ASTA Food Safety Modernization Act (FSMA) Decision Tree©

THE AMERICAN SPICE TRADE ASSOCIATION

1101 17th Street NW, Suite 700
Washington, DC 20036

October 2016

Table of Contents

Introduction and Scope

The Food Safety Modernization Act (FSMA) of 2011 focuses on preventing food safety issues, rather than controlling outbreaks or other hazards after they occur. As part of this preventive approach, FSMA places primary responsibility on the owners and operators of food facilities and farms to identify and control hazards. To this end, beginning in September 2015, the Food and Drug Administration (FDA) released seven foundational final rules that are intended to create a modern, risk-based framework for food safety.

This decision tree is designed to assist ASTA members in evaluating their obligations under the five foundational FSMA rules that could likely apply to ASTA member operations: the final rule for preventive controls in human food, the produce safety final rule, the sanitary food transportation final rule, the foreign supplier verification program final rule, and the final rule on intentional adulteration. Specifically, this decision tree guides the reader through a series of questions about their operations to help determine which FSMA rules could apply. The decision tree also provides an overview of what each rule requires, depending on the nature of the ASTA member's operations.

As a tool developed for ASTA, a trade association representing members of the spice industry, intended for use by ASTA members, this manual covers activities that are typical of all of the segments of that industry, including growing crops, drying crops and processing them into spices, importing raw materials and finished spice products, and transporting spices both outside of and within the United States. This decision tree is not designed to address activities that are not related to the spice industry (e.g., raising animals on a farm that also grows crops that will be used in spice products). When used in this document, the term "crops" refers to raw agricultural commodities that may be processed into spices identified on the **ASTA Spice List**.

Further, this decision tree provides a number of resources ASTA members may wish to consult in developing their food safety systems to comply with FSMA requirements. Within the body of the decision tree are links to FDA guidance documents that provide additional information about a specific FSMA topic. The Appendix of this decision tree contains a glossary of key FSMA terms. In addition, FDA plans to issue guidance on a number of topics, including guidance that details the core criteria, learning objectives, and elements recommended for FSMA training programs. ASTA members should keep apprised of this and other FDA developments.

License to Use the ASTA FSMA Decision Tree©

Disclaimer

The American Spice Trade Association (ASTA) developed the first edition of the ASTA Food Safety and Modernization Act (FSMA) Decision Tree©, dated October 2016, to assist its members in complying with the FSMA. The ASTA FSMA Decision Tree© does not constitute legal advice and reflects FSMA requirements and related guidance issued by the Food and Drug Administration only prior to October 2016. ASTA is not responsible for the use or nonuse of any information presented in the Decision Tree. It is the responsibility of ASTA members and other parties that may use the Decision Tree to verify information presented in the Decision Tree before acting on it. ASTA urges users of the Decision Tree to consult with appropriate experts before acting on any of the information in it. Companies who face legal issues about compliance with FSMA requirements are urged to consult legal counsel. ASTA does not provide any warranties of any kind for the Decision Tree, either express or implied, including but not limited to warranties of merchantability, fitness for a particular purpose, accuracy, design, usage, quality, performance, compatibility, or title.

Which FSMA rules might apply to my operations?

Instructions: To determine which FSMA rules might apply to your operations, please answer all of the questions on the following two pages. If you answer "yes" to a question, the clickable link(s) will take you to a section specific to each potentially applicable rule for further analysis of what requirements likely apply to your operations under that rule. This section also includes links to full definitions of key terms that may assist in answering the questions below.

Is your establishment a domestic or foreign food facility that is registered with FDA?

For example:

- Do you grind or otherwise process spices that you receive from a supplier?
- Do you treat spices that you have grown yourself with microbial reduction techniques?
- Do you pack already ground spices for further distribution or for retail sale?
- Do you prepare herbal extracts or herbal-infused products using spices?

Click **here** for FDA's definition of "facility."

Yes

The following FSMA rules might apply to your establishment:

- **The final rule for preventive controls for human food (PC rule).** Click **here** for more information.
- **The supply-chain requirements of the PC rule.** Click **here** for more information.
- **The final rule on intentional adulteration.** Click **here** for more information.

Is your establishment a domestic or foreign farm that only grows, harvests, packs, or holds produce for consumption in the U.S.?

For example:

- Do you grow crops that will be used as spices?
- Do you harvest or dry crops that will be used as spices?
- Do you grow, package, and label bulk crops that will be used as spices?
- Do you receive crops from another farm under the same ownership that you harvest, pack, hold, dry, package, or label?

Click **here** for FDA's definition of "farm."

Yes

The following FSMA rule might apply to your establishment:

- **The produce safety final rule.** Click **here** for more information.

Are you an importer of spices?

- An "importer" is the person who owns the food that is being offered for import, has purchased it, or has agreed in writing to purchase it.[1]

Click **here** for FDA's definition of "importer."

For example:

- Do you purchase spices from another country for use or sale in the U.S.?
- Do you purchase crops or other food ingredients from another country that you will use in the U.S. to manufacture a spice product?
- Do you purchase packaging materials from another country that you will use to package spices to sell in the U.S.?

Yes

The following FSMA rule might apply to your operations:

- **The Foreign Supplier Verification Program (FSVP) final rule.** Click **here** for more information.

Are you involved in the transportation of spices in one or more of the following capacities?

- ***Shipper***: A person (e.g., the manufacturer or a freight broker) who arranges for the transportation of food in the U.S. by a carrier or multiple carriers sequentially.[2]
- ***Loader***: A person who loads food onto a motor or rail vehicle during transportation operations.[3]
- ***Carrier***: A person who physically moves food by rail or motor vehicle within the U.S. The term carrier does not include any person who transports food while operating as a parcel delivery service.[4]
- ***Receiver***: Any person who receives food at a point in the U.S. after transportation, whether or not that person represents the final point of receipt for the food.[5]

Yes

The following FSMA rule might apply to your operations:

- **The sanitary transportation rule.** Click **here** for more information.

Does the PC rule apply to my establishment?

Is your establishment a "qualified facility"?

Your establishment is a "qualified facility" if any of the following apply to you:

- You are a "very small business": In the last three years
  - your average annual sales of human food (including by any subsidiaries or affiliates), *combined with*
  - the market value of human food that you manufactured, processed, packed, or held without sale (e.g., spices that you treated with a microbial reduction technique under contract but did not offer for sale)

  was less than $1 million.[6]

OR

- When including the sales by subsidiaries and affiliates, in the last three years
  - your average annual sales of food directly to "qualified-end users" (consumers, restaurants, and retail food establishments that are either in-state or within 275 miles of your facility and that sell your food directly to consumers) exceeded those to all other customers; and
  - your average annual sales of food was less than $500,000.[7]

For more information on the definition of "qualified facility" and related requirements, see FDA's guidance document ***here****.*

Yes

You are eligible for a "qualified facility exemption."[8]

This means your facility does not need to comply with the full requirements of the PC rule. Instead, you only must comply with **modified PC requirements**.[9]

To utilize this exemption, you must submit an attestation to FDA that identifies the "modified requirements" you will follow, which states:

- That your facility has identified the potential hazards associated with the food being produced, is implementing PCs to address the hazards, and is monitoring the performance of the PCs to ensure that such controls are effective; *or*
- That your facility is in compliance with state, local, county, tribal, or other applicable non-federal food safety law, including relevant laws of foreign countries.[10]

Your compliance date for the modified PC requirements is September 17, 2018.[11]

You must submit your first attestation to FDA by December 17, 2018.

No

Is your establishment a farm that also performs non-farm activities, such as manufacturing or processing (i.e., a "farm mixed-type facility")?

For example:

- Do you grow crops, dry those crops, and then grind and package the dried crops for use as spice products?
- Do you grow and harvest herbs, which you then use to prepare herbal extracts?

Yes

The PC rule may apply to some of your activities but not others.

The PC rule does not apply to farm activities that are likely subject to the produce safety rule.[12] Click **here** for help making this determination.[13]

The **modified PC requirements** apply to:

- On-farm packing or holding of processed food by a small business (i.e., a business that employs fewer than 500 full-time equivalent employees), if those activities are low risk (e.g., packing, sorting, or storing of herb and spice products such as ground dried herbs and herbal extracts).[14]

- On-farm manufacturing/processing activities by a small business, if those activities are low risk (e.g., extracting from dried/dehydrated herb and spice products or fresh herbs).[15]

The full requirements of the PC rule MAY apply to other activities you conduct at your establishment aside from those identified above. Continue answering the questions below with regard to your establishment's activities that are not identified above.

Is your establishment *solely* engaged in the storage of packaged food that is not exposed to the environment and that does not require time/temperature control for safety?

For example:

- Do you only store and distribute spices that are already fully packaged for individual sale and can be safely held without refrigeration?

Yes

Your establishment does not have to comply with the PC rule.[16]

No

YOU MUST COMPLY WITH THE PC RULE.

Continue below to determine your compliance date and for more details about the requirements

Is your establishment a "small business"?

- A "small business" is a business (including any subsidiaries and affiliates) that employs fewer than 500 full-time equivalent employees.

Yes

Your compliance date for most requirements of the PC rule is **September 18, 2017**.[17]

*See the **requirements** of the PC rule.*

You should separately evaluate whether you must comply with the **supply-chain requirements of the PC rule**, which have a separate compliance date. Click **here** for more information.

No

Your compliance date for most requirements of the PC rule is **September 19, 2016**.[18]

*See the **requirements** of the PC rule.*

You should separately evaluate whether you must comply with the **supply-chain requirements of the PC rule**, which have a separate compliance date. Click **here** for more information.

What are the requirements of the PC rule?

You must develop and implement a food safety system

The PC rule generally requires food facilities to establish and implement a food safety system, documented in a written food safety plan that is prepared by a preventive controls qualified individual (PCQI) and that includes an analysis of hazards and implementation of risk-based preventive controls (PCs). In order to comply with the PC rule, you will need to prepare and implement a **written food safety plan** that contains all of the following parts:

- A hazard analysis;
- A list of PCs to control the hazards identified in the hazard analysis;
- A supply-chain program [if required]; click **here** for help making this determination;
- A recall plan;
- Procedures for monitoring the implementation of the PCs;
- Corrective action procedures; and
- Verification procedures to evaluate the effectiveness of PCs.[19]

Continue below for a step-by-step overview of how to develop a food safety system.

Step One: Designate a PCQI

- Before you develop your food safety plan, you must designate a person to be your facility's PCQI, who will be responsible for overseeing the following aspects of the facility's food safety system:
  - Preparing the written food safety plan;
  - Validating that the PCs are adequate to control the relevant hazard (including making a determination that validation is not required, if appropriate);
  - Reviewing records for effectiveness of the PCs; and
  - Reevaluating the food safety plan.[20]
- You must ensure that the person you designate for this role is qualified to be a PCQI. There are two ways to qualify:
  - Complete training in the development and application of risk-based PCs at least equivalent to a curriculum recognized by FDA; or
  - Otherwise be qualified through job experience to develop and apply a food safety program (i.e., the job experience provides knowledge at least equivalent to that provided through the standardized curriculum).[21]

Step Two: Perform and Maintain a Written Hazard Analysis

The PCQI (or someone under their supervision) must identify known or reasonably foreseeable hazards for each type of food manufactured, processed, packed, or held at the facility, and determine whether any of those hazards requires a PC.[22] A hazard is any biological, chemical, radiological, or physical agent that has the potential to cause illness or injury.[23] For spice products, likely hazards include pathogens (e.g., *Salmonella*), environmental contaminants (e.g., lead), and major food allergens.

Although not required by the PC rule, FDA's PC guidance document (accessible **here**) recommends that covered facilities conduct certain preliminary steps, and set up a Hazard Analysis Worksheet, as a useful framework for organizing and documenting their hazard analysis. Those preliminary steps are:

- Assemble a Food Safety Team of individuals with expertise in the day-to-day operations of the facility to conduct the hazard analysis under the oversight of a PCQI;
- Describe the product, its distribution, intended use, and consumer or end user;
- Develop a process flow diagram (i.e., a clear, simple description of the steps involved in the processing of the food product and its associated ingredients as they "flow" from receipt to distribution) and verify it on site; and
- Develop a detailed process description to supplement the process flow diagram.

The mandatory portion of the hazard analysis step should proceed as follows:

- Identify all the foods manufactured, processed, packed, or held at your facility, and group these foods together by type.[24] You must separately evaluate the hazards for each type of food handled at your facility; you need not analyze individual foods separately if they are of the same type.
- For each type of food, think about each activity you perform with respect to that type of food, and identify hazards that are "known or reasonably foreseeable hazards"—i.e., hazards that are known to be (or have the potential to be) associated with the facility or the food.[25] Consider hazards that (1) occur naturally, (2) may be unintentionally introduced, or (3) may be intentionally introduced for economic gain (i.e., a substance that is dangerous to humans is intentionally introduced for economic gain).[26] These hazards may include:
  - Biological hazards (e.g., *Salmonella* or other pathogens);
  - Chemical hazards (e.g., major food allergens, radiological hazards, pesticide residues that pose a public health risk, mycotoxins, or heavy metal contaminants such as lead); and
  - Physical hazards (e.g., stones, glass, or metal fragments).[27]

  *For an extensive but non-exhaustive list of ingredient-related, process-related, and facility-related hazards, see Chapter 3 of FDA's PC guidance document (accessible **here**)*

- For each "known or reasonably foreseeable hazard," determine whether it is a "hazard requiring a preventive control":
  - Assess both (1) the probability that the hazard will occur in the absence of PCs and (2) the severity of the resulting illness or injury.[28]
  - Determine whether a person knowledgeable about the safe manufacturing of food would establish one or more PCs to significantly minimize or prevent the hazard.
    - If yes: it is a hazard requiring a PC.
    - If no: it is not a hazard requiring a PC.

Step Three: Establish Preventive Controls

You must identify, in writing, PCs to significantly minimize or prevent hazards requiring a PC, and implement those PCs (1) at critical control points (CCPs), which are points, steps, or procedures in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce the hazard to an acceptable level; and (2) anywhere else that they are "appropriate for food safety."[29]

Your PCs must include, "as appropriate to the facility and the food":

- **Process controls**. These are procedures, practices, and processes performed on the food itself, such as refrigerating, heat processing, and irradiating.[30]
- **Food allergen controls**. These procedures, practices, and processes ensure protection of food from allergen cross-contact, including during storage, handling, and use.[31] These controls also include processes for labeling the finished food, to ensure that the allergens are declared.[32] If you conclude that allergens are not a hazard requiring a PC, then you would control allergens exclusively through the applicable current good manufacturing practice (CGMP) requirements in subpart B of the PC rule.[33]
- **Sanitation controls**. These procedures, practices, and processes ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens.[34] These include controls for the cleanliness of food-contact surfaces and controls for the prevention of allergen cross-contact and cross-contamination.
- **Supply-chain controls**. These controls include the supply-chain program (subpart G), if it is required by the PC rule.[35] If the PC rule does not require you to establish a supply-chain program (click **here** for help making this determination), then you may conclude that supply-chain controls are not appropriate to your facility/food.

  *Chapter 4 of FDA's PC guidance document (accessible **here**) identifies common PCs that facilities could use to significantly minimize or prevent the occurrence of biological, chemical, and physical hazards requiring a PC, including process controls, sanitation controls, food allergen controls, supply-chain controls, and recall plans.*

The PC rule provides two exceptions to the requirement to establish PCs for a given hazard:

- (1) You determine and document that the type of food could not be eaten without processing that would control the hazards requiring a PC (e.g., cocoa beans or coffee beans);[36] *or*
- (2) You can demonstrate and document that a hazard requiring a PC will be controlled by another entity in your distribution chain (e.g., a commercial customer will treat spices with microbial reduction techniques before packaging for sale to consumers to control for pathogen growth).[37] You may rely on another entity in your distribution chain, including one that is not a registered facility (such as a restaurant), provided that:
  - You provide documentation to your direct customer that the food is "not processed to control [identified hazard]";
  - Annually, you obtain written assurances from your customers regarding appropriate procedures they will take to control the identified hazards (*note: FDA has issued a **two-year extension** for complying with this requirement*); and
  - The facility controlling the hazard acts consistently with the assurance and documents its actions taken to control the hazard (*note: FDA has issued a **two-year extension** for complying with this requirement*).[38]

Step Four: Establish Procedures for Monitoring the Implementation of the PCs

You must establish written procedures for monitoring the implementation of the PCs, and monitor the PCs with sufficient frequency to provide assurance that they are consistently performed.[39] The PC rule provides flexibility for you to decide how to monitor as well as how frequently to monitor, as appropriate given the nature of the PC and its role in your facility's food safety system.

You must document your monitoring of PCs, in records that are subject to the PC rule's verification and records review requirements.[40] You can do this by either:

- Demonstrating continuous functioning of PCs (e.g., an x-ray system/metal detector/magnet that monitors spices for foreign material that generates records for every scan or quality check it takes); or
- Showing evidence of failures (called "exception records").[41] This might entail continuous monitoring, but the system would generate a record only when it detects a failure (e.g., an x-ray or metal detection system that monitors spices for foreign material that generates a record only when the system detects foreign material).

*For additional information on monitoring the implementation of PCs, see Chapter 4 of FDA's PC guidance document (accessible **here**).*

Step Five: Determine Corrective Actions

Establish and Implement a Corrective Action Plan: You will need to decide what corrective actions are needed in the event that a PC is not properly implemented. A corrective action plan is meant to address food safety issues that might arise when there is a problem *implementing* a PC, not to fix problems on an ongoing basis when a PC is ineffective.

The PC rule identifies two circumstances—product testing and environmental monitoring—for which you must develop written corrective action procedures, but also provides that there may be other circumstances that also require these procedures. Specifically, the PC rule requires you to have a written corrective action plan in place to address, as appropriate:

- The presence of a pathogen or appropriate indicator in an RTE product that was detected as a result of product testing (e.g., if *Salmonella* is detected in testing of a spice product); and
- The presence of an environmental pathogen or indicator detected through environmental monitoring (e.g., *Salmonella* is detected in your facility).[42]

The corrective action plan must describe procedures to:

- Identify and correct the PC-implementation problem;
- Reduce the likelihood that the problem will recur;
- Ensure that all affected food is evaluated for safety; and
- Prevent all affected food from entering commerce, if you cannot ensure that the food is safe/lawful.[43]

Take Corrective Action in the Event of an Unanticipated Problem: The PC rule requires facilities to take corrective action if any of the following circumstances occur:[44]

- A PC is not properly implemented and a corrective action procedure has not been established;
- A PC, combination of PCs, or the entire food safety plan is found to be ineffective;
- A review of the records reveals that the records are not complete, the activities were not conducted according to the food safety plan, or appropriate decisions were not made about corrective actions.[45]

If any of these circumstances occurs, the facility must take corrective action to identify and correct the problem, reduce the likelihood that the problem will recur, evaluate all affected food for safety, and (as necessary) prevent affected food from entering commerce.[46] In addition, the facility must reanalyze the food safety plan to determine whether it needs to be modified.[47]

Make Corrections in Lieu of Corrective Actions: In some circumstances, you may avoid the need for a corrective action by instead making "corrections." The term "correction" means an action to identify and correct a problem that occurred during the production of food, whereas a corrective action plan includes other actions (actions to reduce the likelihood that the problem will recur, to evaluate all affected food for safety, and to prevent affected food from entering commerce).[48]

In lieu of requiring corrective actions, the PC rule allows you to make corrections in a timely manner to address the following issues:

- Conditions and practices that are inconsistent with either allergen controls or sanitation controls; or
- A minor and isolated problem that does not directly impact product safety.[49]

Recordkeeping: It is important that you document any corrective actions or corrections that you take. The PC rule requires facilities to document these actions in records that are subject to verification and records review.[50]

Step Six: Verify that the Food Safety System Is Working

To ensure the effectiveness of the food safety plan, facilities must verify that the preventive controls are consistently implemented and are effectively and significantly minimizing the hazards.[51] This process involves, "as appropriate to the nature of the preventive control and its role in the facility's food safety system":

- Validation that PCs are adequate to control the hazard;
- Verification of PC monitoring, of PC implementation and effectiveness, and to ensure that appropriate decisions are made about corrective actions; and
- Reanalysis of the food safety plan.[52]

You must document all verification activities in records.[53]

Continue below for more information about the first two of these requirements.

Validation Requirements. You must validate that the PCs you have identified and implemented are adequate to control the hazards.[54] In other words, you must evaluate whether, if the PCs are implemented as planned, they will effectively control the hazards. This process entails obtaining and evaluating scientific and technical evidence to determine whether the PC, when properly implemented, will effectively control the hazard.[55]

Your PCQI must perform (or oversee) the validation of the PCs.[56] Validation is required:

- Prior to implementation of the food safety plan. However, when it's necessary to demonstrate the control can be implemented as designed, validation may be performed (1) within the first 90 calendar days of production or (2) within a reasonable timeframe, if the PCQI prepares a written justification of why this cannot be done within 90 days;

- Whenever a change to a control could impact whether it will effectively control the hazard; and
- Whenever reanalysis of the food safety plan calls for it.[57]

However, you do not need to validate every aspect of your food safety plan. Specifically, you do not need to validate: food allergen controls; sanitation controls; the recall plan; the supply-chain program; or other PCs, if the PCQI prepares a written justification of why validation is not applicable based on factors such as the nature of the hazard.

Verification Requirements. Another aspect of ensuring the effectiveness of your food safety system is verifying that you are following your food safety plan. This is the core of the PC rule's verification requirements. There are three main verification requirements:

- Verify that you're conducting PC monitoring as required;
- Verify that you're making appropriate decisions about corrective actions; and
- Verify that the PCs are consistently implemented and are effectively and significantly minimizing the hazards.[58] Specifically, you must consider whether the following activities are necessary, "as appropriate to the facility, the food, and the nature of the preventive control and its role in the facility's food safety system":
  - **Calibration** of process-monitoring and verification instruments (or check them for accuracy);
  - **Product testing** for a pathogen or appropriate indicator organism or other hazard;
  - **Environmental monitoring** for an environmental pathogen or appropriate indicator organism, if contamination of a RTE food with an environmental pathogen is a hazard requiring a PC; and
  - **Review of records** (1) related to monitoring and corrective actions and (2) related to calibration, testing, supplier and supply-chain verification activities, and other verification activities.

Step Seven: Develop a Written Recall Plan

You must establish a written recall plan for any food with a hazard requiring a PC. If you identify one or more hazards requiring a PC in multiple food products, you may use the same recall plan for all applicable food products.[59]

The recall plan must describe procedures (i.e., the steps to be taken and the person/entity responsible for taking those steps), "as appropriate to the facility," to:

- Directly notify direct downstream recipients of the recall, including how to return or dispose of the affected food;
- Notify the public about potential hazards, when appropriate to protect public health;
- Conduct effectiveness checks to verify that the recall is carried out; and
- Dispose of recalled food.[60]

Step Eight: Keep Good Records

The PC rule requires that you establish and maintain the following records (in addition to the written food safety plan itself):

- Documentation for not establishing a PC (i.e., when the hazard analysis determined that a PC was required, but you didn't implement one because you utilized one of the exceptions provided by 21 C.F.R. 117.136(a)—that is, you determined that the food could not be eaten without processing that would control the hazard, or you are relying on an entity further down in the distribution chain to control the hazard);
- Records that document the monitoring of PCs;
- Records that document corrective actions;
- Records that document verification, including (as applicable) those related to: validation; verification of monitoring; verification of corrective actions; calibration of process monitoring and verification instruments; product testing; environmental monitoring; records review; and reanalysis; and
- Records that document applicable training for the PCQI.[61]

The following links may be helpful as you prepare to comply with the requirements of the PC Rule:

- The **final rule**
- **FDA's home page** on the PC Rule
- **FDA guidance** on the PC Rule
- **FDA guidance** on farm/facility activities
- **FDA guidance** for qualified facilities
- Food Safety Preventive Controls Alliance **website** with additional resources

Do the supply chain requirements of the PC rule (Subpart G) apply to my establishment?

Do any of the following apply to your establishment?

- Your facility is a "qualified facility."[62] Defined **here**.
- Your establishment is *solely* engaged in the storage of packaged food that is not exposed to the environment and that does not require time/temperature control for safety. [63]

  For example:
  - Do you only store and distribute spices that are already fully packaged for individual sale and can be safely held without refrigeration?

Yes → Your establishment does not have to comply with the supply chain requirements of the PC rule.

No

Is your establishment a farm that also performs non-farm activities, such as manufacturing or processing (i.e., a "farm mixed-type facility")?

For example:

- Do you grow crops, dry those crops, and then grind and package the dried crops for use as spice products?
- Do you grow and harvest herbs that you then use to prepare herbal extracts?

Yes →

The supply chain requirements of the PC rule may apply to some of your activities but not others.

The supply chain requirements of the PC rule DO NOT apply to:

- Activities that are subject to the produce safety rule (click **here** for help making this determination)[64] or are otherwise within the "farm" **definition**.[65]
- On-farm packing or holding of processed food by a small business (i.e., a business that employs fewer than 500 full-time equivalent employees), if those activities are low risk (e.g., packing, sorting, or storing of herb and spice products such as ground dried herbs and herbal extracts).[66]
- On-farm manufacturing/processing activities by a small business, if those activities are low risk (e.g., extracting from dried/dehydrated herb and spice products or fresh herbs).[67]

The supply chain requirements of the PC rule MAY apply to other activities you conduct at your establishment. Continue answering the questions below with regard to your activities that are not identified above.

Do *both* of the following apply to your establishment?

- Your establishment is a "receiving facility." A "receiving facility" *manufactures* or *processes* a raw material or other ingredient that it receives from a supplier.[68]
- One or more of the raw materials or other ingredients that you receive have a hazard requiring a "supply-chain-applied control." A "supply-chain-applied control" is a PC that is applied before the facility receives the raw material/ingredient.[69]
  (This means that if you, as part of your food safety plan, control the hazards associated with a particular ingredient, or if that ingredient does not have any hazards requiring a PC, the supply-chain program would not apply to that ingredient.)

No → Your establishment does not have to comply with the supply chain requirements of the PC rule.

Yes

Does your establishment meet *all* of the following criteria for any ingredients it receives?

- You are an importer (defined **here**);
- You are in compliance with the FSVP rule requirements (see **here**); and
- You have documentation of verification activities conducted under 21 C.F.R. 1.506(e) (which provides assurance that the hazards requiring a supply-chain-applied control for the raw material or other ingredient have been significantly minimized or prevented).[70]

Yes → Your establishment does not have to comply with the supply chain requirements of the PC rule for these ingredients.

No

YOU MUST COMPLY
WITH THE
SUPPLY CHAIN REQUIREMENTS
OF THE PC RULE.

Continue below to determine your compliance date and for more details about the requirements

Is your establishment a "small business"?

- A "small business" is a business (including any subsidiaries and affiliates) that employs fewer than 500 full-time equivalent employees.

Yes

Your compliance date will depend on the characteristics of your supplier:

- If your supplier will not be subject to the PC rule or the produce safety rule, your compliance date is **September 18, 2017**.
- If your supplier will be subject to the PC rule or the produce safety rule, your compliance date is the later of (1) **September 18, 2017** and (2) **six months after your supplier's compliance date** for those rules.

*See the supply chain **requirements** of the PC rule*

No

Your compliance date will depend on the characteristics of your supplier:

- If your supplier will not be subject to the PC rule or the produce safety rule, your compliance date is **March 17, 2017**.
- If your supplier will be subject to the PC rule or the produce safety rule, your compliance date is **six months after that supplier's compliance date** for those rules.

*See the supply chain **requirements** of the PC rule*

What are the supply chain requirements of the PC rule?

Does your supplier apply the supply-chain-applied control?

For example:

- Do you purchase spices from a supplier who has treated those spices with microbial reduction techniques to control for pathogen growth?
- Does your supplier analyze raw spice materials for lead before you receive those materials?

No

If an entity other than your supplier applies the supply-chain-applied control, then you must:

- Verify the supply-chain applied control; or
- Obtain documentation of an appropriate verification activity from another entity; review and asses the entity's applicable documentation; and document that review and assessment.[71]

Yes

You must use approved suppliers

With respect to ingredients with a hazard requiring a supply-chain-applied control, you must approve your supplier before receiving ingredients from that supplier.[72] In doing so, you generally must consider:

- The hazard analysis of the food received, including the nature of the hazard controlled before receipt of the ingredient;
- The supplier's ability to control hazards that require a supply-chain-applied control; and
- Supplier performance (e.g., food safety history).[73]

AND

You must conduct supplier verification activities

- You must determine, conduct, and document appropriate supplier verification activities,[74] such as onsite audits, sampling and testing of the raw material or other ingredient, and review of a supplier's relevant food safety records.[75]
- You have the flexibility to determine the nature of the verification activity and the frequency of conducting such activities. However, you must conduct an onsite audit of the supplier if there is a reasonable probability that exposure to the hazard will result in serious adverse health consequences or death (e.g., if the hazard is a pathogen or major food allergen).[76]
- You may engage another entity to conduct some or all of your supplier verification activities.[77]

The following links may be helpful as you prepare to comply with these requirements:

- The **final rule**
- **FDA's home page** on the final rule
- **Supplier evaluation resources** compiled by FDA

Does the intentional adulteration rule apply to my establishment?

Do any of the following apply to your establishment?

- Does your establishment hold food?
- Does your establishment pack, re-pack, label, or re-label food where the container that directly contacts the food remains intact?
  For example:
  - Do you label packaged spice products that you receive already packaged?
- Is your establishment a farm that also performs non-farm activities, such as manufacturing or processing (i.e., a "farm mixed-type facility")?
  For example:
  - Do you grow crops, dry those crops, and then grind and package the dried crops for use as spice products?
  - Do you grow and harvest herbs that you then use to prepare herbal extracts?

Yes

The intentional adulteration rule may apply to some of your activities but not others.

The intentional adulteration rule DOES NOT apply to:

- The holding of food, except the holding of food in liquid storage tanks.[78]
- The packing, re-packing, labeling, or re-labeling of food where the container that directly contacts the food remains intact.[79]
- Activities that are within the "farm" **definition**.[80]

The intentional adulteration rule may apply to other activities you conduct at your establishment. Continue answering the questions below with regard to your establishment's activities that are not identified above.

No

Is your establishment a "very small business" under this rule?

- You are a "very small business" under this rule if, in the last three years, your average annual sales of food (including by any subsidiaries or affiliates) was less than $10 million.

Yes

Your establishment does not have to comply with the intentional adulteration rule. However, if requested, you must provide documentation showing your status as a very small business.[81]

No

YOU MUST COMPLY
WITH THE
INTENTIONAL ADULTERATION RULE.

Continue below to determine your compliance date and for more details about the requirements

Is your establishment a "small business"?

- A "small business" is a business (including any subsidiaries and affiliates) that employs fewer than 500 full-time equivalent employees.

Yes

Your compliance date is **July 26, 2020**.[82]

*See the **requirements** of the intentional adulteration rule*

No

Your compliance date is **July 26, 2019**.[83]

*See the **requirements** of the intentional adulteration rule*

What are the requirements of the intentional adulteration rule?

Written food defense plan

You must prepare and implement a written food defense plan that includes[84]:

- A vulnerability assessment to identify significant vulnerabilities and actionable process steps.[85]
- Mitigation strategies for actionable process steps.[86]
- Food defense monitoring procedures.[87]
- Food defense corrective actions procedures.[88]
- Food defense verification procedures.[89]

AND

Training

You must ensure that personnel assigned to the vulnerable areas receive appropriate training.[90]

AND

Recordkeeping

You must maintain records for:

- A vulnerability assessment to identify significant vulnerabilities and actionable process steps[91];
- Mitigation strategies for actionable process steps[92];
- Food defense monitoring procedures[93];
- Food defense corrective actions[94]; and
- Food defense verification procedures.[95]

The following links may be helpful as you prepare to comply with these requirements:

- The **final rule**
- **FDA's home page** on the final rule

Does the produce safety rule apply to my farm or operation?

Does your farm grow, harvest, pack, or hold produce that is a raw agricultural commodity

including operations devoted to the growing and/or harvesting of crops, whose activities may include packing or holding raw agricultural commodities (RACs); manufacturing/processing RACs by drying or dehydrating them to create a distinct commodity; treatment to manipulate the ripening of RACs; and packaging/labeling RACs?

"Produce" means any fruit or vegetable, including mushrooms, sprouts, peanuts, tree nuts, and herbs (e.g., basil and cilantro). [96]

"Produce" includes crops (e.g., herbs and other plant products) intended for use in the production of spice products.

No → Your farm or operation does not have to comply with the produce safety rule.

Yes

In the previous three years, did your farm on average have $25,000 or less in annual produce sales?

Yes → Your farm does not have to comply with the produce safety rule.[97]

No

Is your produce one of the commodities that FDA has identified as rarely consumed raw?

- If you grow, harvest, pack, or hold more than one produce commodity, answer this question separately for each one to determine whether that particular produce commodity is covered by the rule.
- FDA has identified the following products: Asparagus; black beans; great Northern beans; kidney beans; lima beans; navy beans; pinto beans; garden beets (roots and tops); sugar beets; cashews; sour cherries; chickpeas; cocoa beans; coffee beans; collards; corn, sweet; cranberries; dates; dill (seeds and weed); eggplants; figs; ginger; hazelnuts; horseradish; lentils; okra; peanuts; pecans; peppermint; potatoes; pumpkins; winter squash; sweet potatoes; and water chestnuts.[98]

Yes → Your farm does not have to comply with the produce safety rule with regard to these commodities.

No

Is your produce intended for commercial processing that adequately reduces pathogens (e.g., commercial processing with a "kill step")?

Yes → Your farm does not have to comply with the produce safety rule with regard to this produce, provided that:

- You disclose in documents accompanying the produce that it is

For example:

- Do you only grow crops that will be treated with microbial reduction techniques to control for pathogen growth before they are used in food?

"not processed to adequately reduce the presence of microorganisms of public health significance";

- You annually obtain certain written assurances from your customer (see 21 C.F.R. 112.2(b)(3)&(6) for more detail); and
- You document your compliance with the above.[99]

No

Is your farm eligible for a qualified exemption?
To be eligible for a qualified exemption, your farm must meet the following two requirements:

- During the previous three years, your farm's food sales averaged less than $500,000 per year; *and*
- Your farm's sales to "qualified end-users" (consumers and restaurants and retail food establishments that are either in-state or within 275 miles of your farm and that sell your food directly to consumers) exceed sales to all others combined during the previous three years.

Yes

Your farm does not have to comply with the full requirements of the produce safety rule, but instead must meet modified requirements, which include:

- Disclosing the name and the complete business address of the farm where the produce was grown, either on the label of the produce or at the point of purchase (see 21 C.F.R. 112.6(b) for more details); and
- Establishing and keeping certain records (see 21 C.F.R. 112.7 for more details).

Your compliance dates are:

- For labeling requirement: **January 1, 2020**.
- For retaining records showing eligibility for qualified exemption: **January 26, 2016**.
- For all other recordkeeping requirements:
  - Very small business: **January 26, 2020**.
  - Small business: **January 26, 2019**.

No

YOU MUST COMPLY
WITH THE
PRODUCE SAFETY RULE.

Continue below to determine your compliance date and for more details about the requirements

Is your farm a "very small business" or a "small business"?

- A "very small business" is a business that had >$25,000 to $250,000 in average annual produce sales during the previous three-year period.[100]
- A "small business" is a business that had >$250,000 to $500,000 in average annual produce sales during the previous three-year period.[101]

Yes

Your compliance date is:

- Very small business: **January 26, 2020**.
- Small business: **January 26, 2019**.
- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond each respective compliance date above.[102]

See the produce safety rule ***requirements***

No

Your compliance date is **January 26, 2018**.[103]

- The compliance dates for certain aspects of the water quality standards, and related testing and recordkeeping provisions, allow an additional two years beyond this date.

See the produce safety rule ***requirements***

What are the produce safety rule requirements?

Requirements that apply to agricultural water

The produce safety rule establishes two sets of criteria for microbial water quality, both of which are based on the presence of generic *E. coli*, which can indicate the presence of fecal contamination.

- (1) No detectable generic *E. coli* are allowed for certain uses of agricultural water in which it is reasonably likely that potentially dangerous microbes, if present, would be transferred to produce through direct or indirect contact (e.g., water used for washing hands during and after harvest)[104]; and
- (2) The second set of criteria is for agricultural water that is used for growing produce other than sprouts (see 21 C.F.R. 112.44(b) for more details).[105]
- If the water you use does not meet these criteria, you must take corrective actions as soon as practicable, but no later than the following year.[106]

AND

Requirements that apply to biological soil amendments

- FDA is conducting a risk assessment and extensive research on the number of days needed between the application of raw manure as a soil amendment and harvesting to minimize the risk of contamination.
- At this time, FDA does not object to farmers complying with the USDA's National Organic Program standards, which call for a 120-day interval between the application of raw manure for crops in contact with the soil and 90 days for crops not in contact with the soil.
- The produce safety rule requires that untreated biological soil amendments of animal origin be applied in a manner that does not contact covered produce during application and minimizes the potential for contact with covered product after application.[107]

AND

Requirements that apply to domesticated and wild animals

- At a minimum, you must visually examine the growing area and all covered produce to be harvested, regardless of the harvest method used.
- Under certain circumstances, you will need to conduct additional assessments during the growing season and take measures reasonably necessary to assist later during harvest (e.g., placing flags outlining the affected area) if you find significant evidence of potential contamination (see 21 C.F.R. 112.83 for more details).[108]

AND

Requirements that apply to equipment, tools, and buildings

- You must meet standards related to equipment, tools, and buildings (e.g., greenhouses, germination chambers, and toilet and hand-washing facilities) to prevent these sources from contaminating produce.
- Required measures include appropriate storage, maintenance, and cleaning of equipment and tools (see 21 C.F.R. Part 112, Subpart L for more details).[109]

AND

Requirements that apply to worker training and health and hygiene

These requirements include:

- Taking measures to prevent contamination of produce and food-contact surfaces by ill or infected persons;
- Using hygienic practices when handling (contacting) covered produce or food-contact surfaces; and
- Taking measures to prevent visitors from contaminating covered produce and/or food-contact surfaces.[110]

The following links may be helpful as you prepare to comply with these requirements:

- The **final rule**
- **FDA's home page** on the final rule

Does the FSVP rule apply to my operations?

Does your establishment meet both of the following criteria for any ingredients it imports?

- Your establishment is a receiving facility; *and*
- In accordance with the PC rule requirements, your establishment

  (1) has implemented PCs for hazards in the food,

  (2) is not required to implement PCs, *or*

  (3) has established and implemented a risk-based supply-chain program.

Yes

Your establishment does not have to comply with the full requirements of the FSVP rule.[111]
Instead, your establishment must only comply with the following importer identification requirement:

- Ensure that, for each line entry of food product imported into the U.S., the importer's name, electronic mail address, and unique facility identifier, identifying it as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.[112]

*Continue **below** to determine your compliance date*

No

Are you a "very small importer"?

- You are a "very small importer" if, in the last three years, your average annual sales of food (including by any subsidiaries or affiliates) was less than $1 million.[113]

Yes

You do not have to comply with the full requirements of the FSVP rule.[114]
Instead, you must only comply with the following modified requirements:

- Before first importing food and on an annual basis thereafter, document that you meet the definition of very small importer.
- For each food you import, obtain written assurance, before first importing the food and at least every 2 years thereafter, that your foreign supplier is producing the food in compliance with processes and procedures that provide at least the same level of public health protection as those required under the FDCA.
- Promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with this assurance.
- Keep records.
- Comply with the general requirement to develop an FSVP (click **here** for details).
- Identify yourself as the importer when filing entry with U.S. Customs and Border Protection (click **here** for details).

*Continue **below** to determine your compliance date*

Do you import food from either or both of the following types of small foreign suppliers?

- A foreign supplier that is a "qualified facility" under the PC rule (click **here** for help making this determination).
- A foreign supplier that is a "farm" that grows produce and is ***not*** covered by the produce safety rule (click **here** for help making this determination).

Yes

You do not have to comply with the full requirements of the FSVP rule for these suppliers.[115] Instead, you must only comply with the following modified requirements:

- Before first approving the supplier for a calendar year and on an annual basis thereafter, obtain written assurance that your foreign supplier is either (1) a qualified facility or (2) a farm that grows produce and is not covered by the produce safety rule.
- If your foreign supplier is a qualified facility, obtain written assurance, before importing the food and at least every 2 years thereafter, that the foreign supplier is producing the food in compliance with applicable FDA food safety regulations.
- If your foreign supplier is a farm, obtain written assurance, before importing the produce and at least every 2 years thereafter, that the farm acknowledges that its food is subject to section 402 of the FDCA.
- Promptly take appropriate corrective actions if you determine that a foreign supplier of food you import does not produce the food consistent with this assurance.
- Keep records.
- Comply with the general requirement to develop an FSVP (click **here** for details).
- Identify yourself as the importer when filing entry with U.S. Customs and Border Protection (click **here** for details).

*Continue **below** to determine your compliance date*

No

Do you meet all of the following criteria for any ingredients you import?

- You import food from a foreign supplier that is under the regulatory oversight of a country whose food safety system FDA has officially recognized as comparable or equivalent to that of the U.S. (*currently* Canada & New Zealand);
- You supplier is in good compliance standing with the food safety authority of that country;

Yes

You do not have to comply with the full requirements of the FSVP rule.[116] Instead, you must only comply with the following modified requirements:

- ***Importer identification***: Ensure that, for each line entry of food product imported into the U.S., the importer's name, electronic mail address, and unique facility identifier, identifying it as the

and

- The ingredient you import from this supplier is not intended for further manufacturing/processing after import.

importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.[117]

- ***Recordkeeping***: Keep records in accordance with 21 C.F.R. 510.

*Continue **below** to determine your compliance date*

Do you meet both of the following criteria for any ingredients you import?

- Your establishment is a receiving facility; and
- In accordance with the PC rule requirements, your establishment either

  (1) has implemented PCs for hazards in the food,

  (2) is not required to implement PCs, or

  (3) has established and implemented a risk-based supply-chain program.

Yes

Your establishment does not have to comply with the full requirements of the FSVP rule.[118] Instead, your establishment must only comply with the following importer identification requirements:

- Ensure that, for each line entry of food product imported into the U.S., the importer's name, electronic mail address, and unique facility identifier, identifying it as the importer of the food, are provided electronically when filing entry with U.S. Customs and Border Protection.[119]

*Continue **below** to determine your compliance date*

No

YOU MUST COMPLY WITH THE FSVP RULE.

Continue below to determine your compliance date and for more details about the requirements

Your compliance date is the latest of the following dates:

- **May 27, 2017** (i.e., 18 months after publication of the final FSVP rule);
- For the importation of food from a supplier that is subject to the PC rule or produce safety rule, **six months after** your foreign supplier's compliance date for those rules; or
- If you are an importer that is also subject to the supply-chain program provisions of the PC rule (i.e., Subpart G), the date by which you have to comply with those provisions.[120]

*See the **requirements** of the FSVP rule*

What are the FSVP rule requirements?

General requirement to develop an FSVP

- For each food that you import (for example, dried crops or ground spices), you must develop, maintain, and follow an FSVP for each foreign supplier before importing a food into the U.S., as necessary to provide assurance that hazards in food requiring a control are significantly minimized or prevented.[121]
- A qualified individual must develop your FSVP and perform each of the required activities. A qualified individual must have the education, training, and/or experience necessary to perform his or her assigned activities.[122]

AND

Perform a written hazard analysis

- You must perform a written hazard analysis to determine whether, for each type of food you import, there are any known or reasonably foreseeable hazards requiring a control.[123]
- If you identify a hazard requiring a control in a food and document either

  (1) that the type of food cannot be consumed without application of an appropriate control (e.g., cocoa beans) *or* (2) that the hazard will be controlled downstream in the distribution chain, then you are not required to perform the FSVP supplier approval and verification activities detailed in the next two boxes.[124]

  Skip to the corrective actions ***requirements***.

AND

Evaluate the risks posed by the food and the foreign supplier's performance

You must evaluate the risks posed by the food and the performance of the foreign supplier, considering the following:

- The hazard analysis for the food;
- The entity that will be applying hazard controls, such as the foreign supplier or the foreign supplier's ingredient supplier;
- The foreign supplier's food safety practices and procedures;
- Applicable U.S. food safety regulations and information regarding the foreign supplier's compliance with those regulations; and
- The foreign supplier's food safety performance history.[125]

AND

Conduct supplier verification activities

You must conduct appropriate supplier verification activities to provide assurance that the hazards requiring a control in the food you import have been significantly minimized or prevented, including activities such as:

- Annual onsite audits (this must be done by a "qualified auditor," which may include a qualified third party auditor, who has the technical expertise obtained through education, training, and/or experience necessary to conduct an audit[126]);
- Sampling and testing of a food; and
- Reviewing the supplier's relevant food safety records.[127]

You can rely on another entity (other than the foreign supplier) to determine and perform appropriate supplier verification activities, as long as you review and assess the relevant documentation.[128]

AND

Take corrective actions

You must take corrective actions, if necessary, and investigate the adequacy of your FSVP, when appropriate.[129]

AND

Reevaluate the food and foreign supplier at least every 3 years

You must reevaluate the food and foreign supplier every 3 years or sooner if you become aware of new information about the hazards in the food or the foreign supplier's performance.[130]

AND

Identify yourself as the importer

You must identify yourself as the importer when filing for entry with U.S. Customs and Border Protection using the importer's name, electronic mailing address, and unique facility identifier.[131]

The following links may be helpful as you prepare to comply with these requirements:

- The **final rule**
- **FDA's home page** on the final rule
- Food Safety Preventive Controls Alliance **website** with additional resources
- FDA's **home page** on International Cooperation, with Systems Recognition information

Does the sanitary transportation rule apply to my operations?

Is your business a non-covered business?

- Your business is a "non-covered business" if, in the last three years, your average annual revenue was less than $500,000 (as adjusted for inflation), calculated on a rolling basis.[132]

Yes → Your operations do not have to comply with the sanitary transportation rule.[133]

No

Is your establishment a farm?

- Click **here** for FDA's definition of "farm"

Yes → Your operations do not have to comply with the sanitary transportation rule.[134]

No

Do any of the following apply to your operations?

- You transport food that is transshipped through the U.S. to another country.

  For example: Do you transport crops that are imported from Mexico and immediately exported to Canada?

- You transport food that is imported for future export, in accordance with the FDCA's import for export provisions, and is neither consumed nor distributed in the U.S.
- You transport food that is completely enclosed by a container and does not require temperature control for safety.

  For example:
  Do you transport finished spice products that are fully packaged?
  Do you transport bulk spices that are enclosed in a container during transport?

Yes →

The sanitary transportation rule does not apply to these operations.[135]

The sanitary transportation rule applies to the other transportation operations in which you engage.

Continue below to determine your compliance date and for more details about the requirements.

No

YOU MUST COMPLY
WITH THE
SANITARY TRANSPORTATION RULE.

Continue below to determine your compliance date and for more details about the requirements

Is your business a "small business"?

The requirements to be considered a "small business" depend on the entity's function:

- For carriers by motor vehicle that are not also shippers or receivers, a "small business" is one that has less than $27.5 million in annual receipts; and
- For all other businesses, a "small business" is one employing fewer than 500 full-time equivalent employees.[136]

Yes

Your compliance date is **April 6, 2018**.[137]

*See the **requirements** of the sanitary transportation rule*

No

Your compliance date is **April 6, 2017**.[138]

*See the **requirements** of the sanitary transportation rule*

What are the general requirements of the sanitary transportation rule?

General Requirements

- The sanitary transportation rule establishes requirements for shippers, loaders, carriers by motor or rail vehicle, and receivers involved in the transportation of food to use sanitary transportation practices to ensure the safety of the transported food.
- The rule's requirements generally do not require practices to prevent spoilage or other marketability concerns.
- The rule sets general requirements that apply to all covered entities engaged in transportation operations (i.e., shippers, loaders, carriers, and receivers). Continue directly below for more details about these requirements.
- The rule also sets function-specific requirements (e.g., shipper-specific requirements). Click **here** for more details about those requirements.

General requirements that apply to vehicles and transportation equipment

The following requirements apply to vehicles (e.g., a motor vehicle or railcar) and transportation equipment (e.g., bulk and non-bulk containers, bins, and pallets):

- (1) Vehicles and equipment used in transportation operations must be designed, adequately cleanable, and maintained for their intended use to prevent the food they transport from becoming unsafe.[139] The required sanitary practices will depend on the food being transported, the intended use of that food, and the intended use of the vehicle and transportation equipment.
- (2) If vehicles or equipment are used to transport food requiring temperature control for safety, they must be designed, maintained, and equipped as necessary to provide adequate temperature control.[140] FDA acknowledges that this could be accomplished through a variety of mechanisms, including the use of ice, dry ice, or insulated coolers.[141]
- (3) 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 transport.[142]

AND

General requirements that apply to transportation operations

The following general requirements apply to transportation operations:

- All transportation operations must be conducted under such conditions and controls necessary to prevent food from becoming unsafe during transport.[143] In determining the necessary conditions and controls for transportation operations, you must consider the type of food (e.g., human food) and its production stage (e.g., raw material, ingredient, or finished food).[144] These conditions and controls include taking effective measures:
  - To protect food from **contamination by raw foods and nonfood items in the same load** (e.g., through segregation, isolation, or the use of packaging; note that shipping such materials in the same load is not prohibited)[145];
  - To protect **food transported in bulk vehicles or food not completely enclosed by a container from contamination or cross-contact** during transport (e.g., through segregation, isolation, or hand washing)[146]; *and*
  - To ensure that **food that requires temperature control for safety (not just quality) is transported under adequate temperature conditions**.[147]

- If a shipper, loader, receiver, or carrier becomes aware of an indication of a possible material failure of temperature control or other conditions that may render food unsafe during transportation (e.g., spillage of a toxic substance on food items in the same load), that person must take appropriate action, including communication with other parties, to ensure that the food is not sold or otherwise distributed unless a qualified individual determines that the food was not rendered unsafe.[148] A food is not automatically deemed unsafe or adulterated just because a possible material failure of temperature control or other problem occurs.

In addition, note the following:

- A person may be subject to these requirements in multiple capacities (e.g., the shipper may also be the loader and the carrier), if the person performs multiple functions.[149] However, the rule allows a covered entity to contractually assign its responsibilities to another party that is subject to the sanitary transportation rule.
- In all cases, competent supervisory personnel must be responsible for ensuring that transportation operations are carried out in compliance with all the requirements of the sanitary transportation rule.[150]
- If the shipper, loader, carrier, and receiver are all under the ownership or operational control of the same entity, the company may conduct transportation operations in conformance with common, integrated written procedures that ensure the sanitary transportation of food – instead of establishing separate, specific procedures for each of those functions – provided those procedures are consistent with the rule's requirements for transportation operations.

AND

Recordkeeping requirements

- Shippers, carriers, loaders, and receivers all must maintain records required under the final rule and make such records available to FDA upon request.[151]
  *See the entity-specific sections (**shipper**, **loader**, **carrier**, and **receiver**) for a list of records required for each entity engaged in transportation operations.*
- FDA permits offsite storage for all records except for a carrier's written procedures describing its practices for cleaning, sanitizing, and inspecting vehicles and transportation equipment, as long as the records can be retrieved and provided onsite within 24 hours of request for official review.[152] Those carriers' written procedures must remain onsite as long as the procedures are in use in transportation operations.

Which of the following describes your role in transportation operations?

To determine which function-specific requirements apply to your operations, please follow the clickable link(s) for all that apply to your operations (e.g., if you are both a shipper and a loader, follow the clickable links for both):

- ***Shipper***: A person (e.g., the manufacturer or a freight broker) who arranges for the transportation of food in the U.S. by a carrier or multiple carriers sequentially.[153] *Click **here** for shipper-specific requirements.*
- ***Loader***: A person who loads food onto a motor or rail vehicle during transportation operations.[154] *Click **here** for loader-specific requirements.*
- ***Carrier***: A person who physically moves food by rail or motor vehicle in commerce within the U.S. The term carrier does not include any person who transports food while operating as a parcel delivery service.[155] *Click **here** for carrier-specific requirements.*
- ***Receiver***: Any person who receives food at a point in the U.S. after transportation, whether or not that person represents the final point of receipt for the food.[156] *Click **here** for receiver-specific requirements.*

The following links may be helpful as you prepare to comply with these requirements:

- The **final rule**
- **FDA's home page** on the final rule
- Food Safety Preventive Controls Alliance **website** with additional resources

What are the shipper-specific requirements of the sanitary transportation rule?

Assure that vehicles and equipment used in transportation operations are in appropriate sanitary condition

The shipper must develop and implement written procedures adequate to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food (i.e., will prevent the food from becoming unsafe during the transportation operation).[157] The final rule provides the shipper with several options for ensuring that measures are taken to assure that transport vehicles and equipment are in appropriate sanitary condition. Specifically, the shipper may:

- Take measures itself to ensure that vehicles and equipment used in its transportation operations are in appropriate sanitary condition for the transportation of the food, when that is consistent with the shipper's written Standard Operating Procedure (SOP)[158];
- Delegate this responsibility through a written agreement, to the carrier or another party covered by the sanitary transportation rule[159]; or
- Specify in writing to the carrier (and, if necessary, the loader) all necessary sanitary specifications for the carrier's vehicle and transportation equipment to achieve this purpose, including any design specifications and cleaning procedures.[160] One-time notification is sufficient, unless the design requirements and cleaning procedures required for sanitary transport change based upon the type of food being transported (in which case the shipper must notify the carrier in writing before the shipment).

AND

Assure that, for bulk cargo, a previous cargo does not make the food unsafe

The shipper of food transported in bulk must develop and implement written procedures adequate to ensure that a previous cargo does not make the food unsafe.[161] The shipper may implement these measures itself or may delegate this responsibility, through a written agreement, to the carrier or another party covered by the sanitary transportation rule.

- If you, the shipper, choose to implement these measures yourself, then your SOP would describe the actions you will take to provide this assurance (e.g., cleaning the vehicle, using a dedicated vehicle).[162]
- If you choose to delegate this responsibility, then your SOP would include actions that the carrier or another party covered by the rule will take to provide this assurance (e.g., providing information about the last previous cargo of the vehicle, providing a dedicated vehicle).[163] If you wish to delegate this responsibility to more than one carrier, FDA has said that it will allow shippers to use "a written single generic guideline for all hired carriers with procedures addressing prior loads and the cleaning of bulk vehicles."

AND

Assure that foods that require refrigeration for safety are transported under adequate temperature control

The shipper of food that requires temperature control for safety under the conditions of shipment must develop and implement written procedures to ensure that the food is transported under adequate temperature control.[164] The final rule provides the shipper with several options for ensuring that measures are taken to assure that foods that require refrigeration for safety are transported under adequate temperature control. Specifically, the shipper may:

- Take measures itself to ensure that adequate temperature control is provided during the transportation of food that requires temperature control for safety under the conditions of shipment, when that is consistent with the shipper's written SOP[165];

- Delegate this responsibility through a written agreement, to the carrier or another party covered by the sanitary transportation rule.[166] This agreement must include measures equivalent to those specified for the carrier under 21 C.F.R. 1.908(e)(1)-(3), which are:
  - Ensure that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation[167];
  - Once the transportation operation is complete, (1) provide the operating temperature specified by the shipper (if requested by the receiver); and (2) demonstrate that it has maintained temperature conditions during transport consistent with the operating temperature specified by the shipper (if requested by the shipper or receiver)[168]; and
  - Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety, pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper[169];
- Use a carrier who transports the food in a thermally-insulated tank; or
- Provide certain specifications to a carrier who does not transport the food in a thermally-insulated tank (and, if necessary, to the loader).[170] Specifically, the shipper must specify, in writing, an "operating temperature" for the transportation operation, including (if necessary) the pre-cooling phase.
  - The "operating temperature" is a temperature sufficient to ensure that the food will not become unsafe under foreseeable circumstances of temperature variation during transport (e.g., seasonal conditions, refrigeration unit defrosting, multiple vehicle loading and unloading stops).[171]
  - One-time notification is sufficient, unless a factor (e.g., the conditions of shipment) changes and this requires a change in the operating temperature (in which case the shipper must notify the carrier in writing before the shipment).[172]

AND

Recordkeeping requirements

Shippers must retain the following records for the amount of time noted below:

- Records demonstrating that the shipper provides specifications and operating temperatures to carriers as required by §§ 1.908(b)(1) and (2) as a regular part of its transportation operations[173];
  - Retention period: 12 months beyond the termination of the agreements with the carriers
- Records of written agreements and the written procedures required by §§ 1.908(b)(3)-(5)[174];
  - Retention period: 12 months beyond when the agreements and procedures are in use in their transportation operations
- Any other written agreements assigning tasks to comply with the sanitary transportation rule[175];
  - Retention period: 12 months beyond the termination of the agreement
- Written procedures that ensure the sanitary transportation of food consistent with the requirements of § 1.908, which are used by shippers, receivers, loaders, and carriers under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of §§ 1.908(b), (d), and (e).[176]
  - Retention period: 12 months beyond when the procedures are in use in their transportation operations

What are the loader-specific requirements of the sanitary transportation rule?

Requirements that apply to transportation of food that is not completely enclosed by a container

- Before loading food that is not completely enclosed by a container (such as produce in vented crates) onto a vehicle or into transportation equipment, the loader must determine that the vehicle or transportation equipment is in appropriate sanitary condition for the transport of the food.[177] For example, the vehicle or equipment must be:
  - In adequate physical condition; and
  - Free of visible evidence of pest infestation and previous cargo that could cause the food to become unsafe during transportation.
- Although the loader may satisfy this requirement by any appropriate means, the loader must consider, as appropriate, the shipper's specifications for ensuring its vehicles and transportation equipment are in appropriate sanitary condition.

AND

Requirements that apply to transportation of food that requires temperature control for safety

- Before loading food that requires temperature control for safety, the loader must verify that each mechanically refrigerated cold storage compartment or container is adequately prepared for the transportation of such food.[178]
- This includes verifying that each such compartment or container has been properly pre-cooled (if necessary) and meets other sanitary conditions for food transportation.
- In doing so, the loader must consider, as appropriate, the shipper's specifications for ensuring that adequate temperature control is provided during the transport of food that requires temperature control for safety.

AND

Recordkeeping requirements

Loaders must retain the following records for the amount of time noted below:

- Any written agreements assigning tasks to comply with the sanitary transportation rule[179]; and
  - Retention period: 12 months beyond the termination of the agreement
- Written procedures that ensure the sanitary transportation of food consistent with the requirements of § 1.908, which are used by shippers, receivers, loaders, and carriers under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of §§ 1.908(b), (d), and (e).[180]
  - Retention period: 12 months beyond when the procedures are in use in their transportation operations

What are the carrier-specific requirements of the sanitary transportation rule?

Requirements that apply to transportation operations

The final rule's carrier-specific transport requirements (§ 1.908(e)) apply only if the carrier and shipper have a written agreement that the carrier is responsible, in whole or in part, for sanitary conditions during the transportation operation. In this respect, the requirements of section 1.908(e) can be viewed as transforming the carrier's contractual obligation into a regulatory requirement.

In particular, each provision of section 1.908(e) applies only when it is relevant to the terms of the agreement between the carrier and the shipper. Thus, if the written agreement between the shipper and the carrier makes the carrier responsible for any or all sanitary conditions during transportation operations, the carrier must meet each requirement described below that corresponds to the carrier's contractual obligation(s):

- The carrier must ensure that vehicles and transportation equipment meet the shipper's specifications and are otherwise appropriate to prevent the food from becoming unsafe during the transportation operation.[181]
- Once the transportation operation is complete, the carrier must provide the receiver with the operating temperature specified by the shipper, if the receiver requests this information.[182]
- Once the transportation operation is complete, the carrier must demonstrate that it has maintained temperature conditions during transport consistent with the operating temperature specified by the shipper, if the shipper or receiver requests such demonstration.[183] The carrier may accomplish this demonstration by any appropriate means agreeable to the relevant parties. For example, the carrier may present (1) measurements of the ambient temperature upon loading and unloading or (2) time/temperature data taken during the shipment.
- Before offering a vehicle or transportation equipment with an auxiliary refrigeration unit for use for the transportation of food that requires temperature control for safety, a carrier must pre-cool each mechanically refrigerated cold storage compartment as specified by the shipper.[184]
- If requested by the shipper, a carrier that offers a bulk vehicle for food transportation must provide information to the shipper that (1) identifies the previous cargo transported in the vehicle; and/or (2) describes the most recent cleaning of the bulk vehicle.[185] These requirements apply only where the food comes into direct contact with the inner surfaces of the vehicle.[186] They do not apply to circumstances in which the vehicle is used to transport packaged goods.
- The carrier must develop and implement written procedures that:
  - Specify practices for cleaning, sanitizing (if necessary), and inspecting vehicles and transportation equipment that the carrier provides for use in the transportation of food to maintain the vehicles and the transportation equipment in appropriate sanitary conditions;
  - Describe how it will comply with the provisions for temperature control; and
  - Describe how it will comply with the provisions for the use of bulk vehicles.[187]

AND

Training requirements

If the carrier and shipper agree in a written contract that the carrier is responsible for some or all of the sanitary conditions during transportation operations, the carrier must provide adequate training to its personnel engaged in transportation operations. This training, which must be provided upon hiring and as needed thereafter, must cover the following topics:

- The potential food safety problems that might occur during transportation;
- The basic practices to address those problems; and
- The responsibilities of the carrier under the sanitary transportation rule.[188]

AND

Recordkeeping requirements

Carriers must retain the following records for the amount of time noted below:

- Records of the written procedures required by § 1.908(e)(6) (i.e., written procedures describing the carrier's practices for: cleaning, sanitizing, and inspecting vehicles and transportation equipment; complying with provisions related to temperature control and use of bulk vehicles)[189];
  - Retention period: 12 months beyond when the agreements and procedures are in use in their transportation operations
- Training records (i.e., records documenting required training, including (1) the date of the training, (2) the type of training, and (3) the person(s) trained)[190];
  - Retention period: 12 months beyond when the person identified in any such records stops performing the duties for which the training was provided
- Any other written agreements assigning tasks to comply with the sanitary transportation rule[191]; and
  - Retention period: 12 months beyond the termination of the agreement
- Written procedures that ensure the sanitary transportation of food consistent with the requirements of § 1.908, which are used by shippers, receivers, loaders, and carriers under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of §§ 1.908(b), (d), and (e).[192]
  - Retention period: 12 months beyond when the procedures are in use in their transportation operations

What are the receiver-specific requirements of the sanitary transportation rule?

Requirements that apply to transportation operations

Upon receipt of food that requires temperature control for safety under the conditions of shipment, the receiver must take steps to adequately assess whether the food was subjected to significant temperature abuse.[193] These steps may include:

- Determining the food's temperature;
- Determining the ambient temperature of the vehicle and its temperature setting;
- Conducting a sensory inspection (e.g., for off-odors); and
- Reviewing temperature monitoring information from an onboard temperature monitoring device.[194]

A food is not automatically deemed unsafe or adulterated because a possible material failure of temperature control occurs, but a qualified individual must determine that the food was not rendered unsafe before the food can be sold or otherwise distributed.

AND

Recordkeeping requirements

Receivers must retain the following records for the amount of time noted below:

- Any written agreements assigning tasks to comply with the sanitary transportation rule[195]; and
  - Retention period: 12 months beyond the termination of the agreement
- Written procedures that ensure the sanitary transportation of food consistent with the requirements of § 1.908, which are used by shippers, receivers, loaders, and carriers under the ownership or operational control of a single legal entity, as an alternative to meeting the requirements of §§ 1.908(b), (d), and (e).[196]
  - Retention period: 12 months beyond when the procedures are in use in their transportation operations

Glossary of Key Terms

Facility: means any establishment, structure, or structures under one ownership at one general physical location, or, in the case of a mobile facility, traveling to multiple locations, that manufactures/processes, packs, or holds food for consumption in the United States. Transport vehicles are not facilities if they hold food only in the usual course of business as carriers. A facility may consist of one or more contiguous structures, and a single building may house more than one distinct facility if the facilities are under separate ownership.[197] The following facilities do not need to register with FDA:

- *Farms*.[198] However, a "farm mixed-type facility" (i.e., a farm that conducts activities outside the farm definition) needs to register.
- *A foreign facility*, if food from that facility is further manufactured/processed (which includes packaging, but does not include adding labeling or any similar activity of a *de minimis* nature) by another foreign facility before entering the U.S.[199]
- *A restaurant*. A "restaurant" is "a facility that prepares and sells food directly to consumers for immediate consumption."[200] The term does not include "facilities that provide food to interstate conveyances, central kitchens, and other similar facilities that do not prepare and serve food directly to consumers." Entities in which food is provided to humans, however, such as cafeterias, lunchrooms, cafes, bistros, fast food establishments, food stands, saloons, taverns, bars, lounges, catering facilities, hospital kitchens, day care kitchens, and nursing home kitchens are restaurants.[201]
- *A retail food establishment*. A "retail food establishment" is "an establishment that sells food products directly to consumers as its primary function."[202] A retail food establishment may manufacture/process, pack, or hold food and still be exempt from registration, provided that "the establishment's primary function is to sell from that establishment food, including food that it manufactures/processes, packs, or holds, directly to consumers." FDA considers a retail food establishment's primary function to be to sell food directly to consumers "if the annual monetary value of sales of food products directly to consumers [(not including businesses)] exceeds the annual monetary value of sales of food products to all other buyers."

Farm: The following types of operations are farms:

- An operation devoted to the growing and/or harvesting of crops, whose activities may include packing or holding raw agricultural commodities (RACs); manufacturing/processing RACs by drying or dehydrating them to create a distinct commodity; treatment to manipulate the ripening of RACs; and packaging/labeling RACs.[203]
- An operation devoted to harvesting (e.g., hulling or shelling), packing, and/or holding of RACs, if the majority of RACs that the operation handles originate from a farm, as described above, that owns, or jointly owns, a majority interest in the operation. In addition to these activities, the operation may also conduct the activities identified in the first bullet.[204]

Importer: An "importer" is the U.S. owner or consignee of the food offered for import (i.e., the person who owns the food, has purchased it, or has agreed in writing to purchase it). If there is no U.S. owner or consignee at the time of entry, the FSVP importer is the U.S. agent or representative of the foreign owner or consignee, as confirmed in a signed statement of consent.[205]

Major food allergen: A "major food allergen" is an ingredient that is one of the following eight food or food groups, or is an ingredient that contains protein derived from one of them: milk; egg; fish; Crustacean shellfish; tree nuts; wheat; peanuts; and soybeans.[206]

[1] 21 C.F.R. 1.500.
[2] 21 C.F.R. 1.904.
[3] 21 C.F.R. 1.904.
[4] 21 C.F.R. 1.904.
[5] 21 C.F.R. 1.904.
[6] 21 C.F.R. 117.3.
[7] 21 C.F.R. 117.3.
[8] 21 C.F.R. 117.5(a).
[9] 21 C.F.R. 117.201.
[10] 21 C.F.R. 117.201(a)(2).
[11] 80 Fed. Reg. 55,908, 56,128 (Sept. 17, 2015).
[12] 21 C.F.R. 117.5(g)(1).
[13] 21 C.F.R. 117.5(f).
[14] 21 C.F.R. 117.5(g)(3).
[15] 21 C.F.R. 117.5(h)(3).
[16] 21 C.F.R. 117.7(a).
[17] 80 Fed. Reg. 55,908, 56,128 (Sept. 17, 2015).
[18] 80 Fed. Reg. 55,908, 56,128 (Sept. 17, 2015).
[19] 21 C.F.R. 117.126.
[20] 21 C.F.R. 117.180(a).
[21] 21 C.F.R. 117.180(c)(1).
[22] 21 C.F.R. 117.130.
[23] 21 C.F.R. 117.3.
[24] *See* 21 C.F.R. 117.130(a).
[25] *See* 21 C.F.R. 117.3.
[26] *See* 21 C.F.R. 117.130(b)(2).
[27] *See* 21 C.F.R. 117.130(b)(1).
[28] *See* 21 C.F.R. 117.130(c)(1)(i).
[29] 21 C.F.R. 117.135(a)&(b).
[30] 21 C.F.R. 117.135(c)(1).
[31] 21 C.F.R. 117.135(c)(2)(i).
[32] 21 C.F.R. 117.135(c)(2)(ii).
[33] *Cf.* 80 Fed. Reg. 55,908, 56,035 (Sept. 17, 2015).
[34] 21 C.F.R. 117.135(c)(3).
[35] 21 C.F.R. 117.135(c)(4).
[36] 21 C.F.R. 117.136(a)(1)&(b)(1).
[37] 21 C.F.R. 117.136(a).
[38] 21 C.F.R. 117.137.
[39] 21 C.F.R. 117.145(b).
[40] 21 C.F.R. 117.145(c)(1).
[41] 21 C.F.R. 117.145(c)(2).
[42] 21 C.F.R. 117.150(a)(1).
[43] 21 C.F.R. 117.150(a)(2).
[44] 21 C.F.R. 117.150(b).
[45] 21 C.F.R. 117.150(b)(1).
[46] 21 C.F.R. 117.150(b)(2)(i).
[47] 21 C.F.R. 117.150(b)(2)(ii).

[48] 80 Fed. Reg. 55,908, 56,051 (Sept. 17, 2015).
[49] 21 C.F.R. 117.150(c).
[50] 21 C.F.R. 117.150(d).
[51] 21 C.F.R. 117.165(a).
[52] 21 C.F.R. 117.155(a).
[53] 21 C.F.R. 117.155(b).
[54] 21 C.F.R. 117.160(a).
[55] 21 C.F.R. 117.160(b)(2).
[56] 21 C.F.R. 117.160(b)(1).
[57] 21 C.F.R. 117.160(b)(1).
[58] 21 C.F.R. 117.155.
[59] 80 Fed. Reg. 55,908, 56,040 (Sept. 17, 2015).
[60] 21 C.F.R. 117.139.
[61] 21 C.F.R. 117.190.
[62] 21 C.F.R. 117.5(a).
[63] 21 C.F.R. 117.7(a).
[64] 21 C.F.R. 117.5(f).
[65] 21 C.F.R. 117.5(g)(1).
[66] 21 C.F.R. 117.5(g)(3).
[67] 21 C.F.R. 117.5(h)(3).
[68] 21 C.F.R. 117.3 & 117.405.
[69] 21 C.F.R. 117.3.
[70] 21 C.F.R. 117.405(a)(2).
[71] 21 C.F.R. 117.405(c).
[72] 21 C.F.R. 117.420; *see also* 21 C.F.R. 117.410(a)(1) & 415(a)(1).
[73] 21 C.F.R. 117.410(d)(1).
[74] 21 C.F.R. 117.415(a)(2).
[75] 21 C.F.R. 117.410(b).
[76] 21 C.F.R. 117.430(b).
[77] *See* 21 C.F.R. 117.415(a)(3)&(4).
[78] 21 C.F.R. 121.5(b).
[79] 21 C.F.R. 121.5(c).
[80] 21 C.F.R. 121.5(d).
[81] 21 C.F.R. 121.5(a).
[82] 81 Fed. Reg. 34,166, 34,216 (May 27, 2016)
[83] 81 Fed. Reg. 34,166, 34,216 (May 27, 2016)
[84] 21 C.F.R. 121.126.
[85] 21 C.F.R. 121.130(c).
[86] 21 C.F.R. 121.135(b).
[87] 21 C.F.R. 121.140(a).
[88] 21 C.F.R. 121.145(a)(1).
[89] 21 C.F.R. 121.150(b).
[90] 21 C.F.R. 121.4.
[91] 21 C.F.R. 121.130.
[92] 21 C.F.R. 121.135.
[93] 21 C.F.R. 121.140.
[94] 21 C.F.R. 121.145.
[95] 21 C.F.R. 121.150.

[96] 21 C.F.R. 112.3(c).
[97] 21 C.F.R. 112.4(a).
[98] 21 C.F.R. 112.2(a)(1).
[99] 21 C.F.R. 112.2(b).
[100] 21 C.F.R. 112.3(b)(1).
[101] 21 C.F.R. 112.3(b)(2).
[102] 80 Fed. Reg. 74,354, 74,527 (Nov. 27, 2015).
[103] 80 Fed. Reg. 74,354, 74,527 (Nov. 27, 2015).
[104] 21 C.F.R. 112.44(a).
[105] 21 C.F.R. 112.44(b).
[106] 21 C.F.R. 112.45.
[107] 21 C.F.R. 112.56.
[108] 21 C.F.R. 112.83.
[109] 21 C.F.R. Pt. 112, Subpt. L.
[110] 21 C.F.R. Pt. 112, Subpt. D.
[111] 21 C.F.R. 1.502(c).
[112] 21 C.F.R. 1.509(a).
[113] 21 C.F.R. 1.500.
[114] 21 C.F.R. 1.512.
[115] 21 C.F.R. 1.512.
[116] 21 C.F.R. 1.513.
[117] 21 C.F.R. 1.509(a).
[118] 21 C.F.R. 1.502(c).
[119] 21 C.F.R. 1.509(a).
[120] 80 Fed. Reg. 74,226, 74,332-33 (Nov. 27, 2015).
[121] 21 C.F.R. 1.502.
[122] 21 C.F.R. 1.503(a).
[123] 21 C.F.R. 1.504.
[124] 21 C.F.R. 1.507.
[125] 21 C.F.R. 1.505(a).
[126] 21 C.F.R. 1.503(b).
[127] 21 C.F.R. 1.506.
[128] 21 C.F.R. 1.505(d).
[129] 21 C.F.R. 1.508.
[130] 21 C.F.R. 1.505(c).
[131] 21 C.F.R. 1.509(a).
[132] 21 C.F.R. 1.904.
[133] 21 C.F.R. 1.900(a).
[134] 21 C.F.R. 1.904.
[135] 21 C.F.R. 1.900(b) & 1.904.
[136] 21 C.F.R. 1.904.
[137] 81 Fed. Reg. 20,092, 20,160 (Apr. 6, 2016).
[138] 81 Fed. Reg. 20,092, 20,160 (Apr. 6, 2016).
[139] 21 C.F.R. 1.906(a)&(b).
[140] 21 C.F.R. 1.906(c).
[141] 81 Fed. Reg. 20,092, 20,131 (Apr. 6, 2016).
[142] 21 C.F.R. 1.906(d).
[143] 21 C.F.R. 1.908(a)(3).

[144] 21 C.F.R. 1.908(a)(4).
[145] 21 C.F.R. 1.908(a)(3)(i).
[146] 21 C.F.R. 1.908(a)(3)(ii).
[147] 21 C.F.R. 1.908(a)(3)(iii).
[148] 21 C.F.R. 1.908(a)(6); 81 Fed. Reg. 20,092, 20,143 (Apr. 6, 2016).
[149] 21 C.F.R. 1.908(a)(1).
[150] 21 C.F.R. 1.908(a)(2).
[151] 21 C.F.R. 1.912.
[152] 21 C.F.R. 1.912(i).
[153] 21 C.F.R. 1.904.
[154] 21 C.F.R. 1.904.
[155] 21 C.F.R. 1.904.
[156] 21 C.F.R. 1.904.
[157] 21 C.F.R. 1.908(b)(3).
[158] 21 C.F.R. 1.908(b)(1)&(3); 81 Fed. Reg. 20,092, 20,138 (Apr. 6, 2016).
[159] 21 C.F.R. 1.908(b)(1)&(3).
[160] 21 C.F.R. 1.908(b)(1).
[161] 21 C.F.R. 1.908(b)(4).
[162] 81 Fed. Reg. 20,092, 20,151 (Apr. 6, 2016).
[163] 81 Fed. Reg. 20,092, 20,152 (Apr. 6, 2016).
[164] 21 C.F.R. 1.908(b)(5).
[165] 21 C.F.R. 1.908(b)(2)&(5).
[166] 21 C.F.R. 1.908(b)(2)&(5).
[167] 21 C.F.R. 1.908(e)(1).
[168] 21 C.F.R. 1.908(e)(2).
[169] 21 C.F.R. 1.908(e)(3).
[170] 21 C.F.R. 1.908(b)(2).
[171] 21 C.F.R. 1.904.
[172] 21 C.F.R. 1.908(b)(2).
[173] 21 C.F.R. 1.912(a)(1).
[174] 21 C.F.R. 1.912(a)(2).
[175] 21 C.F.R. 1.912(d).
[176] 21 C.F.R. 1.912(e).
[177] 21 C.F.R. 1.908(c)(1).
[178] 21 C.F.R. 1.908(c)(2).
[179] 21 C.F.R. 1.912(d).
[180] 21 C.F.R. 1.912(e).
[181] 21 C.F.R. 1.908(e)(1).
[182] 21 C.F.R. 1.908(e)(2).
[183] 21 C.F.R. 1.908(e)(2).
[184] 21 C.F.R. 1.908(e)(3).
[185] 21 C.F.R. 1.908(e)(4)&(5).
[186] 81 Fed. Reg. 20,092, 20,150 (Apr. 6, 2016).
[187] 21 C.F.R. 1.908(e)(6).
[188] 21 C.F.R. 1.910(a).
[189] 21 C.F.R. 1.912(b).
[190] 21 C.F.R. 1.912(c).
[191] 21 C.F.R. 1.912(d).

[192] 21 C.F.R. 1.912(e).
[193] 21 C.F.R. 1.908(d).
[194] 81 Fed. Reg. 20,092, 20,143 (Apr. 6, 2016).
[195] 21 C.F.R. 1.912(d).
[196] 21 C.F.R. 1.912(e).
[197] 21 C.F.R. 1.227.
[198] 21 C.F.R. 1.226(b).
[199] 21 C.F.R. 1.226(a).
[200] 21 C.F.R. 1.227(b)(10).
[201] 21 C.F.R. 1.227(b)(10)(i).
[202] 21 C.F.R. 1.227(b)(11).
[203] 21 C.F.R. 1.227.
[204] 21 C.F.R. 1.227.
[205] 21 C.F.R. 1.500.
[206] FDCA § 201(qq).