CHAPTER 03: FOODBORNE MICROBIOLOGICAL HAZARDS

SUBJECT	COMPLIANCE PROGRAM (CP) 7303.040 PREVENTIVE CONTROLS AND SANITARY HUMAN FOOD OPERATIONS
IMPLEMENTATION DATE	05/23/2024
PRODUCT CODES	REPORT APPROPRIATE PRODUCT CODES
PRODUCT/ASSIGNMENT CODES (PAC)	**FDA PACs:** **03040** (FOOD CGMP INSPECTIONS) **03040A** (FOOD, DRUG, AND COSMETIC ACT INSPECTIONS) **03040L** (LIMITED SCOPE PCHF INSPECTIONS) **03040F** (FULL SCOPE PCHF INSPECTIONS) **03040Q** (MODIFIED REQUIREMENTS INSPECTIONS AT QUALIFIED FACILITIES) **03040R** (MODIFIED REQUIREMENTS INSPECTIONS AT FACILITIES SOLELY ENGAGED IN STORAGE OF UNEXPOSED PACKAGED FOOD THAT REQUIRE TIME/TEMPERATURE CONTROLS FOR SAFETY) **03040T** (HUMAN FOODS SANITARY TRANSPORTATION INSPECTIONS) **03040U** (FOCUSED PCHF INSPECTIONS) **STATE PACs**: **03S040** (STATE CONTRACT FOOD CGMP INSPECTIONS) **03S040A** (STATE CONTRACT FOOD, DRUG, AND COSMETIC ACT INSPECTIONS) **03S041** (STATE CONTRACT LIMITED SCOPE PCHF INSPECTIONS) **03S042** (STATE CONTRACT FULL SCOPE PCHF INSPECTIONS) **03S043** (STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT QUALIFIED FACILITIES) **03S044** (STATE CONTRACT MODIFIED REQUIREMENTS INSPECTIONS AT FACILITIES SOLELY ENGAGED IN STORAGE OF UNEXPOSED PACKAGED FOOD THAT REQUIRE TIME/TEMPERATURE CONTROLS FOR SAFETY) **03S045** (STATE CONTRACT FOCUSED PCHF INSPECTIONS)

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 8.1.9 *General Investigation Reporting*. Corrective actions taken during inspections must be documented in the Observation and Corrective Action Reporting (OCAR) system within eNSpect.

Contents

Change History

Item	Change	Date
Issuance	CP 7303.040 initial issuance	10/17/2019
Update	• Sanitary Transportation program content added in Part I *Background* and in attachment A *Human Food Sanitary Transportation Inspections* • PCHF Follow-up inspections content added in Parts II *Implementation* and III *Inspectional*. • 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 CP 7307.001 Mycotoxins in Foods – Domestic and Import and CP 7371.000 Comprehensive Animal Food Inspections	10/15/2020

Update	• Updated instructions for performing inspections at qualified facilities.
	• Training prerequisites for each inspection type covered by this CP were removed from this CP and hosted on the Preventive Controls in Human Foods Resource Page.
	• Links added to new Preventive Controls in Human Foods Resource Page which will house controlled copies of all internal resources associated with this compliance program.
	• Updated limited scope PCHF inspection instructions to reflect updated training.
	• Updated broken hyperlinks.
	• Addition of PAC 03040A and 03S040A for inspections of facilities solely subject to the FD&C Act.
	• Updated enforcement terminology to better reflect current practices.
	• 03040U title changed to "Focused PCHF Inspections" and the criteria to perform these inspections were updated. The 03S045 PAC title was also updated to reflect the "focused PCHF" terminology.
	• Updated program interaction language for newly issued or updated compliance programs.
	  ○ Revision of infant formula interacting program instructions including premix facility inspection process and reporting instructions, and clarification on the scope of CGMP&PCHF rule coverage during infant formula inspections.
	  ○ Revision of acidified food interacting program instructions to reflect current processes.
	  ○ Clarification of Comprehensive Animal Food Inspections CP interactions and instructions for when to utilize the 71R909 PAC.
		05/23/2024

Item	Change	Date
	o Addition of CP 7303.050 as a program interaction.	

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; 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 food from farm to table by keeping them 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. 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. Establishments 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. Specifically, management 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 by a downstream customer 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* (FDA 483), 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 qualified facilities and facilities solely engaged in the storage of unexposed packaged food that requires temperature control for safety.

Qualified facilities such as very small businesses are exempt from subparts C and G regardless of whether they attest. Per 21 CFR 117.201, qualified facilities must attest to meeting the definition of a qualified facility in 21 CFR 117.3 *Definitions*, and how they are controlling food safety hazards in their facilities.

Facilities solely engaged in the storage of unexposed packaged food are exempt from subparts C and G. If some or all of the food requires time/temperature control for safety, the facility must comply with the requirements in 21 CFR 117.206.

Note: if a warehouse solely engaged in the storage of unexposed packaged food including food that requires time/temperature control for safety is also a qualified facility, it may choose to comply with either 21 CFR 117.201 or 21 CFR 117.206.

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 such an order to withdraw. FDA is not required to withdraw a qualified facility exemption to consider enforcement action. In general, an order to withdraw the qualified facility exemption would be a rare event, in part because alternative actions would likely provide a more expeditious approach to correcting a problem.

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, and 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 its hazard analysis, the facility must include a written supply-chain program as part of its 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 the 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 part 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**

In general, food facilities that are required to register under section 415(a) of the FD&C Act are subject to the preventive control requirements, primarily in subparts C and G of 21 CFR part 117, unless an exemption applies. Firms that are NOT subject to food facility registration are not subject to the preventive controls requirements. Additionally, both food facilities required to register and establishments that do not have to register may still be subject to the CGMP requirements, primarily in subpart B of 21 CFR part 117, as applicability of the CGMPs is not dependent upon whether a facility is required to register.

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*, including but not limited to qualified facilities, processors subject to Seafood HACCP or Juice HACCP, alcoholic beverage facilities, and dietary supplement manufacturing facilities. Thus, it is important to confirm applicability of subparts C and G at the start of the inspection.

Additionally, facilities solely engaged in the storage of unexposed packaged food are also exempt from the preventive controls requirements but may be subject to modified requirements if some or all of the food requires temperature control for safety. Requirements pertaining to facilities solely engaged in the storage of unexposed packaged food can be found in 21 CFR 117.7.

Information on ST rule exemptions may be found in Part I(2) of attachment A.

Compliance Program (CP) 7303.803 Domestic Food Safety has been discontinued and inspections previously covered by that program now fall under this compliance program. Operations that are under FDA jurisdiction but are not subject to 21 CFR part 117 or other FDA food safety regulations are covered by the FD&C Act. Examples include:

- Establishments solely engaged in the holding of non-produce RACs intended for further distribution or processing (21 CFR 117.5(j) and 21 CFR 117.5(k)(1)(iii))
- Off-farm facilities that only perform farm-related activities such as packing and holding on non-produce RACs (see *Policy Regarding Certain Entities Subject to the Current Good Manufacturing Practice and Preventive Controls, Produce Safety, and/or Foreign Supplier Verification Programs: Guidance for Industry*)

Inspection hours for the coverage of these operations must be reported under the 03040A PAC for FDA or 03S040A PAC for states.

3. **Compliance Dates and Enforcement Discretion**

All nonexempt facilities are required to be in compliance with the CGMP & PCHF rule at this time. However, there are enforcement discretion policies in place for certain entities performing certain activities, including, among others: facilities that would qualify as secondary activities farms except for ownership of the facility; facilities solely engaged in packing and/or holding of produce raw agricultural commodities (RAC); facilities that would qualify as farms if they did not color RACs; and facilities that would qualify as secondary activities farms except that they pack, package, label, and/or hold processed food that consists only of RACs that have been dried/dehydrated to create a distinct commodity. For these entities, we are exercising enforcement discretion from the preventive controls requirements for all activities performed on RACs, and from the CGMP requirements only for activities performed on non-produce 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.

FDA Divisions and States conducting inspections under FDA contract must prioritize the following types of facilities subject to subparts C and G for full scope PCHF inspections or focused PCHF inspections:

- A facility responsible for an outbreak.
- Facilities that have been responsible for a Class I recall that has not been addressed during an inspection.
- A facility for which a limited scope PCHF inspection reveals broad lack of implementation of appropriate controls for significant hazards.
- A facility whose previous inspection was classified "Official Action Indicated" (OAI).
- A facility implicated in an event that may impact public health: the FDA may obtain this information from FDA lab class 3 sample collections; 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.
- A facility known to manufacture high-risk foods as designated in Part II(2)(B) of this program.

In most cases when there are indications of serious adverse health consequences or death to humans or animals (SAHCODHA), the above situations will warrant accelerated follow-up by Divisions regardless of the designated priority tier or FSMA due date. If

the inspection is being conducted as an enforcement follow-up, then coordination with CFSAN Office of Compliance (OC) Division of Enforcement (DE) and the Division's compliance branch may be required to formulate an inspection strategy. In the case of active outbreaks, Divisions must coordinate with CFSAN Coordinated Outbreak Response & Evaluation Network (CORE) who will lead assignment issuance and coordinate follow-up activities. Divisions must weigh public health risk in their work planning and work prioritization. Timely follow-up must be performed regardless of whether there is an assignment issued to the Division. There may be cases in which CFSAN OC issues memos or assignments to Divisions to direct coverage at the above types of facilities when unique coverage is required, but per this compliance program, these responsive inspections should be performed as a normal part of Division operations.

Office of Regulatory Affairs (ORA) Office of Human and Animal Food Operations (OHAFO) Division of Foreign Human and Animal Food Operations (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 survival of a lethal treatment, pathogen cross-contamination (including environmental pathogens), pathogen growth and/or toxin formation, allergen cross-contact, and undeclared allergens 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 contamination with environmental pathogens is a significant hazard, because the 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 food is defined in 21 CFR 117.3 *Definitions.*
- RTE foods that do not undergo a process control to significantly minimize or prevent microorganisms of public health significance.
- Foods for which allergen cross-contact and/or undeclared allergens are a significant hazard.
- Any foods that require a process control (such as cooking, cooling, 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**. The term "high-risk food" used throughout this document does not necessarily refer to foods on the Food 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.

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).

(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.

Table 1 - Resources and Reporting

Reporting PAC	**03040** Food CGMP Inspections **03040A** Food, Drug, and Cosmetic Act Inspections **03040L** Limited Scope PCHF Inspections **03040F** Full Scope PCHF Inspections **03040Q** Modified Requirements Inspections at Qualified Facilities **03040R** Modified Requirements Inspections at Facilities Solely Engaged in the Storage of Unexposed Packaged Food that Require Time/Temperature Controls for Safety **03040T** Human Foods Sanitary Transportation Inspections **03040U** Focused PCHF Inspections **State Contract PAC Codes**

	03S040 State Contract Food CGMP Inspections **03S040A** State Contract Food, Drug, and Cosmetics Act Inspections **03S041** State Contract Limited Scope PCHF Inspections **03S042** State Contract Full Scope PCHF Inspections **03S043** State Contract Modified Requirements Inspections at Qualified Facilities **03S044** State Contract Modified Requirements Inspections at Facilities Solely Engaged in the Storage of Unexposed Packaged Food that Require Time/Temperature Controls for Safety **03S045** State Contract Focused PCHF Inspections
Planning PAC	**03040F** Full Scope PCHF Inspections **03040L** Limited Scope PCHF Inspections **03F813** Responsive Investigative/Laboratory Operations: Follow-up OAI inspections **03040T** Human Foods Sanitary Transportation Inspections
Inspection Op. Code **Investigation Op. Code**	11 (foreign), 12 (domestic) 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, and the Preventive Controls in Human Foods Resource Page.

ST program interaction information may be found in attachment A. Other programs that interact with this compliance program include the following (**note that the below links may become outdated with future compliance program updates and, in this situation, the compliance programs may be accessed by visiting the FDA Food Compliance Programs page**).

(1) Seafood Processor Inspection Program (CP 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 (subpart B) should generally be cited under 21 CFR part 123. Inspectional accomplishment hours for coverage of subparts A (training in food safety and food hygiene), B, and F (training records for food safety and food hygiene) must be reported under the 03040 PAC.

(2) Juice HACCP Inspection Program (CP 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 (subpart B) should generally be cited under 21 CFR 120. Inspectional accomplishment hours for coverage of subparts A (training in food safety and food hygiene), B, and F (training records for food safety and food hygiene) must be reported under the 03040 PAC.

(3) Domestic Acidified and Low-Acid Canned Foods Program (CP 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*, which is intended to control microorganisms of public health significance (*C. botulinum* and most other microbiological hazards). Hazards that are not controlled by thermal processing requirements in 21 CFR part 113 and that require a preventive control are covered by 21 CFR part 117 subparts C and G (e.g., *Staphylococcus aureus* growth and toxin formation, chemical hazards, and physical hazards). See Guidance for Industry: Low-Acid Foods Packaged in Hermetically Sealed Containers (LACF) Regulation and the FDA Food Safety Modernization Act for additional information on the interaction between the CGMP & PCHF Rule and LACF regulations.

Accomplishment hours should be reported under the 03803A PAC for requirements specific to 21 CFR part 108 *Emergency Permit Control* and 21 CFR part 113 for human 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.

(b) Acidified Foods

Acidified foods are subject to the CGMP & PCHF rule. An acidified food facility 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 *Acidified Foods*.

When an acidified food covered during an inspection is subject to subpart C of part 117, there are many cases in which observations pertaining to the control of biological hazards could be cited under 21 CFR part 117, 21 CFR part 108 *Emergency Permit Control*, or 21 CFR part 114. For example, not implementing a scheduled process would be cited under 21 CFR part 114, 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 written corrective action procedures when there is a process deviation might be cited under 21 CFR part 117 during the same inspection. For more information on regulatory requirements that overlap between parts 108, 114, and 117, see Chapter 16 of the Draft Guidance for Industry: Hazard Analysis and Risk-Based Preventive Controls for Human Food. Additional program interactions between acidified foods and the CGMP & PCHF rule, including information on which cites to use in certain circumstances, are detailed in the Conducting Acidified Food Inspections job aid which may be found on the Preventive Controls in Human Foods Resource Page

Accomplishment hours should be reported under the 03803A PAC for requirements specific to 21 CFR part 108 and 21 CFR part 114. 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.

(4) Dietary Supplements Program (CP 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. Inspection hours do not need to be reported under this program if 117 CGMP requirements are not covered during a dietary supplement inspection. 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) 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.

(5) Infant Formula Program (CP 7321.006)

Both exempt and non-exempt infant formulas are 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. Comprehensive coverage of 21 CFR part 117 may not be required during an inspection of non-exempt infant formula manufacturers as those inspections will focus on compliance with 21 CFR part 106 *Infant Formula Requirements Pertaining to Current Good Manufacturing Practice, Quality Control Procedures, Quality Factors, Records and Reports, and Notifications* and 21 CFR part 107

Infant Formula. Investigators only need to cover CGMP & PCHF requirements that do not have equivalent requirements in 21 CFR part 106 as follows:

- Requirements in 21 CFR 117.4(b)(2) and 117.4(d) pertaining to training in food hygiene and food safety and documentation of that training
- Requirements in 21 CFR 117.10 pertaining to unsecured jewelry; storage of personnel belongings, eating food, chewing gum, drinking beverages, or using tobacco; hand sanitizing; and protection against contamination with perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin
- Requirements in 21 CFR 117.20(a) pertaining to harborage, roads, yards, parking lots, drainage areas and waste treatment
- Requirements in 21 CFR 117.35(c) pertaining to pest control
- Requirements in 21 CFR 117.95 pertaining to human food by-products for use as animal food
- Requirements in 21 CFR 117.130 pertaining to conducting a written hazard analysis
- Requirements in 21 CFR part 117 subpart G: Supply-Chain program
- Requirements in 21 CFR part 117 subpart F recordkeeping requirements pertaining to written hazard analysis and supply-chain program.

Manufacturers of exempt infant formula are not subject to the processing requirements in 21 CFR part 106 and therefore cannot be cited under part 106 except if the manufacturer failed to provide notice of adulteration or misbranding as required under 21 CFR 106.150. Observations at facilities that only manufacture exempt infant formulas must be cited under 21 CFR part 117.

In addition to the CGMP and PCHF rule, manufacturers supplying nutrient premixes to infant formula manufacturers are subject to 21 CFR 106.100(d) which requires the premix supplier to maintain the results of all testing conducted to provide all certificates and guarantees concerning nutrient premixes for infant formulas. It also requires that records shall include but are not limited to:

- the results of tests conducted to determine the purity of each nutrient required by section 412(i) of the FD&C Act or 21 CFR 107.100 and any other nutrient listed in the certificate and guarantee,
- the weight of each nutrient added,
- the results of any quantitative tests conducted to determine the amount of each nutrient certified or guaranteed, and
- the results of any quantitative tests conducted to identify the nutrient levels present when nutrient premixes exceed their expiration date or shelf life (retest date).

Thus, inspections of a nutrient premix manufacturer under this compliance program (CP 7303.040) must cover all applicable requirements of 21 CFR part 117 as well as 21 CFR part 106.100(d); time spent on that coverage must be reported under the 21006P PAC (INFANT FORMULA PRE-MIX INSPECTIONS).

(6) Medical Foods Program (CP 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.

(7) Interstate Travel Program-Conveyances and Support Facilities (CP 7318.029)

Field inspection staff conducting inspections of food operations on Interstate Travel Program (ITP) conveyances must be trained in use of the FDA Food Code. In addition, those conducting inspections of ITP caterers and commissaries must have training and experience in conducting inspections in accordance with the CGMP & PCHF rule (21 CFR part 117).

The primary regulations pertaining to ITP conveyances, watering points, and servicing areas are found in 21 CFR part 1240 *Control of Communicable Diseases* and 21 CFR part 1250 *Interstate Conveyance Sanitation*.

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 food safety are exempt from subparts C and G; however, if such a commissary also is holding unexposed packaged food that requires temperature control for food safety, the applicable modified requirements in subpart D generally would apply.

If an operation is not required to register with FDA as a food facility, it would not be subject to the preventive control requirements of 21 CFR part 117. For example, ITP caterers and commissaries that operate as retail food establishments as defined in 21 CFR 1.227 are not required to register with FDA. Food service operations on ITP conveyances (establishment type "F" – i.e. airplanes, buses, trains, and vessels) are not required to register as a food facility and are regulated under 21 CFR parts 1240 and 1250. 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, are not required to register and are regulated under 21 CFR parts 1240 and 1250. However, watering points or servicing areas that also provide ice, coffee, or packaged shelf-stable foods to conveyances, typically to airplanes, are considered commissaries and would be required to register as a food facility. Commissaries are subject to relevant subparts of 21 CFR part 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 ITP PAC from CP7318.029 as follows: 18029A (aircraft), 18029B (buses),

18029C (railroad), and 18029D (vessels) in addition to hours spent covering the CGMP & PCHF rule under the appropriate PAC(s) in Part II(2)(C)(3) of this program.

Meat and poultry products manufactured by caterers for conveyances such as airlines and shipped in interstate commerce can fall under FDA authority and be inspected. They are usually not inspected by United States Department of Agriculture (USDA) Food Safety and Inspection Service (FSIS).

(8) NLEA, Nutrient Sample Analysis, and General Food Labeling Requirements Program (CP 7321.005)

Coverage of the Nutrition Labeling and Education Act (NLEA), Food Allergen Labeling and Consumer Protection Act (FALCPA), and FASTER Act are 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 (CP 7303.040) and associated accomplishment hours should be reported under the appropriate PAC in Part II(2)(C)(3). All label review accomplishment hours should be reported under the 21005 PAC.

(9) Milk Safety Program (CP 7318.003)

Divisions should consult with their Milk Specialist to determine if a dairy plant is on the Interstate Milk Shippers (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 section 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 section 3.2.1.5 *Agricultural Marketing Service (AMS)/ USDA (MOUs)* MOU #8 for additional information.

ORA Division of Milk Safety (DMS) has inspectional responsibility for coverage of all products (exceptions for infant formula and seafood HACCP) in dual Grade A / non-Grade A dairy products plants. DMS will coordinate coverage with OHAFO Divisions for the previously identified exceptions.

(10) Pesticides and Industrial Chemicals in Food Program (CP 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 (CP 7303.040). Misuse 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 CP 7304.004.

(11) Domestic and Import Food Additives and Color Additives (CP 7309.006)

The domestic and import food additives and color additives compliance program primarily covers food and color additives sampling 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 (CP 7303.040). Inspectional operations should not be reported under the PACs in CP 7309.006 as they are solely associated with sampling activities.

(12) Mycotoxins in Food – Domestic and Import (CP 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 CP 7303.001 reveals any mycotoxin amount greater than the action, guidance, or advisory level, an inspection under this program (CP 7303.040) may be required. Sample collections covered under CP 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 (CP 7303.040).

(13) Comprehensive Animal Food Inspection (CP 7371.000)

Field inspection staff should ask if a facility has any product going to animal food during each inspection. If so, consider the below factors when determining what type of inspection should be performed based on the facility's activities with respect to their human food by-products for use as animal food:

- If the facility is not further manufacturing/processing human food by-product for use as animal food, the facility would be inspected under 21 CFR 117.95, holding and distribution CGMPs and time spent covering those requirements should be reported under PAC 71R909. Field inspection staff should ask if a facility performs this activity during each inspection and cover the requirements of 21 CFR 117.95

whenever this activity is performed by a facility. This coverage is additive to the food(s) covered during the inspection.

- If the facility is performing manufacturing/processing activities on their animal food then see CP 7371.000 for additional instruction.

Note: PAC 71R909 and the limited holding and distribution CGMP requirements in 21 CFR 117.95 only apply to by-products of human food that is produced in compliance with FDA requirements. This PAC code and these provisions do not apply to human food that potentially has a human food safety issue, or by-products from such human foods.

(14) Sampling for Foodborne Microbiological Hazards, and Filth – Domestic and Import (DIMS) (CP 7303.050)

CP 7303.050 covers most microbiological and filth sampling that would be performed during an inspection covered under this compliance program (CP 7303.040), including environmental sampling. Additionally, the DIMS program covers microbiological and filth sampling that was previously covered in discontinued compliance programs, including CP 7303.803 *Domestic Food Safety* and CP 7303.037 *Cheese and Cheese Products*. When collecting samples for microbiological or filth analysis during inspections covered under this compliance program (CP 7303.040), please refer to the DIMS program for further instructions.

Please see SOP-001052 and IOM section 4.3.6.6 for additional environmental sampling inspection-related information. The **environmental sampling PAC (03050N) must be reported on all OP 12 inspections when environmental sampling is performed**.

(15) Foreign Supplier Verification Programs Inspections (CP 7303.878)

The Import Food Operations compliance program covers administrative, inspection, and enforcement activities relating to human and animal food imported into the United States. A domestic manufacturer/processor subject to subparts C and G of the CGMP & PCHF rule and also imports food may be subject to the Foreign Supplier Verification Programs for Food Importers rule (21 CFR part 1, subpart L) if they meet the definition of importer in 21 CFR 1.500. In general, inspections of manufacturer/processors that are also the FSVP importer should be performed under this compliance program (CP 7303.040) rather than CP 7303.878.

(16) Toxic Elements in Food and Foodware, and Radionuclides in Food – Domestic and Import (CP 7304.019)

CP 7304.019 covers sampling, analysis, and enforcement instructions for toxic elements in food and foodware and radionuclides in food. This compliance program (CP 7303.040) covers, in part, inspections of manufacturers of foods that may require preventive controls for toxic elements and/or radiological hazards (e.g., foods intended for babies and young children). When prioritizing work to be conducted under this compliance program, CFSAN and OHAFO Divisions must consider the risk of the food and any previous toxic elements sample results. In particular, manufacturers of foods intended for babies and young children with lab class 3 toxic elements analysis results should be considered a high priority for a full

scope PCHF inspection. Conversely, an inspection performed under this compliance program may yield observations that trigger the collection of samples for toxic elements analysis under CP 7304.019. These samples would be reported under the respective PAC from CP 7304.019 while inspections would be reported under the appropriate PAC from this compliance program (CP 7303.040).

(17) Produce Safety Inspections (CP 7303.080)

The purpose of the Produce Safety Inspections CP is to provide overall instruction for conducting inspections on farms subject to 21 CFR part 112 Standards for Growing, Harvesting, Packing, and Holding of Produce for Human Consumption. The Produce Safety Inspections CP includes instructions for OHAFO Divisions to coordinate, as appropriate, with ORA Produce Safety Network, and other stakeholders prior to conducting inspections at farm mixed-type facilities. See Part II.2.F.(2) of this program (CP 7303.040) for additional information on coordinating inspections at farm mixed-type facilities.

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(a) 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 in accordance with IOM subchapter 5.4.1.5.2 *Food Facility Registration Resources*.

A food defense component, conducted in accordance with IOM section 5.4.1.4 *Food and Cosmetic Defense Inspectional Activities*, should be included in all inspections conducted under this program.

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

(1) Federal Agencies

Follow IOM section 3.1.3.2 *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 inspections is important for inspections at farm mixed-type facilities. Coordination would need to extend to multiple states, with the assistance of the State Liaison (SL) and ORA 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 program. The definition of a farm mixed-type facility can be found under "Mixed-type facility" in 21 CFR 117.3 Definitions. A farm mixed-type facility would generally be subject to 21 CFR part 117.

(3) Foreign Authorities

Follow ORA/DFHAFO procedures and IOM section 5.7.3.7.2 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 performing work under contract to request information assistance before and during inspections under 21 CFR part 117. It is not intended to replace the current enforcement communication mechanism between field inspection staff, supervisors, and compliance officers or States.

The rTAN is an information assistance system designed to connect field inspection staff with Subject Matter Experts (SMEs) to get answers and clarification on CGMP & PCHF rule interpretation and commodity-specific questions as needed. Field inspection staff should submit inquiries through the rTAN e-mail inbox at 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 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 common email to everyone to minimize duplication of effort and to ensure consistency of

guidance. A list of commodity-specific SMEs, ORA National Expert SMEs, and lead program contacts can be found on the Preventive Controls in Human Foods Resource Page.

PART III – INSPECTIONAL

1. Operations

Inspections conducted under this compliance program 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 corrective actions 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. Division staff are encouraged to view the eNSpect Corrective Action Report Demonstration and the Compliance Management System Corrective Action Report Demonstration.**

Information on how to respond to the FDA 483 should be provided to the facility's management. **For foreign inspections, FDA 483 responses should be sent to FDA483responseinternational@fda.hhs.gov.** Field inspection staff must inform the facility that their FDA 483 response may impact FDA's determination of the need for follow-up action(s). FDA expects to receive a facility's FDA 483 response 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?* must be provided to the facility's management.

A. Inspections

Training pre-requisites for each type of inspection performed under this compliance program are identified in the CP 7303.040 Inspection Training Prerequisites document on the Preventive Controls in Human Foods Resource Page.

(1) Food CGMP Inspections

Food CGMP inspections should be performed at facilities subject to 21 CFR part 117, subparts A, B, and F. These inspections will include coverage of the CGMP requirements in 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 or juice 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 (FDA) or the 03S040 PAC (state).

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

Inspections should cover the training requirements related to food safety and food hygiene found in subpart A and the applicable requirements in subpart F pertaining to

records of such training. 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 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 non-compliances observed, training records on food hygiene/food safety for responsible employees should be reviewed. If no training records exist, advise the firm of the 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 non-compliances that need to be addressed.

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

CGMPs identified in 21 CFR part 117, subpart B generally address matters including appropriate personal hygienic practices, design and construction of a food plant and maintenance of plant grounds, plant equipment, sanitary operations, facility sanitation, and production and process controls during the production of food. Subpart B also includes requirements pertaining to human food by-products for use as animal food.

(2) Limited Scope PCHF Inspections

Limited scope PCHF inspections may be performed at facilities subject to 21 CFR part 117, subparts A, B, C, F and G. These inspections will focus on preventive controls implementation requirements in subpart C, in addition to subparts A, B, and F. Accomplishment hours for limited scope PCHF inspections must be reported under the 03040L PAC (FDA) or the 03S041 PAC (state) and 03040/03S040 for CGMP coverage.

Field inspection staff should not review written food safety plans (including the facility's hazard analysis, preventive control programs, supply-chain programs, or recall plan), or review implementation records. However, they do need to ask whether the facility has a written food safety plan, including hazard analysis. Staff will conduct a limited hazard analysis to determine if process, allergen, and sanitation preventive controls are necessary based on information gathered during the walkthrough and then broadly assess whether the facility is implementing the necessary controls through a combination of observation and interviewing of employees. Implementation of supply-chain programs is not covered during a limited scope PCHF inspection.

(a) Broad Assessment of Process Control Implementation

Field inspection staff should assess and observe 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 their supervisor.

(b) Broad Assessment of Food Allergen Control Implementation

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 during ingredient and finished product storage, manufacturing/processing (including production sequencing, ingredient addition steps, and employee practices during production), and cleaning of food-contact surfaces of shared equipment during changeover between products with different allergen profiles; and
- assess and observe the facility's controls for ensuring finished products are properly labeled with respect to allergens.

(c) Broad Assessment of Sanitation Control Implementation

If the facility is processing RTE food that is exposed to environmental conditions where contamination with environmental pathogens could occur, and there is no post-packaging processing to address pathogens, and the food can support the persistence and/or growth of pathogens, field inspection staff should:

- assess and observe the facility's sanitation controls including cleaning and sanitizing food-contact surfaces of equipment as well as observe employee hygiene practices; and
- assess and observe the facility's environmental monitoring program as appropriate.

Field inspection staff will not document written observations under subparts C or G during a Limited Scope PCHF inspection. **If a limited scope PCHF inspection reveals issues with implementation of process, allergen, or sanitation preventive controls that do not impact the safety of the food, field inspection staff should use cite 21 CFR 117.135(a)(1) as a discussion item.** If the issues with implementation of preventive controls pose a significant public health risk, field inspection staff should notify Division management to determine whether conversion to a full scope or focused PCHF inspection is warranted. Additional considerations for converting to a full scope inspection include the facility's prior inspection and compliance history as well as the facility's willingness to correct.

Do not conduct a limited scope PCHF inspection when FDA environmental sampling is being conducted during the inspection. Environmental sampling inspections covering facilities subject to subpart C must be either full scope PCHF or focused PCHF inspections.

FDA will not generally pursue advisory, administrative, or judicial actions for observations associated with subparts C or G based only on evidence from a limited scope inspection. The Division must convert the inspection to a full scope PCHF or focused PCHF inspection before recommending such an enforcement action in these cases.

(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, in addition to subparts A, B, and F. Accomplishment hours for full scope PCHF inspections must be reported under the 03040F PAC (FDA) or the 03S042 PAC (state) and 03040/03S040 for CGMP coverage.

(4) Modified Requirements Inspections at Qualified Facilities

Modified Requirements Inspections at Qualified Facilities will be performed at all facilities that meet the definition of a qualified facility in 21 CFR 117.3 *Definitions* – i.e. a very small business. These inspections include coverage of the modified requirements in 21 CFR 117.201 (subpart D) in addition to subparts A, B, and F; however, the inspection should focus on assessing food safety against the CGMP requirements. Field inspection staff will need to check the facility's status in FDA Unified Registration and Listing System (FURLS) or Online Search and Retrieval System (OSAR) FIRM 360 to determine if the facility has attested to being a qualified facility and the provision under which it has attested (i.e., 21 CFR 117.201(a)(2)(i) or 21 CFR 117.201(a)(2)(ii)). Refer to the Instructions for Conducting PCHF Inspections of Qualified Facilities on the Preventive Controls in Human Foods Resource Page for detailed instructions on performing this type of inspection. **A firm that meets the definition of a quality facility is exempt from subparts C and G (see 21 CFR 117.5(a)) regardless of whether it has submitted an attestation.**

Commissioned state partners performing inspections under contract should check the Qualified Facility Attestation Module to determine whether the facility has attested to being a qualified facility prior to each inspection. Users should visit 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 (FDA) or the 03S043 PAC (state) and 03040/03S040 for CGMP coverage.

(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 time/temperature controls to control pathogen growth and/or toxin formation. These inspections will cover the modified requirements in 21 CFR 117.206 (subpart D) in addition to subparts A, B, and F. Accomplishment hours for modified requirements inspections at these facilities must be reported under the 03040R PAC (FDA) or the 03S044 PAC (state) and 03040/03S040 for CGMP coverage.

(6) Focused PCHF Inspections

Focused PCHF inspections allow Divisions to utilize fewer resources during for-cause, compliance follow-up, certain converted limited scope PCHF inspections, or as directed by assignments, by covering only certain requirements in subparts C and G. Focused PCHF inspections may only be performed when:

- a for-cause or a compliance follow-up inspection is being performed that may not require comprehensive subpart C and G coverage, or
- a limited scope PCHF inspection reveals the need to cover only certain requirements of subpart C, or
- comprehensive coverage of 21 CFR 117 subparts C and G is not required because certain requirements are covered under other regulations such as infant formula.

Focused PCHF inspections may include coverage of one or more types of preventive controls including process controls, allergen controls, sanitation controls, supply-chain controls, or other controls as determined by the Division. The purpose and scope of the focused PCHF inspection must be stated clearly in the EIR summary and endorsement text.

Divisions may make the decision to perform a full scope PCHF inspection or a focused PCHF inspection for each for-cause, compliance follow-up, or converted limited scope inspection meeting the above criteria depending on available resources. Accomplishments should be reported under the 03040U PAC for FDA inspections or the 03S045 PAC for state contract inspections, and 03040/03S040 for CGMP coverage.

B. Investigations

Domestic or foreign investigations (OP 13 or OP 15, respectively) may be performed at facilities covered by this program. See IOM subchapter 8.1.9 *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 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 administrative data, full scope PCHF inspections, limited scope PCHF inspections, and ST inspections. Investigational memorandums must be prepared per IOM subchapter 8.1.9 *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 Preventive Controls in Human Foods Resource Page.

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 Compliance Management System (CMS). Voluntary corrective actions 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.

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 the regulatory strategy is to obtain high rates of industry compliance with the CGMP & PCHF rule, and to gain prompt voluntary correction of inspectional findings; however, appropriate swift enforcement action will be taken when significant problems present a threat to public health. If a Division determines that there is a direct or imminent 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 DE to discuss regulatory strategy. Divisions should also consider their state partners' ability and willingness to request industry's prompt voluntary correction of inspectional findings or to pursue state enforcement action.

Information covering the regulatory/administrative strategy for the ST rule is found in attachment A.

Refer to the 21 CFR part 117 citations table which provides a starting point for determining regulatory significance based on public health. **Additionally, investigators should refer to and follow the Structure of Observations (SOFO) for Written Observations job aid when documenting written observations under subparts C and G to ensure that all relevant supporting evidence is included. These documents may be found on the** Preventive Controls in Human Foods Resource Page .

Individual observations are designated as either major (significant) or minor (not significant) in eNSpect. In addition, under this compliance program, overall inspections are categorized as critical, major, or minor; investigators do not make this categorization. Please see the following paragraphs and Table 2 below for correlations among observation designation (major, minor), inspection categorization (critical, major, minor) and inspection classification (OAI, VAI, NAI).

A. Critical

An inspection that is categorized as critical contemplates the most serious non-compliances with the CGMP & PCHF rule. Specifically, the facility has a breakdown of control(s) that results in a reasonable probability of **causing serious adverse health consequences or death to humans or animals (SAHCODHA)**. We expect the categorization of inspections as critical to be limited to situations that are likely to pose an imminent public health threat.

Divisions should urge the facility to cease production and shipping operations, promptly address conditions in the plant, determine the root cause, determine whether affected food should be recalled, and determine how to dispose of affected food held within the facility.

B. Major

An inspection that is categorized as major contemplates non-compliances with the CGMP & PCHF rule that lead to significant public health concern. Specifically, one or more non-compliances result in conditions that **present a food safety risk** and **may lead to a**

breakdown of control(s). A major inspection includes significant observations (designated as major in eNSpect) that are included on an FDA 483.

During the inspection, Divisions should encourage facilities to comprehensively address significant observations.

C. Minor

An inspection that is categorized as minor contemplates non-compliances with the CGMP & PCHF rule that are not of significant public health concern. Specifically, non-compliances result in conditions that, if not addressed, **may present a food safety risk but are not likely to lead to a breakdown of control(s)**. In general, a minor inspection includes not-significant observations (designated as minor in eNSpect) that are not included on an FDA 483. However, a repeat non-compliance may be upgraded to a written Observation as appropriate.

Not-significant observations are typically discussion items. Divisions should encourage facilities to address not-significant observations during the inspection before closeout. As applicable, corrective actions should be verified and documented prior to closing the inspection.

Table 2 provides examples of potential enforcement actions and other activities associated with inspection categorization/classification outcomes. The table is meant to be a starting point for discussion and not an all-inclusive list. It should not be the sole basis for evaluating next steps. The totality of findings should be assessed with a focus on public health significance.

Table 2 – Enforcement and Follow-up Activity Examples

Inspection Categorization	Examples of Non-compliances	Inspection Classification	Issue 483?	Enforcement Actions and Other Activities
Critical	• No written food safety plan (FSP), OR inadequate FSP, OR FSP not implemented; AND observed lack of control(s) that impacts food safety; AND food poses a SAHCODHA risk or is associated with illness/RFR/recall • Egregious CGMP conditions that impact food safety when facility is not subject to PCHF (e.g., under-processing at qualified facility): AND poses a SAHCODHA risk	**Official Action Indicated (OAI)**	Yes	Urge immediate voluntary shutdown and voluntary recall plan, if warranted. Urge submission of corrective action plan. Consider (as appropriate): registration suspension, mandatory recall, administrative detention, injunction (preliminary/ permanent), seizure, prosecution, import alert, modifying PREDICT score, following up with FSVP and Voluntary Qualified Importer Program (VQIP) importers, contacting foreign government authorities to recommend follow-up
Major	• No written FSP, OR inadequate FSP, OR FSP not implemented; AND observed lack of control(s) that could impact food safety • Egregious CGMP conditions (e.g., pest infestation) • Uncorrected, repeat non-compliances that may lead to food safety risk	**OAI**	Yes	Urge submission of corrective action plan. Consider (as appropriate): administrative detention, injunction (permanent), seizure, warning letter, regulatory meeting, import alert, modifying PREDICT score, following up with FSVP and VQIP importers

Inspection Categorization	Examples of Non-compliances	Inspection Classification	Issue 483?	Enforcement Actions and Other Activities
Major		**Voluntary Action Indicated (VAI)** (e.g., if public health risk is not as great)	Yes	Urge submission of corrective action plan. Consider regulatory meeting as appropriate.
Minor	• Inadequate records related to training requirements • FSP not prepared or overseen by a PCQI but controls appear adequate • Recall plan missing required elements • Inadequate CGMP conditions related to quality or filth (not food safety)	**No Action Indicated (NAI)** Generally, minor non-compliances are not significant to public health	No	Urge corrective actions during the inspection. Verify and document them as applicable.
Minor		**VAI** when considering other factors (e.g., if repeat condition or pattern (recidivism))	Yes	Urge submission of corrective action plan

D. Factors to Consider

The following factors should be considered when evaluating significance of non-compliances and considering enforcement action:

- **Is the food ready-to-eat?** Ready-to-eat food is defined in 21 CFR 117.3 *Definitions*. Observations of insanitary conditions in operations where RTE food that can support the survival or growth of pathogens 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 not-significant observations; however, this is less likely for

significant observations as those generally require more time and resources to adequately address.

- **Is the observation indicative of an isolated problem or system failure?** An isolated issue may be not-significant (e.g., a cooler holding temperature-sensitive product is not monitored one day during the last month, but the temperature appears appropriate the rest of the month); but a repeat problem or pattern of deviations may be considered significant (e.g., the cooler is never monitored, or it experiences frequent deviations).
- **Are controls in place?** Observations of missing records or inadequacies with component(s) of the written FSP at a facility that is implementing adequate controls for significant hazards in practice may not be significant. However, if underlying controls are not in place, observations of missing records or inadequate components of the written FSP may be significant and indicative of larger underlying problems.
- **Is the facility or food associated with a recent outbreak, recall, or RFR submission?** If so, observations associated with the likely root cause of the incident may result in a critical inspection categorization, especially if adequate corrective actions have not been made.
- **Is the finding a first-time observation or repeat over multiple inspections?** Repeat observations that are not significant initially may become significant if they are indicative of a general lack of control or an inability to make lasting corrections.

2. Charges

Charges that may be applicable to this program include (but are not limited to):

- An article of food is adulterated under:
  - Section 402(a)(4) of the FD&C Act [21 U.S.C. § 342(a)(4)] in that 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.
  - Section 402(a)(3) of the FD&C Act [21 U.S.C. § 342(a)(3)] in that it consists in whole or in part of any filthy, putrid, or decomposed substance, or is otherwise unfit for food.
- The article of food is misbranded under section 403(w) of the FD&C Act [21 U.S.C. 343(w)] when the food is formulated to contain a major food allergen(s) as an ingredient(s) and fails to declare on the label the major food allergen(s).
- The failure of the owner, operator, or agent in charge of a covered facility to comply with the preventive controls provisions in subparts C, D, E, F, or G of the CGMP & PCHF rule is a prohibited act under section 301(uu) of the FD&C Act (21 U.S.C. 331(uu)).

3. Actions

A. Voluntary Pre-Closeout PCHF Consult Process

When the Division is considering recommending a compliance action necessitating CFSAN concurrence (such as a warning letter, administrative action, or judicial action), the Division Compliance Officer may voluntarily reach out to CFSAN OC DE to request a pre-closeout consult to discuss in-progress inspection findings and their significance. Inspections that may lead to a regulatory meeting are not necessarily within the scope of this process, although

CFSAN OC DE stands ready to assist at the Division's discretion.

The purpose of such a consult meeting is to maximize the chances for downstream support of a potential Division compliance recommendation. The primary vehicle for OHAFO-CFSAN engagement is a verbal consult meeting, which focuses on evidence development per the Structure of Observations (SOFO) Job Aid. Investigator participation in the meeting is highly encouraged to facilitate communication.

A job aid is posted on OHAFO QMS Released Documents. The specific document for the Division Compliance Officer to utilize is JA-000543 – CFSAN & OHAFO Job Aid: Voluntary Pre-Closeout PCHF Consults.

B. Compliance Activities

As of the issuance of this compliance program, CFSAN had not given Direct Reference Authority for any compliance actions related to violations of 21 CFR part 117. At this time, all advisory actions related to violations of 21 CFR part 117 require CFSAN review and concurrence.

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, as appropriate, before moving forward. Divisions should take into consideration the state partner's ability and willingness to request industry's prompt voluntary correction of non-compliances or pursue state enforcement action. Refer to part (V)(1) and Table 2 of this compliance program while evaluating appropriate actions based on findings.

Depending on the circumstances, the Division can consider holding a regulatory meeting to inform responsible individuals from the facility how products, practices/processes, or other activities are considered to be in violation of the law. Regulatory meetings can be an effective enforcement tool to obtain prompt voluntary compliance.

After an inspection, the Division can consider recommending a warning letter. Warning letters are advisory actions intended to achieve voluntary compliance and to establish prior notice. Warning letters are issued only for violations of regulatory significance.

As appropriate for findings, as necessary to protect public health, and/or if facility actions/responses do not appear to adequately correct non-compliances – all available administrative and legal tools should be considered (such as mandatory recall, administrative detention, food facility registration suspension, import alert, seizure, injunction, and/or prosecution). If the Division feels that an administrative or legal action is warranted, management should initiate a preliminary assessment call with CFSAN OC DE. Refer to the Regulatory Procedures Manual (RPM) for more information.

- **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. Refer to RPM Chapter 7 *Recall Procedures* for more information. If a determination is made that there is reasonable probability that an article of food is adulterated under section 402 or misbranded under section 403(w) 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 provided the firm with the opportunity to recall, mandatory recall under section 423 of the FD&C Act 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(h) 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).

- **Suspension of Food Facility Registration**
  If a facility registered under section 415(a) of the FD&C Act manufactures, processes, packs, 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, then 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.

- **Seizure**
  Section 304 of the FD&C Act authorizes civil product seizure following a violation (i.e., adulteration or misbranding), while food is in interstate commerce or after its movement in interstate commerce.

- **Injunction**
  Section 302 of the FD&C Act authorizes civil injunction for committing a prohibited act.

- **Prosecution**
  Section 303 of the FD&C Act authorizes criminal prosecution for committing a prohibited act. Suspected criminal violations must be discussed with the Office of Criminal Investigations.

Refer to the RPM for more information, including the following chapters:

- Chapter 4 *Advisory Actions*
- Chapter 5 *Administrative Actions*
- Chapter 6 *Judicial Actions*
- Chapter 7 *Recall Procedures*
- Chapter 10 *Other Procedures*

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 additional information.

The Division should submit any recommendation for enforcement action via 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 likely be scheduled between the Division and CFSAN OC DE.

Meat and poultry products manufactured by caterers for conveyances such as airlines are usually not inspected by USDA FSIS. FDA may regulate the caterers' production of meat and poultry products for conveyances shipped in interstate commerce. Before initiating any regulatory action involving meat or poultry production at caterers for conveyances, 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/PCHF non-compliances and/or that had significant environmental pathogen contamination according to FMD-86 and RPM Chapter 4. **If there is 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 DE 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 result in the adulteration or allergen-misbranding of foods, the Division should consider more severe enforcement action based on these repeat offenses. Divisions should initiate a call with CFSAN OC DE within 24 hours of determining that an inspection revealed significant repeat observations.

If an inspection is initially classified OAI but reclassified VAI, the Division should re-inspect within 1 year for domestic facilities. Facilities with an inspection classification of NAI or

VAI should be re-inspected at the frequency designated in 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 on the Preventive Controls in Human Foods Resource Page.

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

Purpose	Name	Organization	Contact
General Program Guidance	Mark Farrell	CFSAN/OC/DFPG/PAMB	240-402-2483
Enforcement Guidance	Matthew Noonan	CFSAN/OC/DE	215-605-0860
Technical Information	rTAN	CFSAN	See Part II(2)(G)

B. ORA

Purpose	Name	Organization	Contact
Domestic Inspection Guidance	Larry Stringer	ORA/OHAFO/DDHAFO	312-596-6523
Foreign Inspection Guidance	Leslie A. (Cartmill) Jackanicz	ORA/OHAFO/DFHAFO	813-915-7991
Technical Information	rTAN	ORA/OHAFO	See Part II(2)(G)

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, 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.

SUBJECT:	ATTACHMENT A: HUMAN FOOD SANITARY TRANSPORTATION INSPECTIONS
PRODUCT CODES	USE APPROPRIATE PRODUCT CODES
PRODUCT/ASSIGNMENT CODE (PAC)	**03040T** (HUMAN FOODS SANITARY TRANSPORTATION INSPECTIONS)

PART I – BACKGROUND

See Part I of CP 7303.040 *Preventive Controls and Sanitary Human Food Operations* for additional sanitary transportation background information.

1. **Summary of Requirements**

21 CFR Part 1 subpart O *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 feed, 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 transportation 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).
- Specifications developed and implemented by the carrier (if applicable) regarding sanitation and temperature controls of the vehicles and provisions for bulk vehicles in accordance with § 1.908(e)(6)(iii).
- 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**

The ST rule does not apply to the following:

- Shippers, loaders, receivers, or carriers engaged in food transportation operations that have less than $500,000, as adjusted for inflation, 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 FD&C 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 CP 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 ST 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/firm was OAI and there were significant observations related to the receipt or transport of foods subject to 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., RASFF or information shared by a foreign competent authority under a cooperative arrangement); from the RFR; from information collected during inspections of other facilities, or from consumer complaints.

A firm may be acting in multiple capacities under the ST 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 ST 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 not subject (see Part I(2) of this attachment) to 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 CP 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.

Training prerequisites for each type of inspection performed under this compliance program are identified in the CP 7303.040 Inspection Training Prerequisites document on the Preventive Controls in Human Foods Resource Page.

(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:

Table 3: Resources and Reporting

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

C. Program Interactions

All human food transportation operations that are subject to the ST rule must comply with the applicable requirements in the rule, in addition to requirements in applicable interacting programs. 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 § 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 conduct ST inspections under a contract with 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 § 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 the 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. 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.

If a facility includes preventive controls at the distribution step in their food safety plan, assess adequacy and implementation under the GP/PC rule. Otherwise assess under the ST regulation.

B. Investigations

See Part III(1)(B) of CP 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 8.1.9.

PART IV – ANALYTICAL

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PART V - REGULATORY/ADMINISTRATIVE STRATEGY

1. **Findings**

Public health significance of observations and appropriate follow-up activities is determined on a case-by-case basis. In general, sanitary transportation observations are designated as major or minor. 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;
- Lack of written procedures required by § 1.908(b)(3), (4), and (5), or clearly incomplete procedures for ensuring 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 [21 U.S.C. 350e].
- 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 section 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 section 301 (e) of the FD&C Act [21 U.S.C. 331(e)]. Also see section 703(b) [21 U.S.C. 373(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 non-compliances warrant compliance action, they will be considered on a case-by-case basis with input from CFSAN and ORA. If there are significant non-compliances with other regulatory 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 is 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 DE, ORA OHAFO program contacts, and state partners as applicable 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 DE 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 CP 7303.040.

PART VII - CENTER RESPONSIBILITIES

See Part VII of CP 7303.040 for more information.