held such food, suspension of food facility registration may be considered. If warranted, the State should be engaged to determine if State enforcement actions such as embargo or permit revocation can be utilized to stop the movement of product or production while FDA considers enforcement actions.

B. Compliance Activities

**CFSAN has not given Direct Reference Authority for any compliance actions related to violations of 21 CFR part 117 at this time.**

Please see table 2 below for examples of potential compliance activities associated with ranking and classification outcomes. This summary is a starting point and should not be the sole basis for evaluating the significance of noncompliance. Findings should be assessed on a case-by-case basis and should consider the totality of the observations.

Table 2 – Compliance Activity Examples			
Regulatory Significance	Example Deficiency	Classification	Follow-Up
Critical	<ul style="list-style-type: none"> <li>• No written food safety plan (FSP), no</li> </ul>	OAI	Issue 483

	<p>hazard analysis conducted, or missing or inadequate FSP element;</p> <ul style="list-style-type: none"> <li>• AND observed lack of control;</li> <li>• AND food associated with illness, RFR, recall, or poses a SAHCODHA risk.</li> </ul>		<p><b><u>Domestic</u></b> Urge immediate voluntary shutdown and submission of corrective action plan, urge voluntary recall if warranted.</p> <p>Consider: Registration Suspension, Mandatory Recall, Administrative Detention, Injunction (Preliminary or Permanent), Seizure, Regulatory Meeting, Prosecution</p> <p><b><u>Foreign</u></b> Urge immediate voluntary shutdown and submission of corrective action plan. Consider Import Alert, modifying PREDICT score, following up with FSVP and VQIP importers, contacting foreign government authorities to recommend follow up as appropriate.</p>
<b>Major</b>	<ul style="list-style-type: none"> <li>• No written food safety plan</li> <li>• No hazard analysis conducted</li> <li>• No written procedures to ensure raw materials &amp; other ingredients received only from approved suppliers (when suppliers control a hazard)</li> <li>• No environmental monitoring to verify sanitation is</li> </ul>	<b>OAI</b>	<p><b>Issue 483</b></p> <p><b><u>Domestic</u></b> Consider: Warning Letter, Administrative Detention, Injunction (Permanent), Seizure, Prosecution, regulatory meeting</p> <p><b><u>Foreign</u></b> Consider: Warning Letter, Detention/ Refusal, Import Alert, Modifying PREDICT score, following up with FSVP and VQIP importers</p>



		<b>VAI (repeat condition or pattern of observations)</b>	<b>Issue 483</b>
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C. Additional Information

Voluntary correction is often the most effective and expedient means by which to protect public health and obtain compliance. Divisions should take steps to obtain voluntary correction prior to initiating regulatory action. When voluntary correction is not forthcoming, the Agency should pursue routine regulatory procedures to address significant observations. Refer to [FMD-86 Establishment Inspection Report Conclusions and Decisions](#) for further guidance.

If a facility inspected under this program has a Class I recall, a positive environmental pathogen finding impacting an RTE food or food contact surfaces since the previous inspection, and/or conditions are observed that present a significant public health concern, a conference call between the Division Compliance Branch, and CFSAN/OC program contacts identified in [part VI](#) of this program should be scheduled before closing the inspection to discuss possible enforcement strategies. If this information is known prior to beginning the inspection, a call should be scheduled prior to the start of the inspection.

The Division should submit any recommendation for enforcement follow-up via the Compliance Management System (CMS). If CFSAN feels an inspection classified as VAI should be classified as OAI, a request will be made to the Division to provide the full narrative EIR and exhibits through CMS for review. If an OAI reclassification is suggested by CFSAN, a meeting will be scheduled between the Division and CFSAN/OC.

**Meat and Poultry products manufactured by airline caterers are not inspected by USDA FSIS.** FDA has authority to regulate the airline caterers’ production of meat and poultry products shipped in interstate commerce. Before initiating any regulatory action involving meat or poultry production at airline caterers, Divisions must set up a meeting to discuss the case with CFSAN/OC/DE.

4. Follow-Up

A. Regulatory Follow-Up

To verify the implementation of corrective actions, Divisions should conduct domestic follow-up inspections within **6 months** of the compliance action being finalized for facilities with inspection classifications of **OAI** and that were observed to have significant CGMP

deficiencies, significant FSP deficiencies, and/or that had significant environmental pathogen contamination according to [FMD-86](#) and RPM Chapter 4. **If there are critical deficiencies or a risk to public health, then follow-up must be conducted as soon as possible after the close of the inspection and completion of compliance action.** Follow-up inspections may include the collection of environmental samples and/or product samples at the Division's discretion.

Prior to initiating the re-inspection, Divisions should hold an enforcement strategy discussion with CFSAN/OC, and state partners as applicable to discuss potential follow-up actions if the facility continues to have significant violations. If the follow-up inspection reveals that the facility continues to have conditions that are likely to lead to the adulteration of foods, the Division should consider more severe enforcement action based on these repeat offenses. Divisions should initiate a call with CFSAN/OC within 24 hours of determining that an inspection revealed significant repeat observations.

If an inspection is initially classified OAI but reclassified VAI, the Division will re-inspect within 1 year for domestic inspections. Facilities with an inspection classification of NAI and VAI should be re-inspected at the frequency designated in the Food Safety Modernization Act (FSMA) for high-risk and non-high-risk facilities.

B. Other

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## PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS

### 1. References

Major guidance and reference materials pertaining to this program are listed below. Additional guidance may be found in the [resource library](#) or [PC SharePoint site for FDA staff](#).

- A. [Investigations Operations Manual \(IOM\)](#)
- B. [Regulatory Procedures Manual \(RPM\)](#)
- C. [Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Foods](#)
- D. [21 CFR part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food](#)

### 2. Attachments

- A. Human Food Sanitary Transportation Inspections

### 3. Program Contacts

- A. CFSAN

<b>Purpose</b>	<b>Name</b>	<b>Organization</b>	<b>Contact</b>
General Program Guidance	<a href="#">Mark Farrell</a>	CFSAN/OC/DFPG/PAMB	240-402-2483
Enforcement Guidance	<a href="#">Jamie Hughes</a>	CFSAN/OC/DE	240-701-7399
Technical Information	<a href="#">rTAN</a>	CFSAN/OFS	See <a href="#">part II(2)(G)</a>

- B. ORA

<b>Purpose</b>	<b>Name</b>	<b>Organization</b>	<b>Contact</b>
Domestic Inspection Guidance	<a href="#">Larry Stringer</a>	ORA/OHAFO/DDHAFO	312-596-6523
Foreign Inspection Guidance	<a href="#">Leslie A. (Cartmill) Jackanicz</a>	ORA/OHAFO/DFHAFO	813-915-7991
State Programs	<a href="#">Teresa Bills</a>	ORA/OPOP/OP	615-854-0019
Technical Information	<a href="#">rTAN</a>	ORA/OHAFO	See <a href="#">part II(2)(G)</a>

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## PART VII - CENTER RESPONSIBILITIES

The Office of Food Safety will provide subject matter expertise in the maintenance and evaluation of the Compliance Program and provide guidance to the Office of Compliance with regard to program priorities, relevant evaluation questions, and recommended program changes. The Office of Compliance will lead the effort and work in conjunction with the Office of Food Safety to prepare routine compliance program evaluations. Evaluation will be conducted on a periodic basis and outline the program office's current objectives, general and specific program evaluation questions, list recommendations for process improvement, and highlight data patterns and trends for better targeting and resource allocation. The Office of Compliance will make these evaluations available as well as FSMA Tracker reports that can be run annually or as frequently as needed to track accomplishments. Instructions on how to access these reports are available at:

<http://inside.fda.gov:9003/ProgramsInitiatives/Food/FieldPrograms/ucm016009.htm>

<http://inside.fda.gov:9003/downloads/ProgramsInitiatives/Food/FieldPrograms/UCM609042.pdf>

SUBJECT: <b>ATTACHMENT A: HUMAN FOOD SANITARY                  TRANSPORTATION INSPECTIONS</b>		IMPLEMENTATION DATE: 10/15/2020
DATA REPORTING		
PRODUCT CODES	PRODUCT/ASSIGNMENT CODES (PAC)	
USE APPROPRIATE PRODUCT CODES	REPORT SANITARY TRANSPORTATION ACTIVITIES UNDER:  <b>03040T (HUMAN FOODS SANITARY                  TRANSPORTATION INSPECTIONS)</b>	

## PART I – BACKGROUND

See [Part I](#) of 7303.040 *Preventive Controls and Sanitary Human Food Operations* for additional sanitary transportation background information.

### 1. Summary of Requirements

The *Sanitary Transportation of Human and Animal Food* (ST rule) contains sections including *General Provisions, Vehicles and Transportation Equipment, Transportation Operations, Training, Records, and Waivers*. See below for major requirements of the ST rule.

#### A. Vehicles and Transportation Equipment

- Vehicles and transportation equipment used in transportation operations must be so designed and of such material and workmanship as to be suitable and adequately cleanable for their intended use to prevent the food they transport from becoming unsafe, i.e., adulterated within the meaning of section [402\(a\)\(1\), \(2\), and \(4\)](#) of the [FD&C Act](#).
- Vehicles and transportation equipment must be maintained in such a sanitary condition for their intended use as to prevent the food they transport from becoming unsafe during transportation operations.
- Vehicles and transportation equipment used in transportation operations for food requiring temperature control for safety must be designed, maintained, and equipped as necessary to provide adequate temperature control to prevent the food from becoming unsafe.
- Vehicles and transportation equipment must be stored in a manner that prevents them from harboring pests or becoming contaminated in any other manner that could result in food becoming unsafe during transportation operations.

#### B. Transportation Operations

Transportation operations must be conducted under conditions and controls necessary to prevent food from becoming unsafe, including:

- Taking effective measures such as segregation, isolation, the use of packaging, or other protective measures to protect food from contamination by raw foods and nonfood items in the same load.
- Taking effective measures such as segregation, isolation, or other protective measures, such as hand washing, to protect food transported in bulk vehicles or food not completely enclosed by a container from contamination and cross-contact during transportation operations.
- Ensuring that food that requires temperature control for safety is transported under adequate temperature control throughout transportation operations.

The type of food (e.g., animal food, pet food, human food), and its production stage (e.g., raw material, ingredient or finished food) must be considered in determining the necessary conditions and controls for the transportation operation. Additionally, there are specific

requirements applicable to Shippers, Receivers, Loaders, and Carriers engaged in Transportation Operations in § 1.908(a-e).

#### C. Training

Carriers must provide and maintain documentation of adequate food safety training of personnel engaged in transportation operations when the carrier and shipper agree in writing that the carrier is responsible for sanitary conditions during transportation.

#### D. Records

The ST rule requires the following documents be maintained dependent on the operations of the inspected entity:

- Written procedures to ensure that vehicles and equipment used in their transportation operations are in appropriate sanitary condition for the transportation of food (i.e., will prevent food from becoming unsafe during the transportation operation.)
- Written procedures to ensure food shipped in bulk does not become unsafe due to previous cargo.
- Written procedures to ensure that food requiring temperature control for safety under the conditions of shipment is transported under adequate temperature control throughout their transportation operations.
- If included within the written procedures, records that demonstrate that shipper provides specifications and operating temperatures to carriers as required by § 1.908(b)(1) and (2) as a regular part of their transportation operations.
- Any written agreements between the shipper and a carrier, **IF**, the carrier has agreed to take on any of the food safety responsibilities for transportation as permitted under § 1.908(b)(3), (4), and (5).
- Carrier must develop and implement specifications (if applicable) regarding sanitation and temperature controls of the vehicles and provisions for bulk vehicles in accordance with § 1.908(e)(6).
- Training records required by carriers in accordance with § 1.910(b)
- Any other written agreements between one party and other entities subject to the ST rule (e.g., loaders, receivers, reassigning their responsibilities to a covered party).

#### E. Waivers

The ST rule allows the Agency to waive the requirements of the rule if it determines that the waiver will not result in the transportation of food under conditions that may render the food unsafe for humans or animals

The Agency published [waivers](#) on April 5, 2017 for:

- Shippers, carriers, and receivers who hold valid permits and are inspected under the National Conference on Interstate Milk Shipments (NCIMS) Grade “A” Milk Safety

program. This waiver only applies when Grade A milk and milk products—those produced under certain sanitary conditions—are being transported. FDA acknowledges that controls for such transportation operations already exist under the NCIMS program, with State enforcement and FDA oversight.

- Food establishments holding valid permits issued by a relevant regulatory authority, such as a state, local, territorial, or tribal agency, when engaged as receivers, or as shippers and carriers in operations in which food is relinquished to customers after being transported from the establishment. Examples of such establishments include restaurants, supermarkets, and home grocery delivery operations. FDA acknowledges that controls for such transportation operations already exist under retail food protection programs enforced by state, territorial, tribal and local officials and with FDA oversight.
- Shippers, carriers, and receivers that are appropriately certified and are inspected under the requirements established by the Interstate Shellfish Sanitation Conference's National Shellfish Sanitation Program (NSSP), only when engaged in transportation operations involving molluscan shellfish in vehicles that are permitted by the State NSSP certification authority.

## 2. Exemptions and Modified Requirements

The ST rule provides several exclusions, including:

- Shippers, loaders, receivers, or carriers engaged in food transportation operations that have less than \$500,000 in average annual revenue.
- Transportation activities performed by a farm.
- Transportation of food that is transshipped through the United States to another country.
- Transportation of food that is imported for future export and that is neither consumed nor distributed in the United States.
- Transportation of human food byproducts for use as animal food without further processing.
- Transportation of food that is completely enclosed by a container except a food that requires temperature control for safety.
- Transportation of live food animals, except molluscan shellfish.
- Transportation of compressed food gases, and food contact substances as defined in section 409(h)(6) of the Federal Food, Drug, and Cosmetic Act.

## 3. Compliance Dates and Enforcement Discretion

Any businesses (Large and Small) conducting transportation operations covered by the ST rule, and that are not excluded or otherwise exempt, are subject to the ST Rule.

# PART II – IMPLEMENTATION

## 1. Objectives

See [Part II\(1\)](#) of CPGM 7303.040 *Preventive Controls and Sanitary Human Food Operations*.

## 2. Program Management Instructions

### A. Inspection Priorities

Divisions will be notified of the need to perform surveillance ST inspections via the annual work plan and FSMA inventory. For-cause ST inspections should be performed at carriers or facilities subject to the sanitary transportation rule when:

- an ongoing inspection reveals significant observations related to the transport of food,
- the carrier or facility is responsible for a Class I recall associated with inadequate controls during the transportation of food,
- the previous inspection at the carrier or facility was firm “OAI” and there were significant observations related to the receipt or transport of foods subject the ST Rule, or
- the carrier or facility is implicated in an event that may impact public health. The FDA may obtain this information from federal, state, local, or tribal partners; foreign competent authorities (e.g. the rapid alert system for food and feed (RASFF) or information shared by a foreign competent authority under a cooperative arrangement); from the Reportable Food Registry (RFR); from information collected during inspections of other facilities, or from consumer complaints.

A firm may be acting in multiple capacities under the Sanitary Transportation rule. For example, the firm may be the shipper (arranging the transportation of the food), the loader (loading food onto the vehicle), the carrier (transporting the food), receiver (receiving the food), or any combination thereof. Priority is given to shipping operations, but if a firm is not the shipper of a food subject to the sanitary transportation rule, but receives, loads, or transports a food that is, then those operations may be inspected instead. While the focus of the ST inspection may be the same as the food(s) covered during the non-ST portion of the inspection, there may be cases in which other foods should be covered. To the extent possible, priority should be given to the following shipping operations:

- Foods shipped that are not completely enclosed in a container during motor vehicle or rail car transportation;
- Foods shipped in bulk vehicles such as tankers and rail cars (e.g., flour, grains, and nuts). Bulk vehicles are vehicles in which food is shipped in bulk with the food coming in direct contact with the vehicle; and
- Foods shipped that require temperature control for safety during transport by motor or rail vehicle (e.g., packaged low-acid refrigerated juice with pH above 4.6, packaged low-acid refrigerated soup, fresh-cut vegetables, certain types of seafood, refrigerated ready-to-eat salads).

Firms that are covered under a waiver (see part [I\(1\)\(E\) of this attachment](#)) and transportation activities that are subject to an exclusion (see [part I\(2\) of this attachment](#)) under the ST rule should not be inspected for compliance with the ST Rule. If it is determined that an inspection is warranted at a facility that is not on FDA’s official establishment inventory, the

Division should contact the CFSAN and ORA program contacts in [part VI of CPGM 7303.040](#) before conducting the inspection.

## B. Planning Instructions

### (1) Inspections

Sanitary Transportation inspections should be performed during regularly planned inspectional work under interacting compliance programs unless there is for-cause reason to perform a stand-alone sanitary transportation inspection. Facilities should be selected for ST coverage according to the criteria in [part II\(2\)\(A\) of this attachment](#).

**Sanitary Transportation inspections may only be performed by Food Safety Staff who have completed FD9001W [Sanitary Transportation Training of Human and Animal Food Rule](#).**

### (2) Resources and Reporting

Divisions should make every effort to coordinate resources so that inspections conducted under this program may meet inspection and/or sampling obligations from other programs. Please see the chart below for additional resource and reporting information:

Resources and Reporting	
<b>Priority</b>	Routine
<b>Reporting PAC</b>	03040T Human Foods Sanitary Transportation Inspections
<b>Planning PAC</b>	03040T Human Foods Sanitary Transportation Inspections
<b>Inspection Op. Code</b>	11(foreign), 12 (domestic)
<b>Estimated accomplishment hours human food</b>	1 hour per inspection

## C. Program Interactions

All human food transportation operations that are not excluded from coverage under the ST rule and are not covered by a waiver issued by FDA are subject to 21 CFR part 1 subpart O and are subject to ST coverage in addition to coverage under applicable interacting programs unless the facility is subject to [21 CFR part 123 Fish and Fishery Products](#) (seafood HACCP), [21 CFR part 120 Hazard Analysis and Critical Control Point \(HACCP\) Systems](#) (juice HACCP), and [21 CFR part 117 Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food](#). These facilities are required to establish controls at receiving if a significant hazard is identified, providing equivalent protection for

public health as the sanitary transport requirements for receivers in 21 CFR 1.908; compliance with requirements for receivers should be assessed as part of those facilities' HACCP or preventive controls programs.

D. Interactions with Federal Agencies, State and Local Counterparts, and Foreign Authorities

States may have the option to perform sanitary transportation inspections under contract for the FDA. Divisions also have the option of inviting state, local and tribal counterparts to observe an ST inspection.

While the transportation of certain USDA-regulated foods is covered under the ST rule, inspections of firms regulated exclusively by USDA are not part of this program. Per section [1.900\(b\)\(3\)](#), the provisions of the rule do not apply to shippers, receivers, loaders, or carriers when they are engaged in transportation operations of food when it is located in food facilities that are regulated exclusively, throughout the entire facility, by USDA under Federal Meat Inspection Act (21 U.S.C. 601 et seq.), the Poultry Products Inspection Act (21 U.S.C. 451 et seq.), or the Egg Products Inspection Act (21 U.S.C. 1031 et seq.). In case of inspections of dual jurisdiction firms, inspections should be conducted in accordance with existing MOUs between FDA and USDA.

### PART III – INSPECTIONAL

#### 1. Operations

##### A. Inspections

ST inspections conducted under this program should assess the establishment's compliance with 21 CFR part 1, subpart O. Sanitary transportation inspections may only be performed by field inspection staff who have completed FD9001W [Sanitary Transportation Training of Human and Animal Food Rule](#). Investigators must report time spent covering ST under the sanitary transportation PAC code 03040T *Human Foods Sanitary Transportation Inspections* and report information collected in the eNSpect ST inspection protocol (IP).

When using the IP, investigators will be asked to identify each role that a facility plays in the transportation of food(s) when determining how the sanitary transportation rule applies. A single facility may conduct multiple transportation operations for the specific product inspected and may act as the shipper, loader, receiver, and carrier, or any combination thereof.

##### B. Investigations

See [part III\(1\)\(B\)](#) of CPGM 7303.040 for further Investigation instructions.

##### C. Sample Collections

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**D. Import Activities**

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**E. Other**

If it is determined that an inspection is warranted at a firm not on FDA establishment inventory, for any reason, consult with program contacts in CFSAN Office of Compliance and ORA OHAFO before initiating the inspection.

**2. Reporting**

Establishment inspection reports must be completed in eNspect per [Investigations Operations Manual \(IOM\) subchapter 5.11](#). Investigation memorandums must be prepared per [IOM subchapter 8.10](#).

**PART IV – ANALYTICAL****Intentionally Left Blank****PART V - REGULATORY/ADMINISTRATIVE STRATEGY****1. Findings**

Public health significance of observations and appropriate follow up activities must be determined on a case-by-case basis and should not replace the best judgement of the Division. In general, sanitary transportation observations are categorized critical, major, or minor as detailed in part [V\(1\)](#) of CPGM 7303.040. Some examples of conditions that may warrant regulatory action, depending on firm history, inherent risk of the food, and corrective action/response to observed conditions include:

- Significant insanitary conditions that directly affect vehicle sanitation, food contact surfaces and/or food products;
- Significant temperature deviations that may result in temperature abuse of foods requiring temperature control for safety;
- Conditions that result in cross contamination of foods during transportation
- Conditions that result in cross-contact with major food allergens for human food;
- Written procedures required by § 1.908(b)(3), (4), and (5) are not in place, or procedures are clearly incomplete to ensure food is not rendered unsafe during transportation; and
- Failure to implement written procedures to ensure food is not rendered unsafe during transportation operations.

**2. Charges**

Charges that may be applicable to sanitary transportation under this program include:

- An article of food is adulterated under section 402(i) of the FD&C Act [21 U.S.C. 342(i)] if it is transported or offered for transport by a shipper, loader, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in transportation of food under conditions that are not in compliance with the regulations issued under section 416.
- Failure by a shipper, loader, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in transportation of food to comply with the regulations issued under section 416 is considered a prohibited act under 301(hh) of the FD&C Act [21 U.S.C. 331(hh)].
- Failure by a shipper, loader, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 to allow access to and to copy all records required to be kept under regulations issued under section 416 shall be considered a prohibited act under 301(e) of the FD&C Act [21 U.S.C. 331(e)]. Also see section 703(b) for record requirements.
- Failure by a shipper, loader, carrier by motor vehicle or rail vehicle, or receiver that becomes aware of a possible material failure to temperature control or other condition that may render the food unsafe to take appropriate action, as required in § 1.908(a)(6), to ensure that the food is not sold or otherwise distributed unless a qualified individual determines that the condition did not render the food unsafe.

### 3. Actions

#### A. Compliance Activities

If a firm's deficiencies warrant compliance action, they will be considered on a case by case basis with input from CFSAN and ORA. If there are significant deviations from the other requirements in addition to the ST Rule, the Agency may consider adding a Sanitary Transportation charge to an action that includes other areas, such as preventive controls. All reasonable steps should be taken to obtain voluntary compliance prior to initiating regulatory action.

#### B. Additional Information

In some cases, based on the significance of the findings, voluntary correction may be the most appropriate action by the facility. When voluntary correction is not forthcoming, the Agency should pursue the routine regulatory procedures. Refer to [FMD-86 Establishment Inspection Report Conclusions and Decisions](#) for further guidance.

### 4. Follow-Up

#### A. Regulatory Follow-Up

To verify the implementation of corrective actions, Divisions should conduct follow-up inspections within **6 months** of the compliance action being finalized for facilities with inspection classifications of **OAI** and that were observed to have significant ST rule deficiencies according to [FMD-86](#) and RPM Chapter 4. **If there are critical deficiencies or a risk to public health, then follow-up must be conducted as soon as possible after the close of the inspection and completion of compliance action.**

Prior to initiating the re-inspection, Divisions should hold an enforcement strategy discussion with CFSAN OC, ORA OHAFO program contacts, and state partners to discuss potential follow-up actions if the firm continues to have significant violations. If the follow-up inspection reveals that the firm continues to have conditions that are likely to lead to the adulteration of foods, the division should consider more severe enforcement action based on these repeat offenses. Divisions should initiate a call with CFSAN OC and ORA OHAFO program contacts within 24 hours of determining that an inspection revealed significant repeat observations.

If an inspection is initially classified OAI but reclassified VAI and adequate corrective action has not been taken, the Division will re-inspect within 1 year. Facilities with an inspection classification of NAI and VAI should be re-inspected at the frequency designated in the Food Safety Modernization Act (FSMA) for high risk and non-high risk facilities.

#### B. Other

If it is determined that a for-cause ST inspection is warranted at a food facility for any reason, consult with CFSAN OC DE before initiating the inspection.

### **PART VI REFERENCES, ATTACHMENTS, AND PROGRAM CONTACTS**

#### 1. References

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#### 2. Attachments

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#### 3. Program Contacts

See program contact list in [part VI](#) of CPGM 7303.040.

### **PART VII - CENTER RESPONSIBILITIES**

See [part VII](#) of CPGM 7303.040 for more information